

**FDA Simultaneous Marketing ANPRM
Bracketed Comment Letter Report**

May 19, 2006

Final

**Prepared by
ICF International
Fairfax, VA**

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COMMENT NUMBER - 2005N-0345-C307

2005N-0345-C307 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: GlaxoSmithKline

2005N-0345-C307 - TEXT

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October 28, 2005

Division of Dockets Management
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Rockville
MD 20852

Re: Docket No. 2005N-0345
RIN 0910-AF72

Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product: Advance Notice of Proposed Rulemaking, 70 Federal Register 52050 (September 1, 2005).

Dear Madam or Sir:

In the September, 2005 Federal Register the U.S. Food and Drug Administration ("FDA") published and invited comments on the above proposed rulemaking. Specifically, the FDA request comment on, "whether to initiate a rulemaking to codify its interpretation of section 503(b) . . ." and whether it is necessary to, "explicitly set forth regulations that discuss the processes by which FDA classifies (or re-classifies) drugs as OTC or prescription."

GlaxoSmithKline Consumer Healthcare (GSK CH) has extensive experience of the OTC market place, regulations and re-classification applications, or "Rx-to-OTC switch" submissions. Such applications have been wide ranging in therapeutic category, in U.S. and international markets and both successful, and unsuccessful, in gaining approval for OTC status. This experience is valuable in commenting on the Rx-to-OTC switch process and specifically the FDA proposal to promulgate further associated regulations.

The Agency requests comments to three questions, each in two to three parts. The comments of GSK CH follow a restatement (in italics) of each question below.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

C. If so, would a rulemaking on this issue help dispel that confusion?

<1: 3.2>In response to questions A and B, GSK CH does not believe that FDA should initiate rulemaking to codify its interpretation of section 503 (b). </1: 3.2><2: 3.8.7, 4.2, 5.4.3>We see no need, or benefit, of further regulation. Our FDA submission experience leads GSK CH to conclude that there is no confusion regarding FDA's interpretation of section 503(b). To the contrary, we have found FDA's interpretation very clear. It is our opinion that part C of this question is therefore moot. </2: 3.8.7, 4.2, 5.4.3>

<3: 3.8.4>Quite simply, if the FDA determines that the data and labeling submitted fulfill the requirement of exemption from section 503(b), then the product is a non-prescription (i.e. OTC) drug. Conversely, if the FDA determines that the data and labeling do not fulfill exemption from section 503(b), then the product is a prescription drug. </3: 3.8.4>

<4: 3.8.4>In addition to 21 CFR 310.200 (Prescription-exemption procedure), the Agency's position on switch products and the associated switch process is made clear by correspondence with a Sponsor and/or as matter of general public record. This occurs via Citizens Petition, NDA action packages, the Advisory Committee process, presentations by CDER Management and staff at public meetings and Part 15 Public Hearings (e.g. June 28, 2000). </4: 3.8.4>

<5: 3.9.1>There are many good examples of why active ingredients should be available both as prescription and OTC drugs. These include, for example, oral ibuprofen, H2 antagonists: (cimetidine, ranitidine, famotidine, nizatadine), omeprazole, and topical miconazole and hydrocortisone. For these products FDA have evaluated the data and determined that for some elements of the drug, section 503(b) exemption does not apply, e.g. for reason of indication or dose. Those elements have remained prescription status.

Other actives have switched totally, leaving no prescription status product (e.g. oral & transdermal nicotine replacement therapies (NRT), loratidine). These products were considered section 503(b) exempt in their totality. </5: 3.9.1>

<6: 3.8.4>GSK CH contends that the requirements for exemption from 503(b) regarding OTC suitability are clear. Sponsors should continuously evaluate the healthcare environment for opportunities that benefit both Rx and OTC users. Further regulations would be neither necessary nor helpful and may hinder innovation. </6: 3.8.4>

2.

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g. by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law.

B. If it could would it be able to do so as a practical matter and if so, how?

<7: 6.4.1, 7.3.1.1, 7.3.1.2, 7.4.3>The nature of OTC availability is broad access. Although practical restrictions on such access are limited, the Sponsor and FDA assess product safety and use in that context.

Certain restrictions and limitations may be agreed as a condition of approval. Oral OTC nicotine replacement products are an example. In this total switch, the OTC product was approved for the same age range as the prescription product: (18 years and above). It was a pre-approval requirement to demonstrate that the age limitation was understood at both a label and practical level. Additionally, sales restrictions (no vending machine sale), defined marketing plans that included vendor systems and training to encourage age verification, and a post approval monitoring program were conditions of approval (the intent being to restrict off label use by those under 18 years of age). It was the Sponsor's responsibility to comply with the restrictions as well as monitor and report on their effectiveness. Monitoring included a program of retailer re-training to correct deficiencies and help ensure ongoing compliance. If the sponsor's efforts proved unsuccessful, a practical, regulatory consequence was withdrawal of NDA approval. </7: 6.4.1, 7.3.1.1, 7.3.1.2, 7.4.3>

<8: 6.1, 6.3.1, 7.1>Thus, this is a situation where FDA, in their capacity as:

" . . . experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, . . . for use under the conditions prescribed, recommended, or suggested in the labeling.. ." (FDCA, section 201(p)),

have the authority to determine the approvability of a drug product as described by a Sponsor. As a practical matter, in our experience, it is enforceable. </8: 6.1, 6.3.1, 7.1>

3.

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

B. If the two products may be legally sold in a single package, under what circumstances would it be inappropriate to do so?

<9: 8.3.1>In order for a product to be sold Rx or OTC it is necessary that the labeling requirements of each legal classification be fulfilled.

In much the same way as an OTC drug product may be marketed simultaneously in a single pack as a dietary supplement, provided the label requirements are fulfilled and comprehended, we see nothing in principle to preclude a common pack for Rx and OTC.

However, the regulations describe very different label requirements for Rx and OTC drug products. Therefore we see no way to a "same package" without some modified language. For example, Rx products require a prescription legend on labeling and the inclusion of very detailed prescribing information. The OTC label has uniform format and content requirements so as to be understood by the consumer.

It is our opinion however, as a practical matter, that these differences might be addressed and satisfied within the remit of the FDA, per section 201(p) of the act. Methods could include additional Rx labeling adhered to/accompanying the OTC pack at point of dispensing and specific Rx healthcare professional labeling. The product and labeling approaches would be approved under an OTC- and an Rx NDA.</9: 8.3.1>

<10: 9.1.1>Finally, in response to the last posed question, the only circumstance in which it would be inappropriate to sell a product Rx and OTC in the same package, is when the FDA determines that the data do not support both the Rx and OTC requirements of section 503(b). </10: 9.1.1>

Thank you for your consideration of these comments

Respectfully submitted,

Sue James
Vice President Regulatory Affairs, Compliance and Quality,
GlaxoSmithKline Consumer Healthcare R&D

COMMENT NUMBER - 2005N-0345-C320

2005N-0345-C320 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: University of California, San Francisco

2005N-0345-C320 - TEXT

University of California
San Francisco
Center for Reproductive Health
Research & Policy

October 26, 2005

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket Number 2005N-0345

Dear Acting Commissioner von Eschenbach:

As clinicians and researchers at The Bixby Center for Reproductive Health Research & Policy at the University of California, San Francisco (UCSF), we are writing to you in response to the Advance Notice for Proposed Rulemaking in docket number 2005N- 0345.

<1: 1.2.1, 3.2, 3.8.8>The Food and Drug Administration (FDA) has the authority to switch a prescription drug to over-the-counter (OTC) status if the drug is both safe and effective when self-administered; potential users can self-diagnose the condition for which the drug is needed; and, the drug's label provides clear instructions for use. Though Plan B meets all of the criteria for OTC status, the FDA has failed to remove its prescription requirement and instead has launched down a path of bureaucratic indecision that does not serve U.S. women. The FDA has no scientific basis for discriminating the safety of Plan B among women of reproductive age. We strongly urge the FDA to abandon the proposed rulemaking process and approve the original application to switch Plan B to an OTC product without restrictions. </1: 1.2.1, 3.2, 3.8.8>

<2: 2.1>In a December 16, 2003 joint meeting, the Nonprescription Drugs Advisory Committee and the Reproductive Health Drugs Advisory Committee charged with reviewing the scientific evidence on the merits of Plan B recommended that it be approved for OTC status. However, in February 2004, Dr. Steven Galson, Acting Director of the FDA, issued a non-approval letter citing concerns that Plan B could not be used safely by young adolescent women. In response, Barr Corporation submitted an amendment, proposing to change the indication to allow for marketing of Plan B as a prescription- only product for women younger than 16 years of age and a nonprescription product for women 16 years and older. In August 2005, the FDA announced that it was unable at this time to reach a decision on the approvability of the application because of unresolved regulatory and policy issues that relate to the application's discrimination to access among women of different ages. </2: 2.1>

<3: 10>Teens are a vulnerable population that face a host of barriers accessing family planning services and therefore stand to gain most from increased access to all methods of contraception. There is no scientifically valid reason to restrict teens' access to emergency contraception (EC), and the application under review that proposes to have Plan B remain a prescription-only product for teens will only further contribute to the high rates of teen pregnancy in the U.S. A substantial body of scientific evidence demonstrates that EC offers a safe and effective back-up method of birth control; that teens can use EC safely and correctly without medical supervision; and, that EC does not adversely affect teens' sexual behavior.

The Bixby Center for Reproductive Health Research & Policy at UCSF has conducted research on the safety profile of EC in young adolescents as well as studies that demonstrate that increased availability of EC does not endanger women by affecting sexual risk-taking (see attached studies).¹⁻⁴ These studies, which were provided to the Nonprescription Drugs Advisory Committee and the Reproductive Health Drugs Advisory Committee (either as peer-reviewed manuscripts or as pre-published data with full documentation), are consistent with other national and international data and provide clear evidence that teens with increased access to EC:

- Are more likely to use it when needed
- Are more likely to take it sooner after unprotected sex has occurred
- Do not exhibit significant repeat or excessive use of EC
- Do not engage in higher levels of unprotected sex
- Do not abandon their routine method of contraception or use it less consistently
- Do not switch to a less effective method of contraception
- Do not have greater numbers of sexual partners
- Do not have higher levels of sexually transmitted infections
- Do not become more vulnerable to unwanted sexual activity</3: 10>

<4: 1.2.1>Making Plan B available to teens is imperative given the unacceptably high rates of teen pregnancy in the U.S. Of the 800,000 teen pregnancies in this country each year, nearly 80 percent are unintended, and one-third end in abortion. Not surprisingly, the U.S. lags behind the rest of the developed world in making EC available to women without a prescription and has a teen birth rate that is higher than any other developed country, including Canada (two times higher), Germany (four times higher), France (five times higher), and Japan (nearly nine times higher). The FDA should dispense with the bureaucratic entanglements of a "restricted" Plan B OTC access application. The failure to make a drug as safe and effective as EC available to all women OTC places an unnecessary barrier in the way of women seeking to prevent unintended pregnancy. Given the demonstrated safety and efficacy of EC as an OTC product around the world, removing the prescription requirement offers a viable way to improve access and help reduce the unacceptably high rate of unintended pregnancy in the U.S. We strongly urge the FDA to move decisively and swiftly to switch Plan B to OTC status for women of all reproductive ages. </4: 1.2.1>

Signed,

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Professor and Chief

Felicia Steward, MD
Adjunct Professor, Emeritus

Claire Brindis, DrPH, MPH
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Enclosures:

<5: 10>1. Raine TR, Harper C, Leon K, Damey PD. Emergency contraception: Advance provision in a young, high-risk clinic population. *Obstetrics and Gynecology* 2000;96: 1-7.

2. Harper C, Rocca CH, Darney PD, Von Hertzen H, Raine TR. Tolerability of levonorgestrel emergency contraception in adolescents. *Contraception* 2004; 191: 1158- 63.

3. Raine T, Harper C, Rocca C, Fischer R, Padian N, Klausner J, Damey, P. Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: A randomized controlled trial. *JAMA* 2005;293:54-62.

4. Harper C, Cheong M, Rocca RH, Damey PD, Raine TR. The effect of increased access to emergency contraception among young adolescents. *Obstetrics and Gynecology* 2005;106:483-91. </5: 10>

COMMENT NUMBER - 2005N-0345-C350

2005N-0345-C350 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: American Society for Reproductive Medicine

2005N-0345-C350 - TEXT

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE
Formerly The American Fertility Society

November 1, 2005

BY ELECTRONIC MAIL

Division of Dockets Management
United States Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2005N-0345 - Drug Approvals: Circumstances In Which An Active Ingredient May Be Simultaneously Marketed In Both A Prescription Drug Product And An Over-The-Counter Drug Product

Dear Madam:

On September 1, 2005, the Food and Drug Administration ("FDA") issued an Advanced Notice of Proposed Rulemaking ("ANPR") in connection with its recent decision to delay approval of Barr Laboratories' emergency contraception ("EC") product, Plan B (levonorgestrel), for over-the-counter ("OTC") use in women sixteen and older. Several days earlier, FDA had announced that it was unable to reach a decision on Barr's proposal, contained in a supplemental New Drug Application ("sNDA"), to "switch" the drug from prescription-only to OTC because of the "novel regulatory issues" posed by the simultaneous marketing of a product for prescription and OTC use. See FDA Statement, FDA Takes Action on Plan B: Statement by FDA Commissioner Lester M. Crawford (Aug. 26, 2005) at www.fda.gov/bbs/topics/news/2005/NEW01223.html.

The American Society for Reproductive Medicine ("ASRM") would like to take this opportunity to comment on the issues raised in the ANPR. <1: 3.5.2>Specifically, the regulatory framework governing drug approvals and prescription-to-OTC "switches" are clear and should lead to swift approval of Barr's sNDA.</1: 3.5.2> <2: 3.3.3, 6.4.1>The Federal Food, Drug, and Cosmetic Act ("FDCA") establishes a standard for classifying a drug as prescription-only that allows the agency to impose age requirements on prescription use. Moreover, FDA has ample legal authority to enforce such a restriction and has done so with respect to at least one other product, an "adults only" Nicorette (nicotine polacrilex) gum. </2: 3.3.3, 6.4.1><3: 1.2.2, 2.1>Consequently, FDA should stop this unreasonable delay and grant approval of OTC levonorgestrel. </3: 1.2.2, 2.1>

I. BACKGROUND

Plan B was approved on July 28, 1999, under a new drug application ("NDA") submitted by the Women's Capital Corporation and subsequently purchased by Barr. The NDA referenced clinical data on nearly 15,700 women who had used levonorgestrel for EC from a study conducted by investigators working under the sponsorship of the World Health Organization and World Bank Special Programme of Research, Development and Research Training in Human Reproduction. See NDA No. 21,045, FDA Medical Officer Review, Levonorgestrel 0.75mg for Emergency Contraception (June 23, 1999).

In February 2001, ASRM joined over sixty organizations in filing a citizen petition seeking a switch from prescription to OTC status for Preven Emergency Contraceptive Kit (ethinyl estradiol; levonorgestrel) and Plan B. See Docket No. 2001P-0075. On several occasions since then, ASRM has communicated its view concerning the safety and effectiveness of Plan B to President Bush, then-Commissioner Mark McClellan, Secretary of HHS Tommy Thompson, and FDA's Reproductive Health Drugs Advisory Panel. [Footnote 1: ASRM submitted comments to Docket No. 2001P-0075 on July 29, 2005 and December 8, 2003.] Briefly, ASRM has stated that:

EC is difficult to obtain during the weekend, and emergency rooms do not always provide EC. Access to EC is crucial if it is to work effectively.

To optimize women's health, impediments to obtaining EC should be removed; OTC availability of EC would result in increased use which could prevent 1.7 million unplanned pregnancies per year and countless abortions.

Five states have already made it available directly from pharmacists without prescription.

Studies show the drug is safe and that consumers are easily able to follow package instructions.

Use of EC will not influence consumers to use regular contraception less frequently; if EC is available OTC, they are more likely to use it when necessary.

On April 16, 2003, Women's Capital Corporation filed a prescription-to-OTC switch application with FDA. See www.barrlabs.com. In December 2003, FDA convened a Joint Meeting of the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs (the "Joint Committee") to consider the proposed switch. The Joint Committee voted 23-4 that Plan B should be switched to OTC status.

At least one senior FDA official reviewed data contained in the Barr sNDA and concluded that it is adequate to support approval. On April 22, 2004, Director of New Drugs Dr. John K. Jenkins wrote a memo to the NDA concluding that, "[i]n my opinion, these studies provide adequate evidence that women of childbearing potential can use Plan B safely, effectively, and appropriately for emergency contraception in the non-prescription setting." See Memorandum from John K. Jenkins, MD, Director, Office of New Drugs, FDA to NDA 21-045 (Apr. 22, 2004).

Nevertheless, several days later, FDA notified Barr that its supplemental application for OTC status was not approvable because Barr had not provided adequate data to demonstrate that Plan B can be used safely by young adolescent women without the professional supervision of a practitioner licensed by law to administer the drug. See Letter to Barr from Steven Galson (May 6, 2004) (available at <http://www.barrlabs.com/pages/nprpr.html>). FDA commented that only 29 of the 585 subjects enrolled in the study were 14-16 years of age, and none was under 14 years of age. FDA noted concerns from some members of the Joint Committee that actual use data did not reflect the overall population of non-prescription users, particularly given the small sample of younger age groups.

In July 2004, Barr submitted a revised sNDA seeking approval of OTC Plan B for women 16 years of age and higher. On August 26, 2005, FDA issued a letter to Barr stating that the agency was unable to make a determination on the approvability of the sNDA, and, on September 1, issued the ANPR, which sets out several legal issues for comment. [Footnote 2: According to Barr, the letter states that FDA "has completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an OTC product for women who are 17 years of age and older." See www.barrlabs.com.] <4: 2.1>ASRM is deeply disappointed by the agency's repeated delay in approving Plan B for over-the-counter use, and submits these comments in response to the agency's request. </4: 2.1>

II. DISCUSSION

<5: 3.3.2, 3.6.2, 6.3.2>A. FDA's Legal Authority is Clear and Supports Approval

No statutory provision prevents FDA from imposing an age limitation on the prescription drug status of a new drug. As a fundamental matter, the FDCA presumes that a new drug may be available OTC unless it falls within the definition of a prescription drug in Section 503(b) of the Act. 21 USC 353(b). See, e.g., 21 CFR 330.10(a)(4)(vi); see also Leg. Hist. of Durham-Humphrey Act at S. Rep. No. 946, at 1951 USCCAN 2454, 2461. Section 503(b) provides that FDA shall impose a prescription-only restriction where a new drug

because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.

Thus, the statute allows FDA to determine, based either on the data contained in the sNDA or the lack of necessary data, that Plan B poses a "potential for harmful effect" if used in women under age 16. FDA could also find that "collateral measures" are necessary for its safe use by women under age 16 - namely that distribution be limited to circumstances where a licensed practitioner is available to supervise its use. [Footnote 3: Indeed, the statute is silent with respect to whether age is a relevant factor when interpreting and applying section 503(b). Thus, under settled legal principles, the agency may "fill the gaps" in the statute through reasonable interpretation. See *US. v Mead Corp.*, 533 U.S. 218,234 (2001); *Chevron, USA., Inc v Natural Resources Defense Council, Inc* , 467 U.S. 837 (1984).]

<6: 3.5.2>FDA has published regulations governing OTC drugs. In considering whether to allow a drug to be available OTC through publication of a drug monograph, the agency considers established factors - safety and effectiveness, the benefit-to-risk ratio, and whether clear and understandable labeling can be written for self-medication without the intervention of a health professional. See 21 CFR 330.10(a)(4). Similarly, when considering whether a prescription drug should "switch" to OTC status, the agency considers related factors such as a consumer's ability to self-diagnose and self-treat, the incidence of side effects and adverse events, the potential for misuse, and whether the drug's use might mask more serious conditions that require medical attention. As ASRM has repeatedly asserted, these factors strongly support approval of OTC Plan B. </6: 3.5.2>

<7: 1.2.1, 10>In fact, since Barr filed its application, two studies have been published that address certain of these factors. Most recently, the British Medical Journal published the results of a survey study of approximately 7600 women aged 16-49 finding that nonprescription availability of EC in the United Kingdom did not lead to an increase in unprotected sex, an increase in the use of EC, or a decrease in "more reliable methods of contraception." Marston, et al., *Impact On Contraceptive Practice Of Making Emergency Hormonal Contraception Available Over The Counter In Great Britain: Repeated Cross Sectional Surveys*. 331 *Brit. M.J.* 271 (2005). In January 2005, the Journal of the American Medical Association published the results of a randomized, single-blind, controlled trial of 2117 women, aged 15 to 24 years in which the participants either had pharmacy access to EC, advance provision of Plan B, or clinical access to EC (control group). The researchers found that access to EC through pharmacies or advance provision "did not have a detrimental effect on contraceptive use or sexual behavior." Raine et al., *Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STDs*, 293 *JAMA* 54 (Jan. 2005). This information underscores the widespread belief among women's health professionals that OTC EC would provide tremendous benefits without posing an unwarranted risk of misuse or adverse health consequences. </7: 1.2.1, 10>

<8: 3.9.1, 6.3.4>As the agency recognized in the September 1 ANPR, FDA has allowed marketing of the same active ingredient in products that are both prescription and OTC where "some meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner." 70 *Fed. Reg.* 52050 (Sept. 1, 2005). FDA provided several examples of such drugs, and reiterated that the "key distinction" between the OTC and prescription versions of those products is "some

meaningful difference between the two products," for example, "indication, strength, route of administration. dosage form." Id. </8: 3.9.1, 6.3.4>

<9: 3.3.3, 6.3.4>A drug product is approved for those uses set forth in its labeling, the scope of which is limited to specific statements about the "conditions" of its proper use - those "prescribed, recommended, or suggested" in the labeling. 21 USC 355(d)(1). Thus, labeling that includes specific limitations on the appropriate patient population for which the drug is intended can denote a "meaningful difference" in the prescription drug and the OTC drug product. [Footnote 4: In June 2005, FDA approved a drug for use only in a specific subpopulation -African Americans. The drug, BiDil(R) (hydralazine hydrochloride; isosorbide dinitrate), is indicated for the treatment of heart failure as an adjunct to standard therapy in self-identified black patients.] Quite simply, levonorgestrel labeled for prescription use is a different drug than levonorgestrel labeled for OTC use. Indeed, as FDA acknowledges, it has approved OTC and prescription versions of a product based on differences in "indication," which constitutes a meaningful difference in the two products' intended or labeled uses.

ASRM believes that FDA has ample authority to make a similar distinction between prescription and OTC levonorgestrel and should do so immediately. </9: 3.3.3, 6.3.4>

<10: 6.4.1>B. FDA Has Ample Authority to Enforce an Age Restriction - both as a Matter of Law and in Practice

FDA also requested comments on the enforceability of an age limitation for a product sold both by prescription and over the counter. It is important to note that FDA has approved an sNDA for an "adults only" OTC version of a prescription product - Nicorette gum. In February 1996, FDA issued an approval letter for the OTC sale of Nicorette, a smoking-cessation product, for consumers 18 years of age or older. The letter stated that Nicorette "product cartons must bear the legend: Not for sale to those under 18 years of age. Proof of age required. Not for sale in vending machines or from any source where proof of age cannot be verified." See Letter to Hoechst Marion Roussel, Inc. from Paula Botstein, CDER, FDA (Feb. 9, 1996) ("Nicorette Approval Letter (Feb. 9, 1996)"). We are not aware of any challenge - legal or practical - to FDA's enforcement of this restriction, nor do we foresee any difficulty in enforcing such a limitation on OTC Plan B. </10: 6.4.1>

<11: 6.3.1>1. OTC Levonorgestrel Intended for Use by Women Falling Under the Age Limitation Would be an "Unapproved New Drug"

The FDCA provides a panoply of legal restrictions on the sale of unapproved new drugs. As a matter of law, FDA can restrict the "introduction into interstate commerce" of an unapproved new drug such as OTC Plan B intended for use by a woman under the age of 16.

The statute prohibits the "introduction into interstate commerce [of] any new drug" the approval of which is not in effect under section 505 of the FDCA. 21 USC 355(a); 331 (d). New drugs are approved by the agency after evaluation of the results of clinical investigations designed to demonstrate whether the drug is safe and effective "under the conditions of use prescribed, recommended, or suggested in the proposed labeling." See 21 USC 355(d). Any new "intended use" of the product by the manufacturer beyond the use set forth in the labeling requires "adequate directions for use," which are necessarily lacking without FDA review and approval. See 21 USC 352(f)(1); 21 CFR 201.5; 201.128. Promotion of OTC Plan B to women under the age of 16 would create an unapproved new drug, as would sale of the product "for a purpose for which it is neither labeled nor advertised" by persons legally responsible for its labeling. 21 CFR 201.128. </11: 6.3.1>

<12: 7.3.1.3, 7.3.1.4>2. FDA Can Enforce An Age Limit As a Practical Matter

Moreover, FDA can enforce an age limitation through a variety of measures.

FDA routinely requests from drug applicants commitments to implement post-market surveillance and marketing plans. On approval of Nicorette, for example, the agency stipulated OTC availability for an adult-only population and requested a number of post-marketing commitments, including a surveillance study designed to identify and report on sale to or use by people less than 18 years of age. Nicorette Approval Letter (Feb. 9, 1996). FDA also recently approved a new drug with a post-marketing "risk management plan" that included a commitment that the manufacturer refrain from using direct-to-consumer advertising. Letter to Amylin Pharmaceuticals, Inc. from Robert J. Meyer, CDER, FDA (Mar. 16, 2005) (regarding FDA approval of Symlin (pramlintide acetate)). FDA could request that Barr conduct similar surveillance studies and agree to appropriate advertising limitations. [Footnote 5: Recently, the Pharmaceutical Research and Manufacturers Association published voluntary principles governing direct to consumer advertising. See PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines (July. 2005). These establish that such advertisements "clearly indicate that the medicine is a prescription drug to distinguish such advertising from other advertising for non-prescription products." They also stress that advertisements "be targeted to avoid audiences that are not age appropriate for the message involved."]</12: 7.3.1.3, 7.3.1.4>

<13: 7.3.1.1, 7.3.1.4>Other elements of a possible post-marketing distribution commitments could include elements such as (1) limitations on "trial size" or "sample" packs; (2) use of child-resistant packaging; (3) distribution restrictions excluding channels such as convenience stores or vending machines; (4) incentives to retailers to shelve Plan B close to the pharmacy or with other OTC drugs; and (5) easy access to patient information regarding use of emergency contraception (toll-free phone number on labeling). See Nicorette Approval Letter (Feb. 9, 1996). </13: 7.3.1.1, 7.3.1.4>

<14: 7.4.2>And, both Barr and FDA could cooperate with state pharmacy boards and local pharmacies to ensure enforcement of the age limitation at the point of sale. FDA has entered into memoranda of understanding ("MOUs") with state regulatory agencies to supplement investigative abilities. See FDA, Investigations Operations Manual, Ch. 3 (Federal-State Cooperation) at http://www.fda.gov/ora/inspect_ref/iom/ChapterText/330part1.html#331.02.

In short, FDA has a long record of approving drugs that pose risks to certain populations. It has attempted to address those risks through agreements with the manufacturer and other enforcement agencies so that safe and effective drug products could be made available to the public. FDA assessed those risks and determined that they did not outweigh the benefits such that approval was delayed indefinitely. </14: 7.4.2>

Conclusion

For all these reasons, and those included in ASRM's previous submissions to Docket No. 2001P-0075, we urge FDA to approve Plan B for OTC use.

Sincerely,

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COMMENT NUMBER - 2005N-0345-C403

2005N-0345-C403 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Arnall Golden Gregory LLP

2005N-0345-C403 - TEXT

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October 31, 2005

VIA FEDERAL EXPRESS &
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Division of Dockets Management
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Re: Docket No. 2005N-0345 ("Drug Approvals: Circumstances Under Which An Active Ingredient May Be Simultaneously Marketed In Both A Prescription Drug Product And An Over-the Counter Drug Product")

To Whom It May Concern:

On behalf of a client, Arnall Golden Gregory LLP submits these comments, in triplicate, in response to the Food and Drug Administration's Advance Notice of Proposed Rulemaking (ANPR) regarding circumstances under which an active ingredient may be simultaneously marketed in both a prescription drug product and an over-the-counter drug product (Docket No. 2005-0345). Our client manufactures and distributes both prescription and OTC drug products.

Background

On September 1, 2005, FDA issued an ANPR to request comment on whether to initiate rulemaking to codify its interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 353(b), 70 Fed. Reg. 52050. Section 503(b) identifies the standard used to classify drugs as prescription or OTC. 21 U.S.C. § 353(b). In addition, this statutory provision describes when and how to

switch a drug from prescription to OTC status. Id.

According to the FDC Act, a prescription drug is:

(1) A drug intended for use by man which -

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug.

21 U.S.C. § 353(b)(1). FDA noted in the ANPR that it has:

interpreted the language in section 503(b)(1) of the act to allow marketing of the same active ingredient in products that are both prescription and OTC, assuming some meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner.... To date, FDA has not allowed marketing of the same active ingredient in a prescription product for one population and in an OTC product for a subpopulation.

70 Fed. Reg. at 52051.

The FDC Act does not explicitly define OTC drugs. FDA states:

A drug shall be permitted for OTC sale and use by the laity unless, because of its toxicity or other potential for harmful effect or because of the method or collateral measures necessary to its use, it may safely be sold and used only under the supervision of a practitioner licensed by law to administer such drugs.

See 21 C.F.R. § 330.10(a)(4)(vi); see also 21 C.F.R. § 310.200. OTC drugs typically have these characteristics:

their benefits outweigh their risks;
the potential for misuse and abuse is low;
consumer can use them for self-diagnosed conditions;
they can be adequately labeled; and
health practitioners are not needed for the safe and effective use of the product.

Comments to ANPR

FDA requested comments to specific questions concerning interpretation of section 503(b) of the FDC Act. Before we provide our recommendations, we want to commend the agency for requesting and considering industry input. We appreciate that any decisions made by FDA must first focus on patient safety.

<1: 3.8.2, 3.8.5, 3.8.6>In general, the current system appears to work well. FDA has the authority and flexibility to require unique, product-specific information on a case-by-case basis, and may consult with expert advisory committees, where appropriate. We believe it would be useful for FDA to issue more written guidance to explain further its interpretation of section 503(b), but we recommend that the guidance remain that - guidance, and not rulemaking - so that industry can better understand the agency's

current thinking, without limiting both FDA and companies to a one-size-fits-all approach. While not specifically addressed in this request from FDA, we also suggest that the agency consider, as it formulates its policy in this context, the intermediate designation approach of "behind-the-counter" ("BTC") sale and distribution. </1: 3.8.2, 3.8.5, 3.8.6>

Question 1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the FDC Act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the FDC Act?

C. If so, would a rulemaking on this issue help dispel that confusion?

Response

<2: 3.3.2, 3.8.5>The short answer is no; FDA should not initiate formal rulemaking in this case. The FDC Act clearly identifies when a drug product is for prescription use only. On the other hand, the circumstances under which a product may be considered safe and effective for OTC use vary according to product type and should be reserved for a case-by-case evaluation, e.g., a new drug application or monograph. For example, the amount of safety information that may be needed to allow the OTC sale of statins would be far different from that required for the OTC sale of antihistamines.</2: 3.3.2, 3.8.5>

<3: 3.8.6>As previously noted, we do not see much benefit from formal rulemaking here. However, it would be useful for FDA to issue a clear guidance document to outline the current interpretation by the agency of the circumstances under which an active ingredient may be simultaneously marketed in both a prescription and an OTC product. This guidance could include some recommendations about the amount of safety information that might be required in a marketing application and the format in which it should be presented to FDA. In addition, the written guidance should contain criteria that FDA will consider when evaluating whether there is a "meaningful difference" between a prescription and an OTC drug product.

Another issue that FDA might address in any guidance that it develops is the control of access to certain medications that could be abused or may require additional input from a learned intermediary who is not a physician, such as a pharmacist. </3: 3.8.6>

Question 2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

B. If it could, would it be able to do so as a practical matter and, if so, how?

Response

<4: 7.4.1, 7.5.3>We believe it will be difficult for FDA to restrict or limit sale based on subpopulation. The example that seems to be the most apparent would be to allow a product to be OTC for adults, but by prescription only to the pediatric population. The point of having a prescription-only product is an attempt to ensure the safety of the patients taking or using the particular product by involving a physician. It

would appear to be impractical to allow and enforce OTC access for one subpopulation if FDA concludes the product should be not be available for OTC use in other subpopulations. Again, the agency might consider the intermediate approach of BTC sale and distribution, where the intervention of a learned intermediary, such as a pharmacist, could help ensure that the patient self-administers the product safely.</4: 7.4.1, 7.5.3>

Question 3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

Response

<5: 8.6.1, 8.6.2, 8.9>We interpret FDA's question to focus on whether a company may use similar packaging for products where the same active ingredient is contained in both a prescription and an OTC product. We believe this should not be done. [Footnote 1: We do not understand FDA to ask whether a prescription and an OTC drug product with the same ingredient may be sold together in the same physical package. If this is part of the question, we recommend against such packaging.] Marketing the same active ingredient as a prescription and an OTC product in similar packaging seems to be contrary to the meaningful difference standard. Separate packaging styles make clear that the products are not the same. For the pharmacist who is dispensing products, similar packaging potentially increases the likelihood of medication errors rather than decreases them. In addition, a prescribing physician may be unaware of the packaging similarities, which could lead to prescribing errors, and thereby lead to a potentially unintended and adverse result on patient safety. </5: 8.6.1, 8.6.2, 8.9>

Thank you for the opportunity to submit these comments. Please feel free to contact us if you have any questions.

Respectfully submitted,
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COMMENT NUMBER - 2005N-0345-C407

2005N-0345-C407 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Pfizer, Inc.

2005N-0345-C407 - TEXT

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November 1, 2005

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Re: Pfizer Inc Comments on Docket No. 2005N-0345; Advance Notice of Proposed Rulemaking on Simultaneous Marketing of an Active Ingredient in Both a Prescription Drug Product and OTC Drug Product, 70 Fed. Reg. 52050 (Sept. 1, 2005)

The undersigned, on behalf of Pfizer Inc, submit these comments in response to the Food and Drug Administration's ("FDA") Advance Notice of Proposed Rulemaking requesting comments on the "Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product" ("the ANPRM "). Pfizer recognizes that FDA's Advance Notice arises out of a specific controversy of great concern to many interested parties. Pfizer is not involved in that controversy and takes no position as to its proper resolution under the Federal Food, Drug, and Cosmetic Act ("FDCA") and public health. Pfizer is filing these comments because the ANPRM raises broad issues about the authority vested in FDA under Section 503(b) of the FDCA. As a manufacturer of both prescription drug ("Rx ") and over-the-counter ("OTC ") drug products, Pfizer is filing these comments to assist FDA in its analysis of the Agency's statutory authority under Section 503(b).

I. Statutory Requirements

FDA's role in regulating prescription versus OTC dispensing of drugs is set forth in Section 503(b) of the

FDCA. That section was added to the statute in 1951 by the Humphrey-Durham Amendments. [Footnote 1: Humphrey-Durham Drug Prescriptions Act, Pub. L. No. 82-215, 65 Stat. 648 (1951) (amending 21 U.S.C. § 353(b)).] Prior to Humphrey-Durham, FDA had no authority to determine whether drugs were required to be dispensed by prescription or sold OTC. Such determinations were left solely to the discretion of drug manufacturers.

A. Concerns Giving Rise To The Humphrey-Durham Amendments.

The lack of a regulatory standard prior to the passage of the Humphrey- Durham Amendments for requiring drugs to be dispensed only by prescription led to a number of health and safety concerns. [Footnote 2: See H.R. REP. No. 82-700, at 6 (1951)]

Congress found that lack of a clear standard for the drugs which should be limited to prescription distribution resulted in "many cases of indiscriminate and unauthorized over-the-counter sales of dangerous drugs and other drugs which should be used only under medical supervision." [Footnote 3: Id.]

At the same time, as FDA states in the ANPRM, retail pharmacists and the public faced "burdensome and unnecessary restrictions on the dispensing of drugs that [were] safe for use without the supervision of a physician." [Footnote 4: Advanced Notice of Proposed Rulemaking, 70 Fed. Reg. 52050, 52051 (Sept. 1, 2005).]

Pharmacists were often confused about how particular products should be sold. Because many manufacturers were failing to provide adequate directions for consumer use with drugs not labeled for "prescription-only" use, pharmacists were concerned about liability for improperly dispensing a drug that the manufacturer had not labeled properly for OTC use or that was meant to be limited to prescription sale. [Footnote 5: Hearings Before the S. Subcomm. on Health of the Comm. on Labor & Public Welfare on S. 1186 and H. R. 3298, 82d Cong. 52 (1951) (statement of Roy S. Warnack, Retail Druggist).] They wanted a reformed scheme that would "take the guesswork out of labeling" by making it clear which drugs could be dispensed only on prescription and mandating that manufacturers of a drug not labeled with the prescription legend "must label the drug to meet all of the labeling requirements of the [FDCA] and that the product can lawfully be sold over the counter." [Footnote 6: Id at 50.]

A related lack of uniformity in how the same drug was labeled and sold by different manufacturers led to dozens of drugs containing the same active ingredient and dosage form on the market bearing different labeling; some brands were labeled for prescription sale, some for OTC distribution. [Footnote 7: Id. at 6-7, 53 (providing examples of drugs being sold both prescription and OTC, including quinidine sulfate, theobromine with sodium salicylate, dehydrochloric acid, iron tablets, and tincture of hyoscyamus); H.R. REP. NO. 82-700, at 5-6.]

<1: 3.3.3>B. The Authority Granted to FDA Under Humphrey-Durham.

The specific authority Congress granted to FDA in the Humphrey-Durham Amendments in response to these concerns is of critical importance as FDA considers the issues it raises in the ANPRM. The agency must look to the precise authority Congress provided in the statute itself.

New Section 503(b)(1) directly addressed the protection of consumers from the dangers arising from OTC dispensation of drugs which could not safely be used without physician supervision. That section forbade the OTC sale of any drug which FDA determined "because of its toxicity or other potential for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except for under the supervision of a practitioner licensed by law to administer such drug." [Footnote 8: 21 U.S.C. § 353(b)(1); see also S. REP. NO. 82-946, at 4 (1951), reprinted in 1951 U.S.C.C.A.N. 2454,

2456. Section 503(b)(1) also initially barred OTC sale of habit-forming drugs subject to Section 502(d) and drugs determined to require prescription dispensing in a Section 505 application process. 65 Stat. at 648. However, the provision relating to habit-forming drugs was eliminated when Section 502(d) was repealed in 1997. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 126, 111 Stat. 2296, 2327-2328 (1997).</1: 3.3.3>

<2: 3.3.3, 8.5.1>New Section 503(b)(2), supplemented by Section 503(b)(4), addressed the problem of pharmacists needing guidance on how a drug could be lawfully marketed. Under Section 503(b)(2) and (4), a drug required by FDA to be marketed under prescription was required to have "Rx only" on its label, thus: (a) exempting it from any statutory duty to have adequate directions for consumer use and (b) making it unlawful for a pharmacist to dispense it without a prescription. [Footnote 9: 21 U.S.C. §§ 353(b)(2); (b)(4).] A drug not required by FDA to be dispensed under prescription could not bear the "Rx only" mark and could be sold OTC if the manufacturer supplied adequate instructions for consumer use. [Footnote 10: 21 U.S.C. §§ 353(b)(4); 352(f).] The instruction requirement was expressly made inapplicable to all prescription drug sales, including both those with "Rx only" on the label and those requiring prescription by manufacturer direction. [Footnote 11: *Id.* at § 353(b)(2), stating: "Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of Section 502 [which includes the requirement for adequate directions for consumer use]" This definition applies to all drugs dispensed by a prescription, rather than only those required to be labeled "Rx only" under 21 U.S.C. § 353(b)(4)(A).]

Accordingly, the presence of the "Rx only" symbol advised pharmacists that FDA required a drug to be dispensed with a prescription so that the pharmacist could avoid the legal risks of selling it OTC. Although manufacturers choosing voluntarily to dispense by prescription could not use the "Rx only" symbol, they would have to label their drugs with FDA-approved prescription labeling, and could not put pharmacists in *terrorem* with respect to selling identical drugs sold OTC because the absence of the "Rx only" symbol made it clear that OTC dispensation was FDA sanctioned. [Footnote 12: Pursuant to 21 C.F.R. § 201.100(c)(1), prescription drug labeling - in lieu of OTC adequate directions for consumer use - is required to contain adequate information for use of the drug at the dosage and for the indications recommended, prescribed or suggested in such labeling under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended.]</2: 3.3.3, 8.5.1>

<3: 3.3.3>New Section 503(b)(3) addressed Congress' concern that consumer access to OTC medication not be unduly impaired. The section required FDA to reverse a Section 503(b)(1) determination that a drug be dispensed by prescription only through a rulemaking process "when such requirements are not necessary for the protection of the public health." [Footnote 13: 21 U.S.C. § 353(b)(3).] Thus, when new scientific evidence establishing that OTC dispensation would be safe came to FDA's attention, FDA, on request or at its own initiative, could remove mandatory prescription requirements. A removal of the requirement foreclosed manufacturers from applying the "Rx only" mark, so that pharmacists and other concerned individuals could be made aware that FDA no longer required prescription sale. Manufacturers were also free to propose OTC labeling since OTC distribution was no longer barred. However, nothing in the section prohibited a manufacturer from continuing to limit distribution to prescription-only at its own discretion, as long as the drug continued to have approved prescription labeling and the "Rx-only" mark was not used. </3: 3.3.3>

II. Response to Specific Questions Raised in the ANPRM

<4: 3.3.3>A. The ANPRM's inquiry about the circumstances under which an active ingredient may be simultaneously marketed both as a prescription and OTC drug can be answered directly from Section

503(b).

1. Multiple formulations with different safety profiles are to be sold. Simultaneous Rx/OTC marketing may occur where there are multiple formulations, the manufacturer seeks to market one or more such formulations without an Rx restriction and FDA determines in its review of the manufacturer's application that one or more formulations, but less than all, must be restricted to "Rx-only". In addition, if FDA determines either initially or in a subsequent 503(b)(3) rulemaking that no "Rx-only" designation is required and the manufacturer exercises its right to confine distribution of one or more such formulations to prescription status, simultaneous Rx/OTC marketing is authorized. </4: 3.3.3>

<5: 6.3.1>2. The drug will be marketed to a subpopulation requiring the supervision of a licensed practitioner. Simultaneous Rx/OTC marketing may occur where the manufacturer seeks to label and sell a formulation to a population which includes a sub-population which FDA determines cannot use the drug safely without the supervision of a licensed practitioner but can use it safely on an "Rx-only" basis. In addition, if FDA determines either initially or in a subsequent 503(b)(3) rulemaking that no "Rx-only" designation is required for use by a subpopulation and the manufacturer exercises its right to confine distribution of one or more such formulations to prescription status, simultaneous Rx/OTC marketing is authorized.

As noted in the ANPRM, FDA's determinations under 503(b)(1) and 503(b)(3) may take into account "meaningful differences" in indications for use, active ingredient levels, dosage forms and routes of administration. [Footnote 14: Advanced Notice of Proposed Rulemaking, 70 Fed. Reg. at 52051.] Unless those differences lead to an "Rx-only" determination, however, the ultimate decision on prescription versus OTC marketing lies with the manufacturer. </5: 6.3.1>

<6: 3.3.3, 3.8.7>B. The ANPRM inquires whether a rulemaking to codify FDA's approach would be appropriate. Pfizer does not believe that an expenditure of agency resources on such an endeavor would be justified. Any attempt to describe how FDA would resolve specific safety issues under Sections 503(b)(1) and 503(b)(3) or adequacy of labeling issues under 503(b)(2) would be a complicated undertaking which could either unduly constrain future scientific judgments or result in statements at a level of generality which would be unlikely to advance public understanding of the review process beyond that already established in the Congressional mandate in Section 503. </6: 3.3.3, 3.8.7>

<7: 6.3.1>C. The ANPRM last inquires whether FDA would be able to enforce, as both a matter of law, and a practical matter, a limitation on OTC sales of a product to a particular subpopulation. FDA's ability to enforce such limitation is based on its authority under the Federal Food, Drug, and Cosmetic Act.

FDA is authorized and mandated under Section 502(f) to ensure that OTC labeling permits a drug product to be used safely. [Footnote 15: 21 U.S.C. § 352(f).] If the product labeling does not adequately inform the intended population (or a specific and targeted subpopulation) of a known vulnerability, FDA can and should require an appropriate label modification to ensure that the directions are adequate. FDA is, in fact, working on standards which will better communicate risks and use instructions to all consumers. [Footnote 16: See, e.g., FDA, Guidance, Useful Written Consumer Medication Information (CMI) (draft posted May 25, 2005), available at <http://www.fda.gov/cder/guidance/6520dft.pdf>; FDA, Guidance for Industry, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (draft posted Feb. 4, 2004), available at <http://www.fda.gov/cder/guidance/5669dft.pdf>.]

When FDA is satisfied that the label properly communicates to the relevant subpopulation an effective warning, use contraindication, or other significant safety information it has fulfilled its Congressional mandate and reached the limit of its authority. </7: 6.3.1><8: 6.5.1>FDA has no relevant regulatory authority over consumers or resellers and is not responsible for the elimination of intentional abuse. </8:

6.5.1>

State and local agencies, on the other hand, have both the authority and resources to enforce FDA mandated labeling restrictions, including limitations at point of sale, and have undertaken that task, most recently with respect to certain cold medications. There is no reason for FDA to disturb this Congressionally-mandated division of responsibilities and enforce point-of-sale labeling restrictions on use.

Respectfully submitted,

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COMMENT NUMBER - 2005N-0345-C412

2005N-0345-C412 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Consumer Healthcare Products Association

2005N-0345-C412 - TEXT

Consumer Healthcare Products Association

October 31, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0345
FDA Request for Comments on Advance Notice of Proposed Rulemaking, "Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in both a Prescription Drug Product and an Over-the-Counter Drug Product," 70 Fed. Reg. 52050-51 (September 1, 2005)

Dear Sir or Madam:

In the September 1, 2005, Federal Register, the Food and Drug Administration invited comments on the

above-referenced advance notice of proposed rulemaking (ANPR), regarding circumstances under which an active ingredient may be simultaneously marketed in both prescription and nonprescription, or over-the-counter (OTC), drug products.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of OTC medicines and dietary supplements in the United States. CHPA members account for over 90 percent of the domestic retail sales of OTC medications. As such, we have an interest in the subject matter of the ANPR. CHPA sees no need for the agency to initiate a rulemaking on this matter. Sufficient precedent already exists for an active drug ingredient to be simultaneously marketed in both prescription and OTC drug products based on narrow distinctions.

The comments below use the numbering and lettering for questions on which FDA has invited comments (see 70 Fed. Reg. 52051 [September 1, 2005]).

<1: 3.3.2, 3.8.4>1.A. FDA does not need to initiate a rulemaking to codify its interpretation regarding when an active ingredient can be simultaneously marketed in both a prescription and OTC drug product, since ample precedents already exist to guide the agency and the public. As the agency notes in the background information of this ANPR, the 1951 Durham-Humphrey Amendments to the Food, Drug, and Cosmetic Act removed the confusion that had existed prior to that time when different manufacturers made different decisions about whether to market a drug as prescription or OTC. Under the Durham-Humphrey Amendments, the same drug, at the same dosage form and strength, and for the same indication, cannot simultaneously be available on a prescription and nonprescription basis.

But since the Durham-Humphrey Amendments, FDA has needed to draw fine distinctions among dosage forms, methods of administration, or indications or uses to regulate an ingredient differently in different settings. These fine distinctions are not limited to whether and when a drug ingredient is prescription or OTC. They run across a gamut of issues, from a product's primary mode of action to whether something is a food, drug, biologic, device, cosmetic, or some combination of them, from whether something is generally recognized as safe and effective or whether it requires a new drug application to other fine distinctions. The commonality in drawing these distinctions, and the very reason for drawing them, balances on whether or not an ingredient is the same thing in two related settings.</1: 3.3.2, 3.8.4>

<2: 3.3.2>While FDA has established rules to help guide both interested parties and the agency in walking the line between various distinctions on what is or isn't the same and what triggers different treatment, there is no mandate to do so in every instance. In the case of the instant question of prescription and OTC status, there is no need for a rule, as there are ample precedents to give interested parties paths to follow to distinguish among different labeling requirements, leading to a drug active ingredient in two or more settings not being the "same," even if an outside observer less familiar with the nuances involved would not immediately see the distinctions. There are any number of instances where an active ingredient is seen as an OTC drug in one dosage form and strength for a specified indication(s), and also has uses or additional labeling under consultation with a health professional, whether those different uses or labeling are termed prescription use, professional labeling, professional information, or even off-label use.</2: 3.3.2>

<3: 3.9.1>The examples which follow provide a partial, not exhaustive, list of those instances where a particular ingredient is seen as an OTC drug in one or more settings, but is a prescription drug or includes prescription labeling, professional labeling, or professional information in others.

(1) Dosage strength variations. As FDA notes in the ANPR, ibuprofen and H2 blockers are both examples in which an active ingredient is prescription in one strength and OTC in another. While FDA

also pointed to more readily distinguished differing strengths and indications for the prescription or OTC ibuprofen and H2 blocker examples in the ANPR, one can also point to dosage strength variations where the distinctions between the prescription and OTC versions are finer. For example, prescription-strength 2.5 percent hydrocortisone cream is indicated for relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. OTC 1.0 or 0.5 percent hydrocortisone cream is indicated for temporary relief of itching associated with minor skin irritations, inflammations, and rashes due to a number of listed inflammatory and pruritic conditions, i.e., indications closely related to the higher-dose prescription indication.

As another example, the directions for OTC ibuprofen start at 200 mg, and go up to 400 mg per dose, for aches, pains (including the pain of menstrual cramps), minor pain of arthritis, and reduction of fever. While higher strengths of prescription ibuprofen are available, prescription strength formulations start at 300 mg, between the two OTC doses. In addition, arthritis, including flare-ups of chronic disease, mild to moderate pain, and primary dysmenorrhea are prescription indications. These indications are closely related to the OTC indications.</3: 3.9.1>

<4: 3.9.1>(2) Indication variations. In addition to dosage strength variations (some of which include very similar indications, including the examples mentioned earlier), there are prescription and OTC variations based on the indication using the same dosage strength. Ibuprofen again provides an example, where children's ibuprofen is available OTC for children down to 6 months of age in a suspension --100 mg/5 mL - to temporarily reduce fever or to relieve minor aches and pains due to listed common conditions. The same strength is available as a prescription for children down to 6 months of age for reduction of fever, for relief of mild to moderate pain, and for relief of signs and symptoms of juvenile arthritis. Setting aside the juvenile arthritis indication, which can be readily distinguished, the OTC "'temporarily' reduces fever" indication versus the open-ended prescription "reduction of fever," and the OTC minor aches and pains versus the prescription mild to moderate pain indications illustrate the fine line between two products distinguished as not being the "same."

Clotrimazole is a second example, where 1 percent topicals are available: OTC for athlete's foot, jock itch, or ringworm; OTC for treatment of recurrence of symptoms matching a previously diagnosed vaginal yeast infection; and prescription for treatment of candidiasis due to *Candida albicans* and tinea versicolor due to *Malassezia furfur*. (There are differing creams, lotions, solutions, or delivery vehicle variations in this example. There are also additional strengths for different treatment durations for vaginal yeast infections.) Again, OTC labeling for recurring vaginal yeast infections versus the prescription labeling for open-ended occurrence/recurrence and with reference to more specific causes of the condition draws a fine line between related contexts that aren't seen as the same. It is worth noting that the first reference to the fact that the OTC product is for recurring infections does not occur in the "use" section of the OTC outer package label. Rather, the direction to consult a doctor if this if the first vaginal itch situation occurs under "warnings" - a different section of the OTC "Drug Facts" label from the "use" section.</4: 3.9.1>

<5: 3.9.1>(3) Professional labeling approaches. Under the OTC Review monograph system, many ingredients or classes of ingredients that are generally recognized as safe and effective (GRAS/GRAE) include professional labeling. While it is true that the OTC products with these ingredients are not technically prescription products at the same time, the limitation that this professional labeling is to be provided to health professionals but not to the general public serves the same practical intent: it distinguishes between OTC information (i.e., those uses that are safe and effective for consumers, or information intended to provide for safe and effective use by consumers on the basis of labeling), and information or uses that are intended to be limited to use under the professional supervision of a health practitioner because of potentiality for harmful effect; method of use; or collateral measures necessary to use (i.e., factors in the definition of a prescription drug under 503(b)(1)). Among the many monographs

or tentative final monographs with professional labeling are:

- Antacids: Professional labeling for antacids includes additional details on the neutralizing capacity of the product in terms of dosage per minimum time interval; additional indications (for specific disease states or, for certain ingredients, low phosphate diets); additional warning information on kidney disease for certain ingredients where the OTC label includes a contraindication for kidney disease; and additional warning information on prolonged use for certain ingredients where the OTC label includes a duration of use warning. See 21 CFR sec. 331.80 (April 2004) on professional labeling, and 21 CFR sec 331.30 (April 2004) on OTC labeling of antacid products.

- Antiflatulent: Professional labeling here distinguishes between the basic OTC indication to relieve gas symptoms and indications tied to a particular subpopulation's state: gas pain in postoperative or endoscopic exam settings. See 21 CFR sec. 332.31 (April 2004) on professional labeling compared and contrasted to OTC labeling at 21 CFR 332.30.

- Topical antifungals: Professional labeling for a specific antifungal ingredient includes an additional indication for superficial skin infections caused by yeast (*Candida albicans*). See 21 CFR 333.280 (April 2004) on professional labeling compared and contrasted with the OTC indications for athlete's foot, jock itch, and ringworm at 21 CFR 333.250.

- Cough, cold, allergy, bronchodilator, and antiasthmatic OTCs: Here again professional labeling includes additional information that may be provided to health professionals, but not to the general public, in this instance focused on age distinctions, including dosage schedules for children 6 years of age to 12, and children 2 to under 6. See 21 CFR 341.90 (April 2004). Similar to the case of antiflatulents, professional labeling in this category includes a narrow distinction within the indication for an expectorant tying the expectorant to an underlying condition, but without changing the basic indication: "helps loosen phlegm (mucus) and thin bronchial secretions to" (select one or more of the follow: 'rid the bronchial passageways of bothersome mucus,' 'drain bronchial tubes,' and 'make coughs more productive')" for the OTC indication compared or contrasted with professional labeling that the expectorant "helps loosen phlegm and thin bronchial secretions in patients with stable chronic bronchitis." (Emphasis added.) Compare and contrast 21 CFR 341.78 (April 2004) for OTC expectorant labeling with 21 CFR 341.90(d) for professional labeling.

- Miscellaneous internal OTC products: Cholecystokinetic drug products are GRAS/E for OTC use, and again a distinction is made between consumer labeling and labeling provided to health professionals but not to the general public. Here, the consumer's OTC indication is for the contraction of the gallbladder during diagnostic gallbladder studies, and consumers are directed to take the product only when instructed by a doctor. Left to professional labeling is a description of the implicit 'how' (visualization) of the OTC indication's explicit 'what' (for diagnostic studies): "For visualization of biliary ducts during cholecystography." See 21 CFR 352.350 on OTC labeling and 352.280 on professional labeling. In this final example, there is not free-standing separate indication, or no separate dosage from or strength, to distinguish between the OTC use and the professional (i.e., prescription-like) use. Indeed, in this example, OTC would be predicated on the ultimate professional use. The example yet again illustrates the fine line that can be drawn.

With OTCs subject to a new drug application, FDA has also worked with companies on professional labeling or professional information within approved labeling. For example, at least one of the H2s include not only strength or indication differences between prescription and OTC versions of the ingredient, but professional information for the OTC version discussing pharmacokinetic interactions. Overdosage information provided as professional information in labeling for a number of OTC internal analgesics or antidiarrheals are further illustrations.</5: 3.9.1>

<6: 3.9.1>(4) Age distinctions. As covered in the discussion above on professional labeling, age is frequently used to distinguish either OTC labeling from prescription labeling for the same active ingredient, OTC labeling from professional labeling or professional information, or OTC labeling from an off-label use a physician could choose to prescribe for a patient.

In addition to the GRAS/E OTC ingredients discussed earlier, another example would be nicotine replace therapy, where the directions advise potential users to ask a doctor before use if under 18 years of age. NRT products are further labeled as not for sale to those under 18 years or age, and labeling states that proof of age is required. While a version of these products is not labeled for prescription use for those under 18, a doctor, upon being asked, could chose to prescribe a NRT product within their own practice of medicine.

The same can be said for minoxidil in either 5 percent strength for men, or 2 percent strength for women, where the labels warn against use if you are less than 18 years old.

Clotrimazole for recurring vaginal yeast infections of H2s for heartburn are further examples along the lines of NRT and minoxidil, this time with labeling for use in those 12 and over. (Clotrimazole for athlete's foot, jock itch, and ringworm, meanwhile, warnings against use on children under 2.)

In the case of H2s, similar to NRT, the OTC directions are to ask a doctor for children under 12. How a doctor might respond is not addressed, instead being left to their discretion within the practice of medicine. (Meanwhile, prescription versions of the H2s exist in a variety of other strengths.)

Age distinctions for children who are 6 years of age versus those under 6 are even more common. In addition to the GRAS/E illustrations given earlier, the antidiarrheal loperamide, with OTC directions to ask a doctor before use in children under 6 years of age, includes a professional dosage schedule for children 2-5 years old.</6: 3.9.1>

<7: 3.9.1>(5) Gender distinctions. Distinctions have also been drawn between ingredients in OTC products versus other, prescription, professional information, or presumably off-label uses based on gender. Clotrimazole, discussed earlier, would be one example. Minoxidil would be another.

Minoxidil 5 percent topical solution to help regrow hair is indicated for use in men, and includes warnings against use by women (at the same time, it is not exempt from a general OTC warning to seek the advice of a healthcare professional if the user is pregnant or nursing a baby). Minoxidil 2 percent, meanwhile, is marketed under a brand including a descriptor within the brand name of "For Women." The labeling, however, includes no uses, warnings, or directions limiting its use to women. Earlier versions of OTC minoxidil 2 percent included separate packages and separate labeling for a brand including "for Men" within its brand name, and a version including "for Women" within its brand name. With earlier versions, warnings were included on the "for Women" brand specific to women that were not included in the "for Men" brand (such as the pregnancy/nursing warning). Compare and contrast the "for Men" and "for Women" versions as published in Physicians' Desk Reference for Nonprescription Drugs (1997 edition, Medical Economics). While there neither were not are simultaneous prescription and OTC versions of an ingredient in the minoxidil example, it nonetheless again points to the ability of manufacturers and FDA to draw fine distinctions between two items to make them not the same.</7: 3.9.1>

<8: 4.4.2>B. and C. Given the precedents that already exist, there should not be significant confusion regarding section 503(b), so the question of dispelling confusion is moot. As discussed above, distinctions - some broad, some narrow - have been used for a range of ingredients to allow the

ingredients to be labeled and marketed in more than one way, so there should not be significant confusion regarding section 503(b). A range of paths and precedents exist for both the agency and those wishing to label and market a drug product. The question of dispelling confusion is moot. </8: 4.4.2>

<9: 6.5.1>2. A. and B. Existing law is clear as to what parties the Food, Drug, and Cosmetic Act applies, and existing practice and precedent already recognizes this, already answering the question of whether or how FDA can limit OTC sale of a product to a particular subpopulation. FDA's question as to the practicality of enforcing a limitation on prescription versus OTC status misses the mark. Whether one likes to admit it or not, the Food, Drug, and Cosmetic Act does not and cannot apply to every setting in which any FDA-regulated product is ultimately used. FDA does not regulate the practice of medicine. Apart from limited exceptions, FDA does not control the practice of pharmacy. FDA cannot control the behavior of individual citizens, and that is true whether an active ingredient is OTC, prescription, or both. [Footnote 1: As just one example on the non-use of medicines, two out of five senior citizens said they hadn't taken all the medicines their doctors prescribed for them over the year before being surveyed -- either because they didn't think the drugs were helping them, they didn't think they needed them, or they were concerned about costs. See Safran, et al., "National Survey of Seniors and Prescription Drugs, 2003," available in Health Affairs online edition, April 2005, <http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.152v1?ijkey=Gn1EKoVVrGMv.&keytype=ref&siteid=healthaff.>] FDA does, of course, have an obligation to protect and advance the public health by assuring that drugs are safe, effective, and appropriately labeled. Similarly, our members, as manufacturers of OTC medicines, not only have to meet FDA requirements, but also work to encourage consumers to use their products responsibly in accordance with labeling, and have a need to determine the intended use of their products. </9: 6.5.1>

<10: 6.3.5>While one can speculate as to what has changed in 2005 to raise the question of FDA's ability to enforce a labeling limitation to a particular subpopulation, the fact remains that this issue has always been present. The issue is present when a child is 5 years and 363 days old versus 6, not quite 12 versus 12, or not quite 18 versus 18. It is present when a potential user is a man or a woman. It is present when a condition is occurring temporarily or for the first time versus when it is for a chronic condition or recurring. Yet this is not to say manufacturers or FDA is without means to test, encourage, and improve concordance with label directions. Over generations, the tests and measures by which a manufacturer's and FDA's best intentions for how a product can and should be used have grown. For the current generation of prescription-to-OTC switches, label comprehension studies and actual use studies have become the norm, or at least the norm for early entrants into a new category. Label comprehension studies seek to assure that a proposed OTC label adequately communicate -- i.e. that people understand it -- by testing label versions through an interactive process, with variations in wording, emphasis, or positioning of information. Actual use studies try to simulate the OTC purchase environment by limiting healthcare provider involvement and removing the trial from the clinical setting. The focus of actual use studies is on self-selection (i.e., do the appropriate people choose to use the product and do the inappropriate people deselect, or choose not to use the product), compliance with package labeling, and safety in a minimally supervised environment. Label comprehension, self-selection, or actual use studies have been publicly considered and discussed at FDA advisory committee meetings concerning proposed prescription-to-OTC switches (be they successfully switched, rejected, or pending) for ingredients such as minoxidil, cholesterol-lowering therapies, an analgesic for a migraine indication, a muscle relaxant, a contraceptive sponge, omeprazole, and levonorgestrel, among others.

FDA officials (noting the opinions expressed are those of the speaker, and do not necessarily represent those of the Food and Drug Administration) have discussed the usefulness (including value and limitations) of the label comprehension or actual use studies at a range of meetings, including Drug Information Association meetings, CHPA Regulatory and Scientific Conferences, and others.

The point is that manufacturers and FDA are working toward improved understanding and predictability in how consumers understand and intent to use OTC medicines. We are better equipped today than in the past to assess how well new products will measure up against that goal.</10: 6.3.5>

<11: 8.8>3. A. It is not clear whether or not different marketed and specifically distributed Rx and OTC products may be sold in the same package, but it is clear that prescription uses for a specific OTC product can be accomplished with one package. The agency asks whether, assuming it is legal to market the same active ingredient in both a prescription and OTC product, different products may be legally sold in the same package. Given the fine distinctions to what is or isn't the "same," the answer would appear to be highly case specific, based on how and for what purpose a given product was being marketed. In some of the examples provided earlier, the manufacturer and FDA evidently reached a judgment that different packages were appropriate to distinguish otherwise more closely similar products from one another. Clotrimazole and some of the H2s are examples of this. While both of the original minoxidil 2 percent versions were OTC, they were in different packages. In contrast, in the professional information examples, including explicit dosage instructions based on the age of a child, different packages were not the end result. </11: 8.8>

<12: 8.8, 9.1.1>B. While not entirely clear as a broad rule, there are circumstances where it would be inappropriate to sell to marketed products, one Rx and one OTC, in a single package. Finally, FDA asks, if two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so? As with the previous questions, given the fine distinctions that are sometimes drawn, the answer would appear to be highly case specific. Factors FDA and a manufacturer might consider in answering a case-specific question could include reducing consumer confusion, assuring data exclusivity protections are accounted for, or ease of use, among others. In both the simultaneous prescription and OTC realm, there are any number of examples where distinctions in indications, dosage forms, or strengths have led to separate packages, which in turn reduces the chances of consumer confusion, addresses data exclusivity rights, or eases use. Antifungals (dosage form distinctions, indication distinctions, and/or strength distinctions); an ingredient which can be either an antihistamine or a sleep aid (indication and strength distinctions); minoxidil (gender and strength distinctions); and analgesics (strength and/or indication distinctions) are examples with separate packages.</12: 8.8, 9.1.1>

Conclusion.

<13: 3.8.4>While the same drug, at the same dosage form and strength, and for the same indication, cannot simultaneously be available on a prescription and nonprescription basis, FDA has long needed to draw fine distinctions among dosage forms, strengths, methods of administration, indications or uses, or on other bases to distinguish between OTC and prescription versions of the same active ingredient, or between OTC labels and professional information/labeling for the same active ingredient.

In other areas apart from this ANPR, FDA in some instances has established rules to help guide both interested parties and the agency in walking the line between various distinctions on what is or isn't the same and what triggers different treatment, but there is no mandate to do so. In the case of the instant question of prescription and OTC status, there are ample precedents to give interested parties paths to follow to distinguish among different labeling requirements, leading to an active ingredient in more than one setting not being the "same," even if an outside observer less familiar with the nuances involved would not immediately see the distinctions.

Given the existing precedents, we see no need for the agency to initiate a rulemaking to codify its interpretation regarding when an active ingredient can be simultaneously marketed in a prescription and OTC drug product.</13: 3.8.4>

Respectfully submitted,

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Vice President - International & Assistant General Counsel

COMMENT NUMBER - 2005N-0345-C414

2005N-0345-C414 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.

2005N-0345-C414 - TEXT

November 1, 2005

Via Hand Delivery

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comment to Docket No. 2005N-0345; RIN 0910-AF72 Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription, Drug Product and an Over-the-Counter Drug Product

To Whom it May Concern:

Kirkpatrick & Lockhart Nicholson Graham (K&LNG) submits these Comments to Docket No. 2005N-0345 on behalf of four groups that oppose the dual marketing of the same drug product in both the prescription (Rx) and over-the-counter (OTC) markets. For the legal, medical, and public health reasons set forth below, Concerned Women for America (CWA), the Family Research Council (FRC), the Christian Medical and Dental Associations (CMDA), and the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) oppose the simultaneous marketing of an active ingredient in both an Rx drug product and an OTC drug product. The groups also oppose the Rx-to-OTC switch of Plan B (levonorgestrel) tablets, 0.75 mg, an emergency contraceptive (EC) drug product, also referred to as the "morning after" pill (MAP).

CWA, FRC, CMDA and AAPLOG are non-profit organizations that share a great concern about women's health issues in general, and safe contraception use in particular. CWA represents a membership of 500,000 women in 50 states across the USA. CWA seeks to represent women before Congress and U.S. and International governmental bodies on issues of specific interest to women, including the sanctity of human life from conception until natural death. CWA has been active in contraception-related issues for

over 25 years. FRC is a non-profit organization formed in the 1980's that formulates public policy recommendations that value human life. CMDA is a professional organization with thousands of physician members representing every medical specialty. AAPLOG is a recognized interest group of the American College of Obstetricians and Gynecologists, currently representing over 2,000 physicians throughout the USA.

BACKGROUND

On September 1, 2005, the U.S. Food and Drug Administration (FDA) published an Advance Notice of Proposed Rulemaking requesting public comment on whether, under the Federal Food, Drug, and Cosmetic Act (FDC Act), an active ingredient may be simultaneously marketed in both an Rx and OTC drug product. See 70 Fed. Reg. 52,050 (2005). FDA presented three questions, which we answer briefly as follows:

- (1) Should FDA initiate a rulemaking to codify its interpretation of when simultaneous marketing is permitted under the law? Yes.
- (2) Would FDA be able to enforce an age-related limitation for Rx vs. OTC sales? No.
- (3) May the same drug be sold in the same packaging to both the Rx and OTC markets? No.

In these Comments, we provide detailed legal, medical and public-health-protection analyses to support the brief answers set forth above. We make particular note that in a related action, FDA denied approval to a New Drug Application (NDA) Supplement for Plan B (levonorgestrel) tablets, 0.75 mg, in which the Sponsor requested a switch from Rx-only status to OTC status for women ages 16 years and older. Women under age 16 would have prescription-only access to Plan B. The undersigned support FDA's denial of the NDA Supplement, and we provide evidence herein that this EC product should not be made available OTC to any age group, primarily because physician involvement is paramount to the safe use of the product.

DISCUSSION

<1: 3.3>I. FDA Lacks The Statutory Authority To Permit The Simultaneous Dual Marketing Of The Same Drug As An Rx And An OTC Product

FDA lacks legal authority under the FDC Act, as amended by the Durham-Humphrey Amendments (Public Law 82-215, 65 Stat. 648), to allow the dual marketing of an active ingredient simultaneously in an Rx drug product and an OTC drug product. The statutory language, the legislative history, the implementing regulations, and the Agency's past interpretations all preclude such dual marketing of an active ingredient.

A. Dual Marketing Runs Counter to the Statutory, Language and Congressional Intent

The FDC Act defines a prescription drug as a drug which ""because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. §353(b)(1)(A). The concern is the safety of the drug product, and drug products that are not safe to use except under the supervision of a licensed physician are to be dispensed by prescription only. </1: 3.3>

<2: 3.2, 3.3.2, 3.6.2>The legislative history of the Durham-Humphrey Amendments, as recorded in Senate Report No. 946, notes that the "not safe" language in the statute is intended to have its ordinary meaning. See 1951 U.S.C.A.N. 2,454 at 2,457 and 2,461. If the Agency has determined that a certain drug product is "not safe" for use except under the supervision of a licensed physician, then carving out a

subpopulation (by age, for example) would run counter to this "ordinary meaning" -not safe is not safe, regardless of age. Drugs would not be safe for self-medication if "their unsupervised use may indirectly cause injury," as in the case of drug products that contain potent steroid hormones which affect many organ systems. 1951 U.S.C.C.A.N. 2,454, 2,457. See also 35 Fed. Reg. 9,001 (June 11, 1970). In fact, courts have historically noted the safety risks particular to oral contraceptive prescription drug products. Cf. *Turner v. Edwards*, 1969-1 974 FDLI Jud. Rec. 471,472 (D.D.C. 1970) (stating that "oral contraceptives are prescription drugs, and therefore subject to different requirements as to their use and dispensation than over-the-counter products").

We further note that the legislative history supports the broad applicability of classifying a drug as an Rx product due to the concerns of safety for such drug products. In addressing the concerns in relation to the Durham-Humphrey Amendments, our legislatures made clear that "the broad language of the definition contained in [these provisions] is intended to comprehend all drugs that in fact should be administered under medical supervision in order to insure [sic] their safe use." 1951 U.S.C.C.A.N. 2,454, 2,462 (emphasis added). This Congressional intent on making the definition of a prescription drug apply as broadly as possible is precisely why the statutory language makes sweeping reference to "toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use." See 21 U.S.C. § 353(b)(1)(A). Allowing the marketing of a drug product as OTC based solely on the age of a subpopulation would run counter to the Congressional intent of drafting the statutory language in this broad way. </2: 3.2, 3.3.2, 3.6.2>

<3: 6.5.2>Indeed, the language of the statutory definition for a prescription drug "clearly shows that toxicity is only one fact to be considered" in determining whether a particular drug is safe for use without medical supervision. 1951 U.S.C.C.A.N. 2,454, 2,457. Given the overarching purpose of the FDC Act to protect the public health, the breadth of this statutory definition serves to "effectively restrict to prescription sale all drugs that require professional supervision for their use." 1951 U.S.C.C.A.N. 2,454, 2,457 (emphasis added).

Thus, the concerns for safety, as well as the breadth of the statutory language, indicate that Congress intended the reach of the definition of a "prescription drug" to be as wide as possible. To carve out an OTC exception for a drug product currently approved for prescription use would run counter to this legislative intent set forth in the Congressional record for the Durham-Humphrey Amendments. </3: 6.5.2>

<4: 3.3.2>B. Dual Marketing Runs Counter to the Dichotomous Classification of Drug Products

A plain-meaning interpretation of the statutory language indicates that the Agency may not allow the dual marketing of a drug as both Rx and OTC. The statute states that FDA may "remove drugs.. from the requirements of [21 U.S.C. § 353(b)(1)] when such requirements are not necessary for the protection of the public health." 21 U.S.C. § 353(b)(3) (emphasis added). The statutory language allows for the Agency to "remove drugs" from one classification (Rx) and into another (OTC). The statutory language, in essence, provides for requisite conditions to market a drug as an OTC drug product by noting inapplicability as an Rx product. Cf. 70 Fed. Reg. 52,050 at 52,051 (stating that the term "OTC drug" has been adopted to refer to any drug that does not meet the definition of a prescription drug in 21 U.S.C. § 353(b)(1)). Thus, a dichotomy exists between the prescription and OTC drug "classification." See *id.*; see also 21 C.F.R. § 310.200 (describing FDA's prescription exemption procedure).

If one "removes" a drug from regulation as an Rx drug, then that drug becomes an OTC drug. One cannot "remove" a drug from the prescription classification and still regulate that drug product as an Rx drug. Either the drug is "removed" from the prescription drug regulatory rubric and is therefore an OTC drug, or the drug remains under the Rx rubric and is not an OTC drug. The mutually exclusive nature of the

dichotomous classification of a drug product as either Rx or OTC is manifest in the statutory language. Cf. 21 U.S.C. 353(b)(4). The dual marketing of the same drug as Rx and OTC therefore runs contrary to the plain-language meaning of the statute.</4: 3.3.2>

<5: 3.3.2, 8.5.1>C. Dual Marketing Causes Confusion Between Drug Products

The underlying concern both for FDA and Congress in the statutorily-required dichotomous classification is the potential for confusion that would arise if the statute did not provide for this bifurcation between Rx and OTC drugs. See e.g., 21 U.S.C. §§ 353(b)(4)(A) and (B) (stating, in essence, that a prescription drug must have the "Rx" symbol on its label, whereas an OTC drug must not have this symbol on its label, to avoid the potential for confusion). In fact, courts have noted historically that if birth control pills were extensively disseminated outside distribution channels for prescription drug products, different standards of labeling might be applicable. See, e.g., *Turner v. Edwards*, 1969-1974 FDLI Jud. Rec. 493, 494 (D.D.C. 1971).

Likewise, the legislative history of the statutory language at hand underscores the concern for labeling confusion by stating:

. . . the interstate label on [prescriptions drugs must bear the statement "Caution: Federal law prohibits dispensing without prescription." On the other hand, over-the-counter drugs are forbidden to bear a label containing this caution statement. A prescription drug, the label on which does not bear the specified caution statement, is deemed to be misbranded. So, too, is an over-the-counter drug, the label on which bears this or a substantially similar statement.

See 1951 U.S.C.C.A.N. 2,454, 2,463. Cf. 1951 U.S.C.C.A.N. 2,454, 2,457 (stating that the statutory definition of a prescription drug "could bring an end to the existing confusion in drug labeling and that uniformity can be achieved"). See also 70 Fed. Reg. at 52,051 (noting the resulting confusion and uncertainty that arose due to a lack of criteria in determining when to limit a drug product's approval to prescription use).</5: 3.3.2, 8.5.1>

<6: 4.4.1>The dual marketing of an active ingredient both as an Rx drug and as an OTC drug would only exacerbate this previously-identified confusion, especially if the product was sold in the same package to both markets, or differed only in age-limited dispensing. In order to avoid this confusion, the statutory provisions of the FDC Act prohibit the marketing of the same drug product in an identical package in both the Rx and OTC markets. Instead the law requires, at the very least, labeling with or without the "Rx" symbol. Thus, the inclusion (or exclusion) of the "Rx" symbol on a label would preclude the marketing of a drug product in that package for both the Rx and the OTC markets. Likewise, the FDA's labeling requirements differ substantially for the Rx and OTC markets, such that the labels on the packages could not be the same. See 21 C.F.R. Part 201, subpart B (Rx labeling) and Subpart C (OTC labeling).</6: 4.4.1>

<7: 7.5.3>Moreover, even if a firm attempted to market two different packages, with one package including the "Rx" symbol and the other excluding this symbol, the administrative task of ensuring this dual marketing would be burdensome at best, infeasible at worst. During the approval process, the Agency would need to pass judgment on the Sponsor's plans for utilizing both marketing avenues for the product. During post-approval marketing, the Agency would have to expend its limited resources to ensure that, among other tasks; (1) the manufacturer printed two labels with information appropriate to the distinct markets (i.e., health care providers or consumers), (2) the distributor shipped the packages to the correct retailer, and (3) the pharmacist stocked the relevant shelves with the correct package and dispensed it properly. This extensive regulation of the dual marketed product would be antithetical to the purposes of the FDC Act, which sought precisely to eliminate this type of confusion through the

definition of a prescription drug. </7: 7.5.3>

<8: 8.5.1>D. FDA Regulations Demonstrate the Separation of Rx and OTC Marketing Avenues

The regulatory provisions governing oral contraceptives further demonstrate the difficulty that the Agency would face in allowing the dual marketing of an active ingredient both as an Rx drug and as an OTC drug. The regulations stipulate that "the safe and effective use of oral contraceptive drug products requires that patients be fully informed of the benefits and the risks involved in their use." 21 C.F.R. § 310.501(a). Furthermore, the requirements for the requisite patient package inserts for oral contraceptives are both extensive in reach and exhaustive in content. See 21 C.F.R. § 310.501 (noting the wide-ranging requirements for oral contraceptive patient package inserts).

In contrast, the Drug Facts Panel of an OTC drug product is intended to be comprehended by the layperson without need for medical supervision. By allowing the dual marketing of an active ingredient both as an Rx drug and as an OTC drug, the Agency would be conflating the concerns of safety underlying a prescription package insert with the purposes of simplicity underlying an OTC drug label. Such a decision by the Agency would only add to the confusion that the statutory language and legislative history of the FFDCA precisely sought to avoid.</8: 8.5.1>

<9: 8.5.1>This dichotomy between Rx and OTC drug products is made clear by the fact that FDA has numerous implementing regulations specific to Rx drug products, as well as regulations specific to OTC drug products.

For example, FDA regulates Rx labeling in 21 C.F.R. §§ 201.50-201.59, whereas FDA regulates OTC labeling in 21 C.F.R. §§ 201.60-201.72. Furthermore, under the labeling provisions, with regard to exemptions from adequate directions for use, 21 C.F.R. §§ 201.100 and 201.120 are specific to Rx drug-products. In addition, for specific labeling requirements for specific drug products, FDA again makes this distinction between Rx and OTC drug products. See 21 C.F.R. §§ 201.300-201.323. </9: 8.5.1>

<10: 8.5.1>FDA further delineates the distinction between Rx and OTC drug products by limiting to Rx drugs the Agency's regulations as to advertising (21 C.F.R. § 202), as well as its regulations as to marketing restrictions (21 C.F.R. § 203). Furthermore, FDA regulations as to the guidelines for state licensing of wholesale drug distributors are limited to Rx drugs. See 21 C.F.R. § 205. In addition, the medication guide regulations in 21 C.F.R. § 208 are limited to Rx drug products.

The Agency implements the Rx-exemption procedures, as well-as the exemption for certain drugs limited by NDAs to Rx sale, through its regulations in 21 C.F.R. § 310.200 and 21 C.F.R. § 310.201, respectively.

In addition, FDA's requirement for specific new drugs in 21 C.F.R. §§ 310.501-310.518 are for Rx, whereas the requirements for specific new drugs in 21 C.F.R. §§ 310.519-310.548 are for OTC. Likewise, the FDA regulations in 21 C.F.R. §§ 328-358 are limited to OTC monographs. In contrast, 21 C.F.R. § 361 is limited to Rx drugs used in research. Yet the regulations in 21 C.F.R. § 369 pertain to interpretative statements regarding warnings on OTC drugs. This regulatory separation supports the statutory dichotomy of Rx and OTC drug products. </10: 8.5.1>

<11: 3.3.2, 6.5.1>E. Past Agency Position Precludes Dual Marketing Without Meaningful Difference

According to FDA's present regulatory interpretation of the Durham-Humphrey Amendments, the marketing of the same active ingredient in different drug products in both the Rx and OTC markets assumes some meaningful difference exists between the two marketed drug products. See, e.g., 70 Fed.

Reg. at 52,051 (emphasis added). Historically; FDA has concluded that the meaningful difference relates to five parameters - the product's active ingredient, indication, strength, route of administration, or dosage form. See *id.* Even so, however, FDA has been reticent to acknowledge a "meaningful difference" in a drug product, determining instead that physician supervision is still necessary when a drug product's strength or dosage form, for instance, is distinct. Only in a few cases in the past 50 years has FDA determined that a change in one of the five drug product parameters provided enough of a difference to support the safe use of the product without physician supervision, See 70 Fed. Reg. 52,050 (citing specific product differences in indication, dosage form, and strength). And most of those cases involved two separate indications, for which one of the indications a layperson could clearly self-diagnose and self-treat, but the other indication required a physician diagnosis and supervision (e.g., prescription for ulcers vs. OTC for heartburn). In other words, only rarely can a drug product with one parameter (e.g., lower strength) be used safely without physician supervision, when that physician supervision is required for the safe use of the product with a different parameter (e.g., higher strength). <11: 3.3.2, 6.5.1>

<12: 6.5.2>Furthermore, there is no legal support for an FDA conclusion that a difference in a subpopulation, related to age, constitutes the type of "meaningful. Difference" that would negate the concerns of safety associated with a drug product that is marketed as prescription drug and, thus, support dual marketing. A distinction by age subpopulation does not alleviate the safety concerns associated with the drug product's "toxicity or other potentiality for harmful effect"; if a drug product is not safe for use by one age group except under the supervision of a licensed physician, those same safety concerns, apply to all subpopulations, regardless of age. In sum, the dual marketing of a drug product as prescription-only for one age group and OTC for another age group represents an arbitrary agency action without legal support.<12: 6.5.2>

<13: 6.5.2>II. FDA Lacks The Statutory Authority To Create A Pharmacist-Dispensed "Behind The Counter" Class or "Third Class" Of Drugs

A. A Third Class of Drugs Runs Counter to the Durham-Humphrey Amendments

By considering the dual Rx and OTC marketing of Plan B based on an age limitation, FDA is necessarily contemplating the creation of a third class of drugs intended for sale "behind-the-counter" (BTC) by pharmacists. This third class would be inevitable because the product's labeling would have an age-related limitation for OTC sale (i.e., 17 years and above), In all likelihood, then, pharmacists would need to control access to the drug to enforce the age limitation.

FDA itself does not have, the authority to ensure that-this age limitation. is enforced. Furthermore, the creation of a "third class" of drugs beyond the Rx and OTC markets is unlawful without legislative changes to the FDC Act because, as discussed above, the distribution of medicine in the United States is based on a two-class system - prescription and OTC - that was formalized by Congress in 1951. The goals of the prescription-nonprescription distinction were to protect the public from abuses in the sale of potent prescription, drugs, and to relieve pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of safe OTC medicines. This law directed FDA to distinguish between drugs that were too dangerous for use without professional supervision and those that were safe on an OTC basis with adequate directions and warnings on the label. The statute provides no authority for FDA to establish a new class, i.e., a third class of drugs - whether because the labeling needs to be supplemented by a pharmacist's instructions, or because a certain subpopulation might misuse the drug with direct access. [Footnote 1: Some have suggested that Plan B's proposed age distinction- is no different from age restrictions for alcohol or tobacco sales. These proponents of the age distinction assume incorrectly that enforcement of the age restrictions for the sale of alcohol and tobacco is successful. In 1998, underage buyers were able to buy alcohol in 97% of purchase attempts in Washington, DC, 82% of attempts in Westchester County, NY, 44% attempts in Schenectady, NY, and

59% of attempts in northwestern New Jersey. See Preusser, D.F., and A.F. Williams, Sales of alcohol to underage to underage purchasers in three New York counties and Washington D.C., *Journal of Public Health Policy* 13(3):306-317 (1992). For every 100,000 occasions of youth drinking, only 5 alcohol outlets incur actions by a state Alcohol Beverage Control Agency. See Wagenaar, A.C., and M. Wolfson, Enforcement of the legal minimum drinking age in the United States, *Journal of Public Health Policy* 15(1):37-58 (1994). Certain state police forces have instituted effective compliance check programs; however, successful enforcement of the minimum drinking age requires the enactment of laws prohibiting such action, implementing regulations that prevent adults from buying, alcohol for minors and enclosing areas for alcohol sales and consumption to make it more difficult for adults to pass alcohol to minors. The framework for enforcement of tobacco and alcohol age restrictions may be theoretically present, but the reality is, enforcement is difficult and often not realized. In addition since there is no statutory enforcement provision in the context of age limits for approved drugs, the framework cannot be easily translated to a BTC drug class.]</13: 6.5.2> <14: 6.5.3> Moreover, at least one court has questioned FDA's authority in this area. In *APhA v. Weinberger*, the Court held that FDA lacked statutory authority to impose or authorize the imposition of certain post-approval controls on methadone and declared the regulations invalid to the extent that they prohibited or restricted shipment to, or receipt or dispensing by, a duly- licensed pharmacy. [Footnote 2: *APhA v. Weinberger*, 377 F. Supp. 824 (D.D.C. 1974).] Similarly, the U.S. Justice Department and the National Association of Attorneys General have opposed a third class of drugs, calling such proposals anti-competitive and anti-consumer because they create a monopoly in the distribution on nonprescription drugs. [Footnote 3 Consumer Healthcare Products Association (CHPA) comment to FDA, Docket No. 00N-1256; Over-the-Counter Drug Products, August 25, 2000, p. 19, footnote 16.]</14: 6.5.3>

<15: 7.5.1, 7.5.2>B. FDA Does Not Have The Authority or the Resources To Enforce An Age Restriction for the Same Drug to be Marketed as Rx and OTC

Because FDA does not have the statutory authority or the economic or personnel resources to enforce an age restriction for Plan B sales, enforcement activities would fall to the states, local governments, or pharmacies. Yet, FDA has no regulations to instruct third parties in appropriate enforcement activities, nor is there any mechanism for FDA to ensure that enforcement is carried out. </15: 7.5.1, 7.5.2>

<16: 6.6.1>Some states have shown a willingness to create a framework for BTC drugs. Alaska, California, Hawaii, Maine, New Mexico, and Washington currently offer emergency contraception behind the counter. However, other states, such as Louisiana, are unable or unwilling to expend the financial resources necessary to promulgate pharmacy access laws and enforce the regulation's restrictions. This uneven regional enforcement illustrates the imprudent and illegal nature of a dual marketing approval for Plan B. It is also unclear that FDA has the requisite legal authority to supervise and correct the states' efforts, or lack thereof.</16: 6.6.1>

<17: 6.6.1>Furthermore, previous attempts to restrict consumer access to nonprescription substances have effectively failed. Some states restrict consumer access to-Schedule V (e.g., cough medicines with codeine) nonprescription controlled substances to pharmacist-only sales. These restrictions were imposed under state controlled substance laws, not federal law. The original intent of the restrictions was to prevent abuse, but many states that originally placed Schedule V nonprescription drugs behind the counter realized that the restrictions did not achieve their intended purpose. As a result, roughly half of the states placed these nonprescription drugs on prescription status under the states' controlled substance laws. [Footnote 4: Among others, these include California, Colorado, Louisiana, Montana, Nebraska, New Hampshire, North Dakota, Oregon, Rhode Island, and Texas, See-R. William Soller, Eve E Bachrach, Doc. No. 00N-1256: Over-The-Counter (OTC) -Drug Products: Request for Comments; 65 Fed. Reg. 24704, April 27,2000 (August 25, 2000), available at www.chpa-info.org/web/advocacy/submissions/08_25_00_OTC~commets.pdf.]</17: 6.6.1>

<18: 6.6.1>Some proponents of a third class of drugs have offered-as precedent certain restrictive drug distribution models in the United States. Upon closer examination, however, these examples do not provide a basis for pharmacist-only third class distribution of nonprescription drugs. For example, the state of Florida initiated an experiment in 1985 under the Pharmacist Self-Care Consultant Law to permit pharmacists to prescribe a limited number of prescription drugs without physician supervision. The GAO Report described below, found that the authority was rarely used because pharmacists and/or pharmacies were unwilling to assume the liability risks. [Footnote 5: See Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Determined, Report GAO/PEMD-95-12. Washington, DC.: U.S. General Accounting Office, Program Evaluation and Methodology Division, August 1995 at 57-59, 65, 79 [hereinafter, GAO Report].]When the prescribing authority was used, the law's record-keeping requirements were seldom followed because pharmacists were already burdened, by time pressures to address other responsibilities. Given that there is currently a shortage of pharmacists, the time-pressures that a pharmacy-only class of nonprescription drugs would add make such a plan even less appealing. </18: 6.6.1>

<19: 7.5.3>C. From Both Practical and Public Policy Standpoints, the Health Care System in the US. Does Not Support a Third Class of Drugs

In addition to the legal impediments, the U.S. health care system as a practical matter does not have the necessary infrastructure to support a BTC class of drugs. With respect to pharmacy practice, pharmacists in the U.S. and elsewhere often do not perform the roles on which the benefits of the third class are premised, even when such roles are expected or required. Pharmacists are expected, among other things, to provide complete counseling, report adverse drug events, and maintain patient profiles, but often do not. [Footnote 6: See GAO Report at 28.]

A third class of BTC drugs in the U.S. will necessitate the active participation of pharmacists. Pharmacists will be forced to provide meaningful advice and counseling before, offering products from behind the counter. The education of pharmacists would have to include training on retail patient counseling, which, for the most part, is currently lacking. Pharmacies would also have to grant their pharmacists time away from dispensing drugs to meet with patients. The burden of this financial cost will not be willingly absorbed by the pharmacies, and will most likely be borne by the patients themselves. The push for BTC drugs to reduce the cost of prescription drugs may ironically result in inflation of drug costs. At this time, there is nothing available from insurance companies or other sources for patient reimbursement for patient drug counseling.</19: 7.5.3>

<20: 7.5.3>As a public policy matter, evidence of the-need for QT benefit of a third class of drugs is lacking. In 1995, the U.S. General Accounting Office (now called the present Accountability Office) researched other countries that use the BTC drug avenue and found that use of a pharmacy only class to prevent abuse met -with similarly poor results in other-countries. In a study performed in Germany, for instance, children between 10 and 14 were directed to purchase medicines containing alcohol from pharmacies. In all 54 pharmacies visited, the children were allowed to purchase the drugs, and in only one instance was the child questioned intensively. [Footnote 7: See GAO Report at 28.] The GAO also found that safeguards against abuse are easily circumvented and that actual counseling of patients by pharmacists is infrequent and incomplete. [Footnote 8: Id.] The GAO stated specifically that other countries' experiences "do not support a fundamental change in the drug distribution of the United States such as creating an intermediate class of drugs The evidence that does exist tends to undermine the contention that major benefits are being obtained in countries with a pharmacist or pharmacy only class" [Footnote 9: Id.] Among the organizations opposing a third class of drugs are the American Medical Association, Interamerican College of Physicians and Surgeons, National Black Caucus of State Legislators, National League of Nursing, Food Marketing Institute, Consumer Alert, National Black

Women's Wealth Project, National Coalition of Hispanic Health and Human Services Organizations, National Grange, National Council on Aging, Food Industry Association Executives, and many others. [Footnote10: See Third Class of Drugs, CHPA, available at http://www.chpa-info.org/web/advocacy/general_issues/third_class.aspx .] </20: 7.5.3> <21: 6.5.2> Regardless of the public policy issues associated with a BTC class of drugs, the existing dichotomy of prescription and OTC drugs is well established in the FDC Act and any alterations would require explicit action by Congress. </21: 6.5.2>

<22: 7.5.3> The existence of third class drugs in other countries does not support establishing the same in the United States. No public health advantages have been identified to justify creating a third class of drugs, nor to provide patients with better access to medicines. In its 1995 report to Congress, the GAO concluded that "the existence of a third class does not make regulatory officials more or less likely to approve new OTC products or switch prescription drugs to unrestricted nonprescription status." [Footnote 11: See GAO Report at 42-43, 78.] </22: 7.5.3>

<23: 3.8.3, 6.6.2, 7.5.3> D. Without A Third Class of Drugs, OTC Sale Is Unregulated and Uncontrolled

Whether Congress creates a third class, or FDA by regulation creates a third class, without such a creation the Plan B product will be freely available to all consumers. Presently in the U.S., an OTC drug can be sold anywhere to any consumer unless restricted by state law. Thus, if FDA approves Plan B for OTC sale and a state does not restrict the sale to pharmacies, the drug would be available at any gas station, 7-11, or other business that wanted to sell the drug. In such a setting, does anyone believe the under-17 age limit will be observed, much less enforceable? [Footnote 12: For the remainder of these Comments, we will refer to the proposed age restriction for Plan B OTC sales as 17-and-over and under-17, as delineated by FDA, though we acknowledge that the Sponsor's NDA Supplement requested a restriction at age 16. See Not Approvable Letter, Lester M. Crawford, DVM, Ph.D., Commissioner, FDA, to Duramed Research, Inc. (Aug. 26, 2005).] FDA has been given the statutory tools to protect the public health for the nation, and the switch of Plan B without a regulatory framework to control the drug's use in under-age children is without precedent. It may be that some statutory plan can be created to provide this drug OTC to adults, but the current statutes and regulatory scheme do not provide them. Moreover, FDA should not usurp the role of Congress by creating a marketing exception to the laws and regulations currently on the books. </23: 3.8.3, 6.6.2, 7.5.3>

<24: 3.1> III. FDA Must Initiate And Complete Full Rulemaking Proceedings In Order To Institute The Simultaneous Dual Marketing Of The Same Rx/OTC Drug Product

FDA has asked whether it should proceed with notice and comment rulemaking to codify the FDA's interpretation of Section 503(b) as to when a drug can be dually marketed as OTC and by prescription, since FDA historically has not allowed marketing of the same active ingredient in a prescription for one population and OTC for another. The brief answer is yes. </24: 3.1>

<25: 3.4> Agency "rules" are broadly defined in Section 551 of the Administrative Procedures Act (APA) as the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law & policy, or describing the organization, procedure, or practice requirements of an agency. Agency rules include the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing. [Footnote 13: See 5 U.S.C. § 551.] Given the magnitude of the regulatory change that FDA would be enacting, despite the Durham-Humphrey Amendments, any FDA approval of an active ingredient for simultaneous Rx and OTC marketing is a new Agency "rule" that triggers notice and comment rulemaking.

In order to issue a rule, an agency must complete a three step process - issuance of a notice of proposed rulemaking, receipt and consideration of comments on the proposed rule, and issuance of a final rule incorporating a statement of its basis and purpose. Section 553(b)(A) of the APA exempts several types of rules from the rulemaking process. The exemptions cover interpretative rules, general statements of policy, procedural rules, rules the agency has "good cause" to issue without the rulemaking process, and rules that apply to particular subject matters -e.g. military or foreign affairs, However, none of these apply to the Plan B dual marketing. </25: 3.4>

<26: 3.6.1>In particular, if the Agency issues a general statement of policy, it need not go through notice and comment. However, the task of distinguishing between a rule and a general statement of policy is complicated by the reality that many rules are also general statements of policy. To determine what procedures an agency must use, courts distinguish between rules and policy statements based on whether the agency statement has binding effect on members of the public. Thus, if a general statement of policy binds the public, the agency must issue the statement using notice and comment procedures. See *Pacific Gas and Electric v. FERC*, 506 F.2d 33 (D.C. Cir. 1974). The issue of simultaneous marketing would bind the public in the case of Plan B, as well as establish Agency precedent for future Rx-to-OTC switch decisions. Consequently, the issue is not merely a general statement of policy.

An additional exemption to the notice and comment procedures is issuance of an interpretative rule. A majority of the Circuits, the DC Circuit included, utilize the following factors to determine when an agency action is legislative, requiring notice and comment, or interpretative, which is exempt from notice and comment: (1) whether in the absence of the rule, there would not be a basis for enforcement action, (2) whether the legislative rule claimed to be interpretative is too vague or open ended to support the interpretive rule, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. See *Health Insurance Association v. Shalala*, 23.F.3d 412 (D.C. Cir. 1994) and *ANR Pipeline v. FERC*, 205 F.3d 403 (D.C. Cir. 2000) Interpretive rules which do not require notice and comment are those which merely clarify or explain existing law or regulations. *Malone v. BIA*, 38 F.3d 433 (9th Cir. 1994). As argued above, simultaneous dual marketing presents a new and about-face interpretation of the FDC Act, not a mere clarification.

Any claim of exemption from the rulemaking requirements of the APA will be narrowly construed. Further, when rules to be adopted by an agency will have a broad impact not merely on the regulated industry but also on the general public in a matter which concerns the public and transcends economic issues, the notice requirements of the APA must be interpreted liberally. See *NRDC V. SEC*, 389 F. Supp. 689 (D.D.C , 1974). Also, when an agency statement effects a change in existing law or policy, it will be considered a substantive rule requiring notice and comment even if the agency labels the action as interpretative. *D&W Food v. Block*, 786 F.2d 751 (6th Cir. 1986): Similarly, if a rule constitutes a change in prior agency position and has a substantial impact on the rights and obligations of members of then public, the rule is invalid if there has not been compliance with notice and comment procedures. *NRTA v. USPS*, 430 F. Supp 141 (D.D.C. 1977), affirmed 593 F.2d 1360. See also *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992). Notice and comment rulemaking is required before FDA can approve an NDA Supplement that would produce the kind of sea-change presented by simultaneous dual marketing of an Rx and OTC drug product.</26: 3.6.1>

<27: 3.7.1, 8.5.4>With regard to the matter at hand, we question whether the current Rx labeling for Plan B can be simplified to the extent necessary to present information in the OTC-required Drug Facts Format (21 CFR § 201.66), while also adequately warning patients of risks, side effects, and contraindications. For example, the labeling of human prescription drugs requires not only a summary of the essential scientific information needed for the safe and effective use of the drug, but also specific information required under 21 CFR § 201.57 including clinical pharmacology, and detailed contraindications, drug

interactions' and warnings. This information on prescription labeling consists of concise, yet still dense paragraphs of detailed drug information.

In contrast, during the rulemaking process for OTC drug labeling, FDA cited literature studies confirming that OTC drug product labeling requires short statements and clear graphical features and visual cues to ensure readability and comprehension. See 64 Fed. Reg. 13254 (March 17, 1999). These and other studies described the importance of adherence to directions for use, and reported on a number of preventable adverse drug reactions from OTC drug products with confusing labeling. *Id.*, Accordingly, for certain drugs it is not possible to convey the amount of information needed to adequately inform consumers of the required directions for use and safety information using the simplified OTC labeling requirements. [Footnote 14: In the proposed rule making for CDTC labeling, the FDA stated "information . . . presented in a paragraph format . . . is unappealing to the eyes and may cause the reader to lose interest." 62 Fed. Reg. 9,024, 9,028. (February 27, 1997).] Plan B is such a drug. </27: 3.7.1, 8.5.4>

<28: 3.7.1>Moreover, FDA promulgated a regulation acknowledging safe and effective use of contraceptives requires that patients be fully informed of the benefits and risks involved in their use. See 21 CFR § 310.501. To provide full information a patient package insert must be distributed. *Id.* That package insert must include a number of warnings including: information on medical conditions that are not contraindications to use but deserve special consideration in connection with oral contraceptive use and about which the patient should inform the prescriber; a warning regarding the most serious side effects of oral contraceptives; a statement of other serious adverse reactions and potential safety hazards that may result from the use of an oral contraceptive; a statement concerning common, but less serious side effects which may help the patient evaluate the benefits and risks from the use of an oral contraceptive; as well as eight additional areas of information. *Id.*

These two rulemakings are in direct conflict with each other in the case of the Plan B oral contraceptive product. We assert that the conflict may only be resolved by FDA adherence to the most comprehensive set of labeling - the patient package insert which, in turn, requires physician interpretation and prescription-only sale.</28: 3.7.1> <29: 3.4>Nevertheless, even in the alternative, it is clear that FDA cannot approve OTC labeling in the Drug Facts Format for Plan B without complying with APA notice and comment rulemaking to fully examine this regulatory conflict. Thus, FDA must initiate and complete full rulemaking proceedings in order to institute the simultaneous dual marketing of the same drug product as Rx and OTC. </29: 3.4>

<30: 1.2.3>IV. The FDA Approval Of An NDA Supplement Permitting The Simultaneous Dual Marketing Of Plan B (Levonorgestrel) Tablets As An Rx And An OTC Product Would Be Arbitrary, Capricious, And Unlawful Agency Action

A. The Safety Profile and Method of Use of Plan B Requires the Supervision of a Physician and, Thus, an Rx Classification

As explained above, the FDC Act, FDA regulations, and Agency precedent all dictate that, in order for a drug to be approved for an OTC switch, it must be proven safe and effective for use by the lay public without the involvement of a physician. For Plan B, however, physician supervision is paramount to the safe use of the drug, for physical, emotional, and societal reasons. According to the drug's approved labeling, Plan B is used "to prevent pregnancy after known or suspected contraceptive failure or unprotected intercourse", and not for routine birth control. Consequently, its proper method of use involves a certain degree of knowledge of birth control options, failure rates of those options, and female biological cycles. To our knowledge, the Sponsor has provided no data on a woman's age-related or maturity-related ability to assess these items and appropriately choose Plan B as her contraception option without physician involvement. A physician/patient conversation on the proper use, risks, warnings, and

range of birth control and emergency contraceptives, no matter how brief is beneficial for women's health.</30: 1.2.3>

<31: 1.2.3>1. The FDA Lacks Proof that Plan B is Safe and Effective for OTC Use By Patients Ages 17 Years and Older

Health Risks Identified In the Approved Labeling of Plan B

An Rx-to-OTC switch may occur only when the prescription marketing of particular drug is not necessary for the protection of the public health. See 21 U.S.C. § 353(b)(3). Yet, the Plan B switch fails to meet this statutory requirement. In fact, at least four health risks are inherent in Plan B use, including serious drug interactions, increase in known risks, adverse reactions, and lack of patient compliance. These risks will only be heightened by the drugs OTC marketing, with the likely result of increased adverse health events.

First, because Plan B interacts with other drugs and has the propensity to cause serious adverse events from drug interactions, the public health would be jeopardized if FDA permitted its OTC marketing. Specifically, the approved labeling warns against Plan B with nevirapine, rifampin or St. John's wort. These therapies are used to treat HIV-1, tuberculosis, and mild to moderate depression - diseases that affect more than 21 million people nationwide. [Footnote 15: According to the Centers for Disease Control (CDC); at the end of 2003, an estimated 1,039,000 to 1,185,000 persons in the U.S. were living with HIV/AIDS. See CDC National Center for HIV, STD and TB Prevention, Division of HIV/AIDS Prevention, Basic Statistics, at <http://www.cdc.gov/hiv/stats.htm>. More than 14,000 cases of tuberculosis were reported in 2003 in the United States, See CDC National Center for HIV, STD and TB Prevention, Division of Tuberculosis Elimination, Questions and Answers About TB, 2005, at http://www.cdc.gov/nchstp/tb/faqs/qu_introduction.htm. According to the National Institutes of Health (NIH), depression affects nearly 19 million Americans each year. See NIH National Center for Complementary and Alternative Medicine, St. John's Wort and the Treatment of Depression, at <http://www.nih.gov/health/stjohnswort/>.] The amount of women who are taking these drugs to treat these diseases and, thus, should not take Plan B, is numerous and must be considered by FDA. Does FDA have evidence that, without physician involvement, women in these disease categories will understand the drug interaction risks and refrain from using Plan B? The OTC switch would remove the supervisory activity provided routinely by physicians and pharmacists who monitor and evaluate a patient's drug profile for drug/drug interactions. The combination of serious drug interactions with the lack of physician/pharmacist supervision inherent in the OTC marketplace supports the necessity of prescription dispensing to ensure the safe use of Plan B.</31: 1.2.3>

<32: 1.2.3>Second, without physician involvement, there is likely to be an increase in the known/expected risks described in the approved labeling. Oral contraceptives are associated with DVT's, ectopic pregnancies, dysplasia, liver hemangiomas, and other risks. An increase in these risks would be caused by a lack of screening for medical contraindications. The group Alabama Physicians For Life, Inc, (APFLI) noted in comments to FDA that in order for a patient to receive low hormone dose oral contraceptives the patient is typically given a physical examination before receiving a prescription, while for a high dose of hormones is supplied in Plan B, the OTC use would not require a medical examinations, medical history, or other physician counseling. [Footnote 16: See APFLI letters to FDA dated Sept. 20, 2004, Jan. 14, 2005, and Aug. 22, 2005, available at <http://www.physiciansforlife.org/content/view/793/36/>.]

Ectopic pregnancies can lead to rupture and internal bleeding and may damage fertility. AAPLOG notes that in World Health Organization (WHO) EC Task Force trials, the ectopic pregnancy rate for EC users was triple the regular rate. [Footnote 17: CMO Update 35A [communication to all doctors from the Chief

Medical Officer] January 2003; Department of Health, Published 04/02/2003. Overseas Post-marketing Surveillance of EC use (Levonelle, reported to the Committee on Safety of Medicines from the WHO Task Force trial) showed a reported ectopic pregnancy rate of 6%, three times the usual rate. The UK Dept of Health even issued a warning to its doctors to be aware of this.

http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/CMOUpdate/CMOUpdateArticle/fs/en?CONTENT_ID=4003844&chk=2uZJEX.] Another, doctor commented to CWA that it is possible that a woman could have an ectopic pregnancy and believes that it was aborted when in fact, the pregnancy was not terminated, only to find out that the EC did not work when the pregnancy ruptures. [Footnote 18: See Letter from, Chris Kahlenborn, MD, Oct. 24, 2005, referencing Testimony before the FDA, December 16, 2003, re: Plan B, on file with the authors.] Schering Health Care, the makers of the morning-after-pill in the UK, was ordered to change the wording of patient information leaflets to make clear the potential risk of ectopic pregnancy. Does FDA have a plan to include a pre- and post-usage pregnancy test in the packaging to prevent or identify ectopic pregnancies?.

In Australia, of the women who have remained pregnant despite taking a morning-after- pill, more than 1 in 20 have suffered an ectopic pregnancy. (Beezy Marsh, Anna Patty, Ectopic Pregnancy Linked to Morning-After-Pill, Nationwide News Pty Lmt., The Daily Telegraph, January 31, 2003.) It is important that women be aware of risks and to seek medical assessment if their period does not return to normal after taking-the morning-after- pill. Ordinarily, a doctor prescribing Plan B would advise the patient-of these risks before giving the prescription. To prevent delay in the diagnosis of ectopic pregnancy, FDA should require a OTC Plan B label to advise women that ectopic gestation can occur with emergency contraceptive pill failure. See also Nielsen, C.L., Miller L., Ectopic Gestation Following Emergency Contraceptive Pill Administration, *Contraception*, 2000 November, 62(5): 275-276; Galit Sheffer-Mimouni, et al., Ectopic Pregnancies following Emergency Levonorgestrel Contraception, *Contraception*, 2003. Without adequate labeling and pregnancy tests, Plan B must remain in the Rx-only category for all age groups.

Numerous studies have shown that more research is needed to improve tolerance of progestin-only contraceptives and identify alternative techniques that will not interfere with the endocrine events of the cycle. Outstanding research issues include the mechanisms of endometrial bleeding, definition of molecular and cellular targets for an endometrial approach to contraception, progesterone action, integrins, placental protein 14, insulin growth factor binding protein- 1, and plasminogen activators. Emergency contraception has been found to suppress progesterone-associated endometrial protein in the midluteal uterus, potentially altering the endometrial environment unfavorably and affecting the survival of the early embryo, (Young, D.C., et al., Emergency Contraception Alters Progesterone-Associated Endometrial Protein in Serum and Uterine Luminal Fluid, *Obstet Gynecol*, 1994 August, 84(2):226-271.)

Other hormonal treatments have noted damage to the delicate balance of reproductive hormones. A study published in 2000 found that the Yuzpe regimen of emergency contraception reduced endometrial MUC-1 expression, increased endometrial oestrogen receptors, lowered luteal phase serum oestrogen concentrations, reduced endometrial thickness, and increased proportion of glandular supranuclear vacuoles in a statistically significant way. (Raymond, E.G., Lovely, L.P., Chen-Mok, M., Seppala, M., Kurman, R.J., Lessey, B.A., Effect of the Yuzpe Regimen of Emergency Contraception on Markers of Endometrial Receptivity, *Hum. Reprod.*, 2000 Nov, 15(11): 2351-2355). </32: 1.2.3>

<33: 1.2.3>Third, FDA must further analyze the propensity for and severity of adverse events for Plan B, accumulated since the Agency's Oct. 31, 2003 Office of Drug Safety Postmarketing Safety Review. The signatories below maintain that this data supports the Rx-only sale of Plan B. Also, CWA has received comments from an OB/GYN who works with middle school students, regarding the possible steroidal abuse of Plan B by young athletes who believe that ingesting Plan B will help them delay epiphyseal

closure. [Footnote 19: Physician comments are on file with the author] The Physicians Desk Reference lists post-marketing reports demonstrating myocardial infarctions and strokes coincident with Norplant System (75 mg levonorgestrel implant). "Plasma concentrations average approximately 0.03 ng/mL over 5 years but are very highly variable as a function of individual metabolism and body weight. Diffusion of levonorgestrel through the wall of each capsule provides a continuous low dose of the progestin. Resulting blood levels are substantially below those generally observed among users of combination oral contraceptives containing the progestins norgestrel or levonorgestrel." (1999 Physicians Desk Reference, 53rd Edition, pg. 3344-3345.) The physician argues that higher doses of levonorgestrel in Plan B, if used on a regular basis, would quite likely result in myocardial infarctions, particularly with the lipid profile of males. Is FDA prepared to study the effects of Plan B in males and require the addition of a specific warning before approving Plan B for OTC?

Fourth, FDA must consider, but does not have data on, the potential extent of a lack of patient compliance with the approved labeling for Plan B in the OTC setting. The approved labeling calls for limited usage, on an "emergency" basis, with two pills to be used per "dosage". If the product is misused in frequency or extent, either by taking it 10 days in a row or 12 times per year or 5 pills instead of two, FDA should have data to support the safe use of the product in these foreseeable ways. For example, Plan B is a progestin which is linked to breast cancer and repeated use could lead to an increase in the risk of breast cancer. Data on the safety and efficacy of Plan B for long term or frequent use must be further explored before the product is switched to the OTC market for any age group.

<34: 1.2.3>No Doctor/Patient Relationship for Addressing Complications (Physical and Emotional)

The American Academy of Pediatrics (AAP) Policy Statement on Emergency Contraception given by the Committee on Adolescence (Ped 116: 1026-1035 (Sept. 1, 2005)) recommends that teens who receive prescription EC via telephone receive a follow-up appointment to exclude an already existing pregnancy and/or to deal with issues of contraception and screening for sexually transmitted diseases. The statement also recommends doing an appropriate medical history analysis of the patient before prescribing EC. The policy statement further recommends pregnancy testing, antibiotic prophylaxis; and counseling for rape victims. These policies to ensure appropriate usage and adequate provision of aftercare assume a relationship between the doctor and the patient. Although recognizing "social pressures" to make EC more readily available, the AAP does not conclude that EC should be made available OTC. Indeed, doing so would undermine the doctor-patient relationship that provides a safety net for the patient and ensures that EC is used safely and effectively.

AAPLOG observes that the proposed Plan B OTC status would result in lack of physician oversight for patients at risk of failed MAP treatment and potential ectopic pregnancy. Furthermore, patients who elect to use MAP are generally also at high risk of getting STDs, and without physician oversight, undiagnosed and untreated STD's lead to infertility and cervical disease. AAPLOG maintains that use of the-MAP is attendant with very serious long-term risks for the health of the women involved. AAPLOG insists that physician oversight, with STD testing, pap smears, and pregnancy tests-as indicated, is essential for the well-being of women's health, as discussed in more detail below.

<35: 1.2.3>2. The FDA Lacks Proof that Plan B is Safe and Effective for OTC Use By Patients Under 17 Years of Age

In addition to the specific safety-related and public health concerns described above - all of which would apply to the use of Plan B in both the 17-and-over and under-17 patient subpopulations, CWA and its physician contacts have specific concerns about the safe use of Plan B by children and adolescents under 17 years of age.

Lack of Control with OTC Sale/Black Market to Underage Adolescents and Children

CWA has received multiple comments from doctors citing a concern over the ease with which underage adolescents and children will be able to obtain Plan B from their older friends, boyfriends, or relatives, based on currently insufficient age restriction mechanisms (e.g., age restriction mechanisms for cigarettes and alcohol have little effect on preventing underage minors from obtaining cigarettes and alcohol) [Footnote 20: Physician comments are on file with the author.] The unintended creation of a "black market" for Plan B mitigates against an OTC bifurcation for Plan B. </35: 1.2.3>

<36: 1.2.3>Physical and Biological Changes in Pre-Pubescent and Early Pubescent Girls

Dr. Harold Wallis, a Texas-based OB/GYN, has observed that the MAP primarily inhibits ovulation, disrupts follicular development, and produces pathophysiological symptoms in pre-pubescent and early pubescent girls. [Footnote 21: Physician comments are on file with the author.] He notes that teenagers with abnormal menstrual cycles are commonly treated for the same kind of pathophysiological problems. Thus, without adequate age restriction enforcement to support Rx sales and physician supervision for this subpopulation, girls in this variable "biological" age range may create the same pathophysiological problems through the use of Plan B that necessitate common treatment by OB/GYNs.

Furthermore, this age group's general lack of understanding and experience with monthly biological cycles and the cause pregnancy may lead to the misuse of Plan B. One study concludes that risk-taking behavior and poor assessment of the future consequences of their actions are common characteristics of 15 - 17 year olds. (Burgis, J. and J. Bacon, Communicating with the Adolescent Gynecology Patient, Obstetrics and Gynecology clinics of North America, 30:251-260, 2003.) Similarly, the AAP's Policy Statement on Emergency Contraception given by the Committee on Adolescence notes; "Teens may not be able to give sufficiently adequate menstrual histories to exclude a preexisting pregnancy, and some teens already pregnant may try to use EC as an abortifacient." (Ped 116:1026-1035 (Sept. 1, 2005).)</36: 1.2.3>

<37: 1.2.3>Connection Between Plan B and STDs

APFLI noted in a letter to FDA that there has been a demonstrated link between the availability of MAP and exposure to STDs. APFLI cited data from the Swedish Institute for Disease Control and the Washington State Health Department demonstrating a significant increase in chlamydia infection in women, especially teens, in the five years following OTC availability of MAP.

AAPLOG comments that in the five years following a Washington State pilot program to provide OTC MAP, teenage women showed a 23% increase in chlamydia infections. (Sexually Transmitted Disease Morbidity, Washington, State, Infection, Disease, and Reproductive Health, STD/TB Services & IDRH Assessment Unit, Washington State Dept. of Health 1997, available at <http://www.doh.wa.gov.cfg.STD/morbidity.htm>.) AAPLOG comments that these increases may well be associated with the increased and unprotected sexual activity facilitated by OTC MAP. Chlamydia causes infertility in a quarter of women and can reduce men's chances of becoming a father by 33%. As untreated chlamydia is a major cause for infertility, the availability of MAP OTC could lead to many women, especially teens, becoming infertile after several years of untreated and asymptomatic chlamydia.

Plan B offers no protection against STDs. In the UK where EC has been OTC for five years, figures show that over the past four years there has been a 76% increase in chlamydia diagnoses, a 55% increase in gonorrhea, a 54% increase in syphilis, and a 20% increase in genital warts. In all of these infections, the highest rates and the fastest increases were found in the 16-24 age group. (The Observer, May 15, 2005,

available at <http://observer.guardian.co.uk/magazine/story/0,11931,1482669,00.html>.) In Scotland, rates of chlamydia rose by 106 percent between 1998 and 2004. Scottish Executive figures reveal almost half of all chlamydia cases diagnosed in 2002 were in people under 25, and there has been a 66% increase in cases involving youth under 16. A possible reason for this increase is that teenagers comforted by the idea of a contraceptive pill use condoms less. "Too often teens think that by taking the contraceptive pill, or ensuring their partner is taking the pill, that's all the protection they need.. .The pill can protect against pregnancy, but it's the ever increasing numbers of nasty diseases that will do your health more long-term harm." (Julia Hunt, Experts Fear Rise In Infertility as Chlamydia Cases Soar by 66 Percent, Scottish Daily Record & Sunday Mail, May 2, 2004, pg. 40, 41.)

A Swedish study published in 2002 reported that STDs were on the rise among adolescents who had OTC access to emergency contraception. and other forms of contraception. (January W. Payne, Is Plan B Unsafe? Current Research Does Not Support Fears of Day-After Pill Dangers, September 6, 2005, Page HE01 .) From 1999-2002, the cases of genital chlamydial infections increased between 20-28% in the teenage population, and 14-20% among 20-25 year olds. (K. Edgardh, Adolescent Sexual Health in Sweden, Sexually Transmitted Infections, 2002. 78:352-356.) </37: 1.2.3>

<38: 1.2.3>B. The Risk/Benefit Profile of Plan B is Enhanced by Physician Involvement

As discussed below, the Sponsor's label comprehension study - conducted specifically to support the OTC switch of Plan B -reveals significant label comprehension problems with the medical information that should be provided to patients for this drug product. A proper understanding of the risks, warnings, contraindications, and benefits can be provided only through physician involvement in the prescribing of Plan B. Only by marketing Plan B as a prescription product can proper patient education be undertaken.

Furthermore, physician involvement is necessary for patient counseling on the extra-label considerations related to contraception choices in the U.S., including physical, medical, emotional, and moral questions. Plan B should not be placed in the same category as an aspirin, a Tylenol, or an antacid. Use of Plan B without a prescription will lead to fewer or no follow up visits with doctors, no STD testing, pap smears; pregnancy tests and/or counseling about the effects of unprotected intercourse. AAPLOG notes that the most common reason young women visit a physician is to obtain contraception. The Association comments that it is in that environment where women have the best chance to be properly counseled, have detection of STDs, and make their best selections for family planning. FDA should not approve Plan B for OTC use but continue to require the use of a prescription so women of all ages will be provided the necessary medical care they deserve. </38: 1.2.3>

<39: 1.2.3>A physician contact shared his experience with providing emergency contraceptives to CWA. He maintains that most women and teenage girls are uneducated about the risks associated with being sexually active, including cervical cancer, human papilloma viral (HPV) infection, and other sexually transmitted diseases. Women under the age of 17 are at high risk for cervical cancer because the cells on the cervix are more sensitive to HPV infection. About the age of 17, these cells become covered with more protective cells. HPV infections cause cancer that can sterilize the woman, increase the risk of miscarriages in the future, or death. Because of the prevalent ignorance of the risks of HPV and cervical cancer, clinical standard of care requires a pap smear for cervical cancer screening before patients may receive a prescription for birth control pills. This physician argues that if birth control pills or MAP are ever made available OTC, cervical cancer rates will skyrocket, since the incentive to have pap smears done will largely cease in this at risk population. The physician reasons that when a shortcut is created for women to obtain contraceptive services without seeing a health professional, women who are ignorant of STDs and their long-term effects, will remain ignorant. [Footnote 22: Physician comments are on file with the author, by Donald F. Thompson, MD, MPh, TM, Colonel, USAF, MC, SFS, National Defense University, Fort McNair, Washington, DC, (the comments reflect this physician's personal experiences

and do not represent the views of the NDU or the federal government). His anecdotal experiences are as follows: "I was caring for a 20 year old woman who was a junior in college, where I was performing periodic pap smears and microscopic examinations (colposcopy) of her cervix after her outpatient cryosurgery to treat the precancerous changes discovered on an earlier pap smear. As part of my evaluation, I always identify risk factors that help identify which patients are at high risk versus lower risk so treatment and counseling can be directed most appropriately. This young lady was at high risk because she had had over three lifetime sexual partners (she had had four), and she had first had sex at age 15 (anytime before age 17 is high risk because of HPV sensitivity). When I asked her what she had been taught in high school about sex and its risks, she said that the risks were just glossed over and that the message was that if you are going to have sex, then you just needed to use birth control to avoid getting pregnant. No one had ever explained the other risks of sex, like cervical cancer and other sexually transmitted infections. Another patient was a 17 year old who had only started having sex in the previous year and had only had one sexual partner. She was referred for evaluation of an abnormal pap smear that was discovered during her first exam when she was prescribed birth control pills for the first time. Her colposcopic exam was abnormal, and I did several biopsies of her cervix. When I tried to schedule her for a follow-up exam two weeks later, her main concern (and that of her mother) was that the appointment not conflict with her high school graduation celebration. Her biopsies came back highly abnormal, with a result of carcinoma in situ, a condition that required urgent surgery to remove the cancer before it spread. Instead of celebrating the major step of graduating high school with her classmates, she was faced with a diagnosis of cancer and the anxiety of wondering if the cone biopsy of her cervix was able to get all the cancer, and if she was ever going to be able to get pregnant and carry a baby to term. She and her mother were totally ignorant of the risks of sexually transmitted infections and cervical cancer and had only come into the clinic to get birth control pills so she would not get pregnant. If she had been able to get the MAP without seeing a healthcare professional, she probably would have gone on to develop invasive cervical cancer in the next year because of the aggressive strain of human papilloma virus with which she was infected. I had another 18 year old patient who suffered from anorexia nervosa. She had an insatiable need for reassurance from others, and moved from one dependent relationship to another, using sex as the foundation for her relationships. I treated her and one boyfriend for Chlamydia and worked closely with our counseling center to provide supportive services for her issues with her distorted body image. Despite cautions, about sexual activity and sexually transmitted diseases, she continued in self destructive relationships. Our clinic had a policy that the MAP must be provided to anyone who requested it, and she was a regular client on Monday mornings. Despite counseling, she refused to think ahead and use other forms of birth control, but instead continued to engage in "spontaneous" sexual activity since she had easy access to the morning after pill.]

Published studies support this concern. A study published in 2001 found that EC users were more likely than controls to have never had a pelvic examination (26% vs. 6%, $P < 0.002$) or a Pap smear (24% vs. 6%, $P < 0.002$) (Stewart HE., et. al., The Impact of Using Emergency Contraception on Reproductive Health Outcomes: A Retrospective Review in an Urban Adolescent Clinic, *J. Pediatric Adolescent Gynecology*, 2001 Nov, 14(4): 163-9). A Washington State Pharmacy study published in 2001 found that among 126 adolescents who obtained EC directly from a pharmacist without a prescription, 81% needed a new method of ongoing contraception, an evaluation for sexually transmitted disease, or both. The study concluded that many adolescents using EC need additional medical care and recommended that programs designed to increase EC access should use opportunities to link adolescents with more comprehensive reproductive health care services. (Sucato, G.S., Adolescent's Use of Emergency Contraception Provided by Washington State Pharmacists, *Contraception*, 2001 March; 63(3):123-129.)

An article from the International Peace Maternity and Child Health Hospital of the China Welfare Institute stated that although reported ectopic gestation after failed EC have been rare, clinicians should be aware of the possibility of an ectopic gestation when an EC pill fails. The department recommended

women use the established service networks to enhance education and dissemination of information on emergency contraception. The dearest also urgently advised that health care providers should advise women very clearly that ectopic gestation is possible after failed EC treatment. (Jian, Z., Linan, C., Ectopic Gestation Following Emergency Contraception with Levonorgestrel, *Contraception*, 2002 December, 66(6): 433-437).</39: 1.2.3>

<40: 1.2>A discussion of the medical/societal discourse on whether life begins at fertilization, conception, implantation or the embryo stage is beyond the scope of these Comments. FDA would be remiss, however, if it did not acknowledge that women's views differ on this point in the U.S. At least one national survey shows that almost half of American women believe that human life and pregnancy begin at fertilization (Zogby J., *American values*, vol. V: Zogby International, 2000.) Similarly, a 1998 survey of physicians who were predominantly ACOG members noted that 50% indicated that pregnancy begins with fertilization (Spinnato JA., *Informed consent and redefining of conception: a decision ill-conceived?*, *J. Matern. Fetal Med.* 1998; 7:264-,268.) Likewise, whether a "therapeutic" effect of Plan B that may occur after fertilization but before implantation could be consistent with the term abortifacient will not be discussed here. Given these facts, however, the RX-to-OTC switch of Plan B and resultant removal of physician involvement from the use of this drug has negative implications for patient informed consent. Specifically, via informed consent, patients should fully understand the risks and benefits of the drugs they take. Even strong proponents of EC agree that women should be informed about its mechanisms of effect for adequate consent. See Drazen; J.M., Green, M.F. Wood, A.J.J., *The FDA, politics, and Plan B* [letter]. *N. Engl. J. Med* 2904; 350:2414. Only through the physician/patient relationship can a patient's philosophical or religious convictions and Plan B's contraceptive mechanisms be addressed. OTC labeling alone cannot adequately describe these biologically-sophisticated and morally controversial issues. see, e.g., *Letters to the Editor, Contraception* 72 (2005) 394-395. </40: 1.2>

<41: 1.2, 1.2.3, 3.5.1, 3.11>C. FDA's Jurisdiction Over the "Safety and Efficacy" of Drugs Provides it With Sufficient Authority to Consider Potentially Negative Societal Ramification Related to the OTC Sale of Plan B

FDA's jurisdiction over the "safety and efficacy" of drugs provides it with legal authority to consider morality, misuse, age-appropriate sexual behavior, and related social issues in the context of the Plan B approval for OTC marketing. [Footnote 23: Those who argue that morality should not, affect FDA's decision-making hypocritically cite moral judgments in support of the OTC approval of Plan B. For example, certain Congressional representatives have asserted that "Public health experts have estimated that over-the-counter sales of the emergency contraception pill Plan B would cut the rate of unintended pregnancies in half and reduce the number of abortions by more than 500,000 per year." U.S. Reps. Henry Waxman, D-CA, and Louise Slaughter, D-NY, circulated a "Dear Colleague" letter and Fact Sheet on October 12, 2005, referencing these factors as a reason that FDA should approve the OTC sale of Plan B. FDA cannot take the Societal concern of unintended pregnancies into account, while refusing to consider the social concerns of an increase in unprotected sex and STDs, off-label over-use/repeat, use of Plan B, and sexual abuse.] There is no question that FDA can and should, as a matter of law, take issues of morality and social conscience into account when those issues relate directly to the drug's risk/benefit analysis or safety/efficacy profile -two concepts with which FDA has decades of experiences and" for which the courts provide deference to the Agency. If there is evidence that the expected patient population is likely to use the drug in a way that decreases the drug's safety, negatively impacts the patient's health, or tips the risk/benefit balance toward greater risk, FDA must consider this evidence when addressing the approval decision. FDA routinely takes potentially harmful patient use scenarios into account in its NDA approval decisions, whether for potent pain drugs (for which abuse and misuse are Agency considerations), for obesity drugs (for which preferences for nutritive and exercise are Agency considerations), or for HIV home test kits (for which the patient's mental well-being and need for a learned intermediary or counselor was an Agency consideration). OTC emergency contraceptives fall

squarely within this listing of drugs in which self-destructive patient actions may cause more harm than good. [Footnote 24: FDA should reject the argument posited by some that an FDA decision denying OTC approval to Plan B is too paternalistic. FDA has ample precedent over the years where it has made an "unpopular" decision for reasons that were arguably paternalistic. FDA's mission is to protect the public health by assuring the safety, efficacy, and security of human drugs. FDA has viewed this mission broadly over the years to include the "blocking" of access to certain drug products that, while safe and effective on a scientific basis, were not appropriate for OTC use for broader public health reasons. For example, the FDA removed phenacetin from the market after use as an ingredient, in OTC drug products for over 80 years. In the FDA's notice of the withdrawal of phenacetin from the market, the basis cited for approval was "phenacetin's high potential for misuse and its unfavorable benefit-to-risk ratio when incorporated in analgesic combinations which are then subject to excessive chronic use." (Emphasis in original) 48 Fed. Reg. 45486 (Oct. 5, 1983). In the proposed rule, the FDA stated that phenacetin was not alone among analgesics in its ability to cause nephropathy, but because of its greater likelihood for abuse, the agency believed other safe and effective analgesics would be sufficient for consumers. 47 Fed. Reg. 34636, 34638 (Aug. 10, 1982). Similarly, in 1972 the FDA severely restricted the allowable OTC uses for the drug hexachlorophene as an antibacterial product. The restrictions on the use of hexachlorophene followed the deaths of a number of infants in France due to the use of a baby powder contaminated with six percent hexachlorophene. 37 Fed. Reg. 20160 (Sept. 27, 1972). Although hexachlorophene was recognized as a safe and effective bacteriostatic skin cleanser, FDA concluded that a "risk to benefit ratio" analysis justified restriction of the availability of the drug even though the at-risk population was extremely small. Id.]

<42: 1.2>1. OTC Sale of Plan B Would Further the Interests of Sexual Predators

Evidence suggests that making Plan B available OTC would serve to further the predatory interests of sexual offenders who molest family members, children of friends, or students, as well as adult "boyfriends" who commit statutory rape. Namely, rapists and sexual predators could "stock up" on emergency contraceptives and keep a ready supply in, for example, their bedroom drawers or pockets to give to their victims after committing each sexual crime. [Footnote 25: For our discussion on the societal ramifications of OTC marketing for emergency contraceptives, we draw on the Written Testimony of Jill L. Stanek, on behalf of CWA of Illinois, regarding the MAP, presented at the Joint Meeting of the FDA Nonprescription Drugs Advisory Committee and the FDA Advisory Committee for Reproductive Health Drugs (Docket No. 01P-0075) (Dec. 16, 2003).. This written testimony can be found at <http://www.cfa.org/articles/4998/CWA/life/index.htm> (last accessed October 29, 2005).] Cf. Press Release for Congressman Don Manzullo 16th District of Illinois, entitled "Manzullo's Title X Statutory Rape Reporting Provision" Will Become Law" (Oct. 21, 1998) (noting the incident of a 37-year-old teacher having his 14-year-old student take birth control injections so that he could "continue molesting her at will"). See also Paul Bissell & Claire Anderson, Supplying Emergency Contraception Via Community Pharmacies in the UK: Reflections on the Experiences of Users and Providers, 57 Social Science & Medicine 2,367 (2003) (noting the concern that the widened availability of EC might provide an opportunity for men to coerce women into having unprotected sexual intercourse against their will).

In fact, several studies have shown that men are the most frequent buyers of MAP and that many learn about these drug products from advertisements in men's magazines. See Karnjariya Sukrung, Morning-After Blues, Bangkok Post, June 10, 2002. The Bangkok Post further states that "[sexual predators], buy pills for their girlfriends or wives so that they don't have to wear condoms. . . Some women, . . . said they that they didn't even know what they were taking; that the guy just said it was a health supplement." See id. The Bangkok Post continues, "Although many feminists believe that the morning-after pill gives them more control over their own bodies, it would seem, judging from the few studies conducted so far, that it is actually being used by men to exploit women." See id. Thus, the unrestricted access of Plan B would give these sexual predators another method to shield their abusive behavior. OTC Plan B opens the door

farther to sexual predators by reducing a woman's bargaining power at the critical moment when the decision is made whether or not to have sex.</42: 1.2>

<43: 1.2>The OTC availability of the MAP would in fact only increase this likelihood of sexual abuse of young girls by adult men. Without a link to medical services for emergency contraceptives, the likelihood is much greater that a sexual predator will continue to commit his crime without detection and with greater frequency if he can find a way to keep his victim from seeing a licensed physician to seek contraception. Cf. Cathy O'Leary, Abbott Wants Clamp on Morning-After Pill, *The West Australian*, June 8, 2004. How much more will minor girls be exploited if emergency contraceptives are available OTC? OTC access to emergency contraception will increase the likelihood that sexual perpetrators will go undetected and that young girls will be sexually abused. Switching Plan B to OTC would thwart Congressional attempts to protect minors from sexual abuse.

Conversely, if Plan B remains in the Rx-only category; physicians will remain involved with its prescribing and the potential for proper reporting of sexual predators will be increased. CWA has received comments from a physician advocating that victims of sexual abuse need medical consultation, not quick fixes in complete secrecy and isolation. According to APFLI, public health policy dictates that victims of rape or incest should be encouraged by medical professionals to go to a hospital emergency room where equipment and training advances the collection of forensic evidence and the provision of victim care. Similarly, AAPLOG comments that there is no question that Plan B OTC will become the leading "rape" drug in the country. AAPLOG is apprehensive of the "benefits" of Plan B OTC for sexual predators; namely, quietly hiding the rape, leading to "covering up" of crime, and the victim's perception of a second societal abuse, since rapes are criminal matters that require medical examination to assess injury, collect forensic evidence, get baseline STD testing, and possibly treat infections.</43: 1.2>

<44: 1.2>2. OTC Sale of Plan B Would Exacerbate -The Abuse of Teenage Girls

Evidence also suggests a relationship between the age of a woman, the risk of abuse, and the likelihood of pregnancy. For example,. Planned Parenthood reported that teenage girls with older partners are more likely to become pregnant than those with partners closer in age. [Footnote 26: As noted in the Written Testimony of Jill L. Stanek.] Among women younger than 18, the pregnancy rate among those with a partner who is six or more years older is 3.7 times as high as the rate among those whose partner is no more-than two years older. See M. Joycelyn Elders, Adolescent Pregnancy and Sexual Abuse, 280 *Journal of Amer. Med. Assoc.* 648 (1998) (noting that "coercive sex acts against adolescent girls are frequently perpetrated by their boyfriends Boyfriends who are considerably older than their adolescent girlfriends have been found to be responsible for a majority of teen pregnancies"). Furthermore, Planned Parenthood also reported that teenagers who have been raped or abused also experience higher rates of pregnancy -in a sample of 500 teen mothers, two-thirds had histories of sexual and physical abuse, primarily by adult men averaging age 27. Cf. ME. Joycelyn Elders, Adolescent Pregnancy and Sexual Abuse, 280 *Journal of Amer. Med. Assoc.* 648 (1998) (noting that sexual abuse is a common antecedent of adolescent pregnancy, with up to 66% of pregnant teens reporting histories of abuse). Thus, evidence indicates that sexually active young girls are likely to be the victims of sexual abuse and carry a higher risk for pregnancy.

This relationship between age and abuse suggests the particular vulnerability of young girls to sexual abuse. If FDA approves Plan B for OTC use, this medication will be more readily available, and sexual predators will in effect have lower barriers to restrain their actions - they will have less fear of impregnating a woman, and the patterns of abuse will become more prevalent. This abuse will in turn target younger victims, as indicated by the correlation discussed above.</44: 1.2>

<45: 1.2>3. OTC Sale of Plan B Will Not Reduce the Number of Abortions and Unintended Pregnancies

A potential reduction in the number of abortions and unintended pregnancies is not a sufficient reason to allow the OTC marketing of Plan B, and evidence exists to the contrary. While some argue that Plan B OTC status is desirable because the unwanted pregnancy rate and abortion rate would decrease, studies indicate that this relationship may not be true. One study showed that the advanced provision of emergency contraceptives had no effect on abortion rates. See Anna Glasier, Karen Fairhurst, et al., *Advanced Provision of Emergency Contraception Does Not Reduce Abortion Rates*, 69 *Contraception* 361 (2004). See also Stuart Nicolson, *Morning-After Pill Campaign Fails to Stem Abortion Rate*, *Daily Mail* (London), December 3, 2004 (noting that new research indicates that distributing EC more freely does nothing to reduce the number of abortions).

Further research, released on January 5, 2005, also fails to support the contention that OTC marketing of Plan B would decrease the number of pregnancies. A study of 2,117 young women ages 15-24 reported in the *Journal of the American Medical Association (JAMA)* demonstrated that providing young women with non-prescription access to emergency contraception did not lead to any decrease in the pregnancy rate. Even women provided with an advance supply of EC did not have a decreased pregnancy rate. The study demonstrates that readily available EC does not lead to a reduction in unintended pregnancies, despite erroneous claims to the contrary by the study's conclusion and other EC proponents. See Raine, TR, et al, *Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs*, *JAMA* 2005, 293:54-62, at www.jama.com. [Footnote 27: CWA has received comments questioning whether the author's conflict of interest dilutes the significance of certain studies. CWA understands that Dr. Tina R. Raine served on the expert advisory panel for the Sponsor for the OTC application of Plan B to the FDA. She did so while at the same time arranging to conduct two studies designed to directly counter the concerns raised by opponents of Plan B's OTC status.</45: 1.2>

<46: 10>Dr. Raine previously published a study that ostensibly refutes any concerns about possible increased STDs and risky sexual behavior in women with EC availability (*Emergency Contraception: Advance Provision in a Young, High-Risk Clinic Populations* (*Obstetrics & Gynecology* 2000; 96: 1-7). Interestingly enough, her study cites data that women in the treatment group (those that had access to EC) were more likely than those in the control group to report using less effective contraception. Furthermore, the women who did not have access to EC were more likely than the treatment group to report consistent birth control pill use. Raine's study demonstrates that easier access did not lead to changes in risky sexual behavior or routine contraception use. The Raine study clearly shows that there was no difference in pregnancy rates between those women who had access to EC, and those who did not. In other words, the very justification for proving EC, namely decreased unintended pregnancies, was lacking. [Footnote 28: If the rebuttal to this concern is that the study was not large enough to find a difference in this young age group, the same argument can be made regarding the lack of differences they found in teens' sexual behavior or the rate of acquiring new STDs. In other words, if one argues that it will take time for pregnancy rates to decrease, or a larger population studied to see the benefit, then one can just as properly argue that with time or a larger population size, one will also see an increase in risk-taking behavior and an increase in STDs among these individuals.] Furthermore, the adolescents in this study stated themselves that they would have more unprotected intercourse with the availability of EC. The examination of behavior in the study's short time frame of six months could not confirm this but, with the passage of time, and with the increased comfort and familiarity with EC, CWA's physician contacts believe that this increased unprotected intercourse would likely occur.

Other CWA physician contacts have commented that in a review of all studies relating to the topic of OTC MAP and its effects on the sexual activity of women, there has not been found to be a difference in either abortion rates or pregnancy rates. The groups in the studies are actually given advance provision of the MAP, which is more aggressive than actually having access to the drug OTC. The women were also in a clinical study setting, knowing they were under observation, and were educated and instructed

regarding the drug's use. Presumably, the physicians note, this setting should be optimal to observe a decrease in abortions and unintended pregnancies. Instead, the studies reflect no change, and in fact, demonstrate increased risky sexual behaviors after experience with MAP access. Furthermore, to our knowledge, there has never been a randomized study with a control group not utilizing MAP; therefore, the comparative number studies used to prove efficacy over using nothing is simply anecdotal and not a generally acceptable manner in which to determine the efficacy of a product. </46: 10>

<47: 10>AAPLOG highlights the UK study above and a separate San Francisco study, referenced herein, showing that there is no difference in the abortion rate or in the unintended pregnancy rate between women who are given the MAP free to take home for immediate use and women who have to obtain prescriptions for MAP.

A CMDA member comments that there are multiple studies that show that easier access to contraception increases sexual activity rates, decreases the age of onset of sexual activity, and increases the incidence of STDs. One study found that pregnancy rates are unaffected by readily available MAP; that increasing the availability of birth control to teenagers. increases STD rates, especially when MAP is made available; and that teens make rational decisions based on available options (i.e., when contraception is less available, they have sex less frequently). (David Paton, Random Behavior or Rational Choice? Family Planning Teenage Pregnancy and STIs, Nottingham University Business School, UK, presented at the Royal Economic Society Conference, April, 2004.) Another study shows that widespread distribution of advanced supplies of MAP did not reduce unintended pregnancy, and MAP may be less effective than believed; namely, efficacy is based on unreliable data and a great number of assumptions that have been questioned both in the past and more recently. (Anna Glasier et. al, Advanced Provision of Emergency Contraception does not Reduce Abortion Rates, Contraception 69 (5): 361-366, May 2004).

While it has been argued that OTC .MAP would reduce abortion rates by up to 50%, the evidence presented does not support this contention. As noted above, a 2004 study showed that there was no effect on abortion rates with the advanced provision-of-MAP. (Anna Glasier, et al., Advanced Provision of Emergency Contraception Does Not Reduce Abortion Rates, Contraception 69 (2004) 361-366.) The study suggested that widespread distribution of advanced supplies of MAP may not be an effective way to reduce the incidence of unintended pregnancy. Indeed, in Great Britain, abortion rates have increased for teenagers in the years since OTC availability. A UK article reports that there were 2.1% more abortions performed in England and Wales in 2004 than 2003. In the last three years, abortions in the UK have increased from 176,000 in 2002, to 181,000 in 2003, to 185,400 in 2004. (Steven Ertelt, British Abortion Figures Show Increase of Two Percent in 2004, LifeNews Editor, July 27, 2005, London England.) The number of abortions increased despite the government's spending 540 million to promote contraception. Id. An article in the Observer, a British publication, states that since the morning-after-pill was made available without prescription five years ago, there has been little change in teenage conception rates. Teenage conceptions have fallen by about 10 percent, but in 13 local authorities with the highest rates, 11 have seen the numbers of teenage pregnancies increase. (The Observer, May 15, 2005, available at <http://observer.guardian.co.uk/magazine/story/0,11913,1484669,00.html>.)</47: 10>

<48: 10>Similarly, while the sales of emergency contraceptives have risen, sharply in Belgium, there appears to be no signs of a reduction in the number of abortions. See Abortions "Rise " Despite Morning After Pill, Expatica, August 27, 2004 (stating that some "estimate that the number of abortions has gone up, despite the morning after pill").

In Scotland, one in five 16 year old girls takes the morning-after-pill each year. However, the birthrate for 16-19 year olds rose from 63.6/1000 in 1983 to 68.1/1000 in 2004. (Julia Hunt, Experts Fear Rise In Infertility as Chlamydia Cases Soar by 66 Percent, Scottish Daily Record & Sunday Mail, May 2, 2004, pg. 40,41.)

In Sweden, teenage pregnancies declined from 1975-1985; abortions decreased as well. However, in the late 1980s, abortions increased. A changing pattern of contraceptive use was discussed as a contributing factor (e.g., less use of oral contraceptives due to fear of adverse effects). Since then, subsidies for oral contraceptives have emerged, and emergency hormonal contraception has become easily available. In spite of these factors, teenage abortion rates have been increasing, from 17/1000 in 1995 to 22.5/1000 in 2001. Furthermore, widespread availability of sexual education, contraception, and abortion services does not protect teenagers from STDs, pregnancy, and sexual victimization. (K. Edgardh, Adolescent Sexual Health in Sweden, Sexually Transmitted Infections: 2002; 78:352-356.) AAPLOG notes that in the 5 years following non-prescription EC availability, Sweden experienced a 31% increase in teen abortion. (K. Edgardh, Adolescent Sexual Health in Sweden, Sexually Transmitted Infections, 2002, 78: 352-356.) A Swedish study assessing the short- and long- term risk of unintended pregnancy in women receiving emergency contraception (and contraceptive counseling) found that in a long-term follow up, 10 of 134 women experienced an unplanned pregnancy, 9 of which resulted in abortions. All these women had either started and terminated oral contraceptives or had never commenced the prescribed oral contraceptives.. The study concluded that women who request emergency contraception are, despite a planned follow-up with contraceptive counseling, a high risk group for new unintended pregnancies. (Falk, G. et al, Young Women Requesting Emergency Contraception Are, Despite Contraceptive Counseling, a High Risk Group for New Unintended Pregnancies, Contraception, 64(1):23-27 (July 2001)).

Given that accumulating sound scientific evidence that OTC access to EC doesn't decrease unintended pregnancy or abortion rates, any claim that OTC access will cut these social ills betrays the public trust. [Footnote 29: See AAPLOG News Release, Statement of the American Association of Pro-Life Obstetricians and Gynecologists on JAMA Emergency Contraception Study, January 12, 2005.] Moreover, any FDA reliance on such argument is improper and unsupportable. </48: 10>

<49: 1.2>D. It Is Unlawful For FDA To Approve the Plan B NDA Supplement Without Data from a Clinical Study Involving the Relevant Pediatric Subpopulation

In a case where the Sponsor intends to label a drug for use in the pediatric population, FDA has only limited authority to cede the requirement for pediatric testing. [Footnote 30: We note that Plan B is not eligible for a waiver of the pediatric requirements. FDA may grant a full waiver of the requirement to submit pediatric assessments only if the applicant certifies and FDA finds one or more of the following: (a) Necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed) (section 505B(a)(4)(A)(i) of the Act). (b) There is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups (section 505B(a)(4)(A)(ii) of the Act). (c) The drug or biological product, (1) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients, and (2) is not likely to be used in a substantial number of pediatric patients (section 505B(a)(4)(A)(iii) of the Act). See Draft Guidance for industry: How to Comply with the Pediatric Research Equity Act (2005), pp. 9-10. Plan B does not fulfill any of these conditions. First, studies are both possible and practicable. Secondly, the Sponsor of OTC marketing for Plan B seeks the Rx-to-OTC switch precisely because it presumes that Plan B would be safe and effective in pediatric age groups. Lastly, the intention of marketing Plan B OTC specifically contemplates the drug's use in a substantial number of pediatric patients. Thus, Plan B does not meet any of the criteria for a full waiver of pediatric requirements.] FDA cannot approve an NDA or an NDA Supplement without the submission of data that are adequate (1) to assess the safety and effectiveness of a drug product in pediatric subpopulations and (2) to support dosing and administration in these subpopulations. See 21 U.S.C. § 355(a)(2).

The Pediatric Research Equity Act (Public Law 108-155) (PREA), which amended the FDC Act, requires

the conduct of pediatric studies for NDAs and NDA Supplements requesting approval for a new indication and a new dosing regimen, among other items. See 21 U.S.C. § 355c(a)(1); see also Draft Guidance for Industry: How to Comply with the Pediatric Research Equity Act (2005), p. 3 (hereafter, "Pediatric Research Guidance") (stating that PREA requires all NDAs or NDA supplements to contain a pediatric assessment). Because PREA makes this legislation retroactive, all NDAs submitted on or after April 1, 1999 are subject to PREA. See *id.* The Plan B NDA Supplement was submitted after April 1, 1999 and requested approval for the new indication/dosing regimen of OTC use by women 16 years and older for pregnancy prevention and, thus, is subject to the PREA requirements. </49: 1.2>

<50: 1.2.3>PREA requires the submission of a pediatric assessment "in all relevant pediatric populations." PREA requires a pediatric assessment for each age group in which the drug product is expected to provide a meaningful therapeutic benefit over existing therapies for pediatric patients or is likely to be used in a substantial number of pediatric patients. See Pediatric Research Guidance (emphasis added). A "pediatric assessment" consists of data gathered from pediatric studies using appropriate formulations for each age group for which the assessment is required, as well as other data that are adequate to assess the safety and effectiveness of the drug product in pediatric subpopulations and to support dosing and administration for each pediatric subpopulation. See 21 U.S.C., § 355c(a)(2). See also Pediatric Research Guidance.

In the case of Plan B, a pediatric assessment should have been required for two pediatric subpopulations: Children, ages 2 to 12, and adolescents, ages 12 to 16. Given its indication as an emergency contraceptive, the Plan B patient population logically includes all females who can become pregnant - that is, as of the age their first menstrual period begins (i.e., "menarche") until they no longer have a menstrual period (i.e., "menopause"). According to FDA, the average age of menarche in the United States is 12 years, although menstruation may commence in healthy females as early as age 10. [Footnote 31: See On the Teen Scene: A Balanced Look at the Menstrual Cycle, FDA Consumer Magazine (Dec. 1993) (available at http://www.fda.gov/fdac/reprints/ots_mens.html). In the U.S., the average age of the start of menopause is 51. See Taking Charge of Menopause, FDA Consumer Magazine (Nov.-Dec. 1999) (available at http://www.fda.gov/fdac/features/1999/699_meno.html).] In the past, the Agency defined "pediatric population(s)" and "pediatric patient(s)" as the age group "from birth to 16 years, including age groups often called . . . adolescents." [Footnote 32: See, formerly, 21 C.F.R. § 201.57(f)(9).] Therefore, the population of menstruating females (i.e., 10 or 12 and older) and the pediatric population (i.e., up to 16) overlap by up to 6 years, Because Plan B will be used by some number of adolescent girls who become pregnant, FDA should have required the Sponsor to produce specific and statically relevant safety and effectiveness data for the pediatric population. Extrapolation from adult data alone is not appropriate for this product because of the broad range of "normal", physiologic issues experienced by the subpopulation of adolescent girls. The safety and effectiveness data in adults would not be sufficiently similar to the under-17 subpopulation to support such extrapolation. See Pediatric Research Guidance, at 5-6. </50: 1.2.3>

<51: 1.2.3>If a pediatric assessment is not submitted by an applicant in accordance with PREA, not only may FDA deny approval to the drug application, but also the drug product may be considered misbranded solely because of that failure to submit a pediatric assessment, See Pediatric Research Guidance. Thus, if a firm submits a supplemental NDA providing for a switch of a drug product from Rx-only status to OTC status (for a certain subpopulation based on age, for example), that firm would need to submit a pediatric assessment in order to comply with the provisions of PREA. The need for such an assessment is especially salient for a drug product intended to be sold OTC (even if just for adults) because of the high likelihood of such a drug product to be used in a substantial number of pediatric patients - whether access is obtained improperly through a "black market" scenario or lawfully with physician supervision.

After more than a decade of supporting "the legislative and regulatory attempts to address the lack of

pediatric use information in drug product labeling" that culminated in the PREA, it is curious that, here, FDA failed to require a pediatric study for a drug that is being marketed specifically to the under-16 patient subpopulation. See Pediatric Research Guidance, at 2. </51: 1.2.3>

<52: 1.2.3>E. It Is Unlawful for FDA to Approve the Plan B NDA Supplement on The Basis of the Sponsor's Label Comprehension/Actual Use Study

FDA balances numerous factors when considering a drug sponsor's application for an RX-to-OTC switch. First and foremost, patients using an OTC drug should be able to self-medicate after reading the drug's labeling. Consequently, FDA expends considerable effort to analyze the results of label comprehension studies conducted by the drug sponsor. FDA's review of the Sponsor's label comprehension study was presented on December 16, 2003, by Dr. Karen Lechter at a joint meeting of the FDA's Nonprescription Drugs Advisory Committee and its Advisory Committee for Reproductive Health Drugs, and shows that the Sponsor's study is not adequate to support the Rx-to-OTC-switch of Plan B. [Footnote 33: FDA, Center for Drug Evaluation and Research, Nonprescription Drugs Advisory Committee (NDAC) in Joint Session with the Advisory Committee for Reproductive Health Drugs (Dec. 16, 2003) ("Joint Hearing"), at 118-124. Dr. Lechter (J.D., Ph.D) is an FDA social scientist.]

The information presented casts considerable doubt on FDA's conclusion that Plan B can be safely self-administered by adults - not to mention by adolescent girls. [Footnote 34: <http://www.fda.gov/ohrms/dockets/ac/03/slides/4015s1.htm>.] Only 75% of all respondents answered that Plan B should not be taken in the presence of unexplained vaginal bleeding. Among the low-level literacy group that figure declined to 69%; with high-literacy respondents answering correctly only 81% of the time. Thus, one-quarter of all respondents failed to understand this crucial fact. [Footnote 35: http://www.fda.gov/ohrms/dockets/ac/03/slides/4015S1_04_FDA-Lechter_files/frame.htm.] Only 67% of all respondents answered correctly that Plan B is designed to serve as a backup for regular contraception methods -not as a replacement for them. Among those of low-literacy this figure dropped to 46%; whereas for women of high literacy the figure was 78%. [Footnote 36: http://www.fda.gov/ohrms/dockets/ac/03/slides/401581_04_FDA-Lechter_files/frame.htm.] Accordingly, one-third of all respondents failed to understand that Plan B is not a typical method of contraception. </52: 1.2.3>

<53: 1.2.3>Given results like these it is not surprising that Dr. Louis Cantilena (M.D., Ph.D.), Plan B Joint Hearing, noted that "if you look at other studies that . . . we've heard about in the past for statins and the heartburn drugs, the overall success of the [Plan B] comprehension study was really not that good[.]" [Footnote 37: Joint Hearing at 136.] Later, Dr. Cantilena observed, "The label comprehension] study was, I think, an overall failure." [Footnote 38: Joint Hearing at 411.]

Furthermore, Dr. David Hager asked the FDA panelists about data received from Washington State pharmacists who had participated in Plan B's actual use studies. The pharmacists indicated that 85% of the Plan B patients required medical follow-up - usually consisting of medical evaluation and counseling. Dr. Hager asked whether there was any concern about a potential failure to diagnose ectopic pregnancies in this population if the drug were made available OTC. [Footnote 39: Joint Hearing at 137.] Dr. Hager does not appear to have received an answer to his question during the hearing. The question needs to be asked: if 85% of a population of women using Plan B needed medical follow-up, how will those patients receive the care and information they need in an OTC environment? </53: 1.2.3>

<54: 1.2.3>FDA improperly focused its concerns on whether Plan B could be safely used by young teenage girls, rather than considering also women with pathophysiological issues. In FDA's 2004 "Not Approvable Letter" to the Sponsor, Dr. Steven Galson noted that FDA had "concluded that you have not provided adequate data to support a conclusion that Plan B can be used safely by young adolescent

women for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug." [Footnote 40: Not Approvable Letter, Steven Galson, M.D., Acting Director of the Center for Drug Evaluation and Research, FDA, to Barr Research, Inc. (May 6, 2004) at 1. Galson noted the small sampling of adolescent women in Barr's actual use study: "You propose OTC status for Plan B for both adults and children based primarily on an actual use study in 585 subjects. Only 29 of the 585 subjects enrolled in the study were 14-16 years of age, and none was under 14 years of age." Id.] The Sponsor chose not to propose new label comprehension and actual use studies designed to demonstrate Plan B's safety in this younger population. Rather, the Sponsor redoubled its efforts to advance a proposal it had made to FDA on March 11, 2004 in an amendment to its application that called for a dual approach for Plan B in which the drug would be available OTC to women 16 and older and as a prescription drug for women under age 16. [Footnote 41: See Not Approvable Letter, Lester M. Crawford, DVM, Ph.D., Commissioner, FDA, to Duramed Research, Inc. (August 26, 2005), referencing Sponsor's Research Submission of July 21, 2004.]

As stated above, we believe that FDA lacks the legal authority under section 503(b) of the FDC Act to allow this drug product to be sold OTC to women 17 years old and over while requiring a prescription for girls under 17. With that in mind, FDA should reexamine the abysmal results produced by Plan B's proposed labeling in the Sponsor's label comprehension study. It is our contention that FDA erred in concluding that the drug could be safely distributed even to adults OTC, and we ask FDA to reconsider that decision. If it does not reconsider that decision, the Agency should state what standards it uses to evaluate when label comprehension failure becomes so great that OTC sale is not supportable. </54: 1.2.3>

<55: 1.2.3>CONCLUSION

There can be no legal or scientific doubt that Plan B is unsafe for women under age 16 as an OTC product, since the Sponsor's July 21, 2004 submission admits this explicitly. Since the Plan B label comprehension study, actual use study, and FDA's safety analysis have not been altered by any new evidence presented by the Sponsor, the Agency must conclude that even on the Sponsor's terms Plan B is not safe for girls under 16 years of age for OTC sale. Furthermore, because FDA lacks the legal authority to approve the simultaneous dual marketing of an active ingredient in the Rx and OTC distribution regimes, Plan B cannot legally be sold as an OTC product to any age group. </55: 1.2.3>

Sincerely,

Gary L. Yingling, J.D., M.S.
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November 2, 2005 Fax: 202.778.9100

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comment to Docket No. 2005N-0345; RIN 0910-AF72
Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a
Prescription Drug Product and an Over-the-Counter Drug Product

To Whom It May Concern:

Please file the attached original Amended Comments in Docket No. 2005N-0345 and file stamp and return the additional copy to my messenger. The Amended Comments should replace the Comments filed by this author by facsimile at 4:45 p.m. yesterday, November 1, 2005. The Amended Comments include corrections to typographical errors and misstated citations, and add the signatory of CMDA.

Thank you for your attention to this matter.

Sincerely,

Gary L. Yingling

Enclosures

COMMENT NUMBER - 2005N-0345-C415

2005N-0345-C415 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.

2005N-0345-C415 - TEXT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

RESPONSE OF DURAMED PHARMACEUTICALS, INC. AND DURAMED RESEARCH, INC. TO
ADVANCE NOTICE OF PROPOSED RULEMAKING

DRUG APPROVALS: CIRCUMSTANCES UNDER WHICH AN ACTIVE INGREDIENT MAY BE SIMULTANEOUSLY MARKETED IN BOTH A PRESCRIPTION DRUG PRODUCT AND AN OVER-THE-COUNTER DRUG PRODUCT

Docket No. 2005N-0345
RIN No. 0910-AF72

On September 1, 2005, the Food and Drug Administration ("FDA ") published in the Federal Register an Advance Notice of Proposed Rulemaking (Docket No. 2005N-0345) (the "Notice"). 70 Fed. Reg. 52,050 (Sept. 1, 2005). The Notice requests comment on whether FDA should initiate rulemaking to codify its interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 ("FDCA "), regarding when an active ingredient may be marketed simultaneously in both a prescription ("Rx") and an over-the-counter ("OTC ") drug product and other issues related to its consideration of Supplement 011 to approved New Drug Application 21-045 ("NDA 21-045/S011").

Duramed Research, Inc. and Duramed Pharmaceuticals, Inc. (together "Duramed") respectfully submit these comments in response to the above-referenced Notice. Duramed is the sponsor of the drug product, Plan B, which is the subject of NDA 21-045-S011.

Duramed believes that Plan B is safe and effective for OTC use for all women - a view that is shared by an overwhelming majority of the members of two separate FDA Advisory Committees, professional healthcare organizations and practitioners. However, at FDA's suggestion, and consistent with FDA's expression of concerns regarding the nonprescription use of the product by women under the age of sixteen, Duramed has proposed, in a supplement to its NDA, a dual-label product that would be an OTC product for women sixteen and older and a prescription product for women under sixteen.

EXECUTIVE SUMMARY

<1: 5.4.3>1. FDA's existing interpretation of section 503(b), 21 U.S.C. § 353(b)(1), regarding simultaneous marketing of an active ingredient as an Rx and OTC product has not caused any confusion, and therefore FDA does not need to initiate any rulemaking on its interpretation. As FDA states in the Notice, it has repeatedly approved simultaneous Rx and OTC marketing in the past; and Duramed has not been able to locate any evidence to support the contention that FDA 's interpretation of section 503(b) as permitting such use is erroneous or needs clarification.</1: 5.4.3>

<2: 4.4.2>The public has been aware since at least May 2004 that FDA is considering permitting simultaneous Rx and OTC marketing of Plan B to different subpopulations, yet Duramed has been unable to find any basis to conclude that the FDCA does not authorize FDA to approve such marketing. It is beyond dispute that, since Duramed filed its supplement, there has been extensive public discussion -in articles and editorials in newspapers, professional journals, and other publications, on television and radio, and elsewhere -of the issues relating to Plan B, including limitation of OTC to a particular subpopulation. Interested members of the public have already had ample opportunity to express their views to the Agency, and have done so. It is time for FDA to take final action on NDA 21-045/S011.</2: 4.4.2>

<3: 6.3.4, 7.3.1.2>2. FDA has authority to enforce the limitation of Rx products to a subpopulation, just as it has authority to enforce the limitation of Rx products by indication, strength, route of administration, and dosage form. Moreover, FDA can enforce this limitation in actual practice through a variety of mechanisms, including, but not limited to, random inspections of pharmacies by FDA investigators and coordination with state and local law enforcement officials. To aid in FDA's efforts, Duramed has proposed a marketing program for Plan B that will include limiting distribution of Plan B to retail

operations with pharmacy services and clinics. It will also include an educational component to help ensure the compliant, safe and effective use of Plan B. This program would be designed to educate pharmacists and health care practitioners on the Rx requirement for women age 15 and younger. It will also educate women age 15 and younger to discuss Plan B with their health care practitioners.</3: 6.3.4, 7.3.1.2>

<4: 8.3.1>3. Rx and OTC products can lawfully be sold in the same initial packaging, as long as the products do not call for different doses, different strengths, or different directions for use. Because marketing of Plan B to different subpopulations does not implicate any of these differences, the same initial packaging can be used for Plan B when dispensed pursuant to a prescription and when dispensed OTC. Specifically, FDCA § 503 can be satisfied by ensuring that all packages contain (i) adequate information and directions to ensure safe, effective, and appropriate OTC use, (ii) the legend "Rx only for women age 15 and younger," and (iii) appropriate space for the traditional Rx label, to be affixed by a pharmacist when dispensing the product pursuant to a prescription.</4: 8.3.1>

<5: 2.1>These answers to the questions in FDA's Notice are straightforward and, we think, not seriously in dispute. FDA has already determined that Plan B is safe and effective when dispensed OTC to women age 17 and older, yet FDA's continued delay in approving OTC status for the drug when so dispensed is effectively preventing or delaying women of all ages from obtaining the drug as soon as possible and within its critical 72 hour period of effectiveness. This delay is contrary to the Agency's mission as set forth in FDCA § 903(b)(1), 21 U.S.C. § 393(b)(1), to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."</5: 2.1>

BACKGROUND

<37: 1.2>Plan B is currently approved as a prescription drug indicated as "an emergency contraceptive that can be used to prevent pregnancy following unprotected intercourse or a known or suspected contraceptive failure." Plan B Package Insert. In a supplement to NDA 21-045 (S-011) submitted to FDA on April 16, 2003, Women's Capital Corporation proposed that Plan B be switched from Rx to OTC status. The American College of Obstetricians and Gynecologists has estimated that making Plan B available OTC could prevent about 2 million pregnancies (about half of all unintended pregnancies in the United States), and about 500,000 abortions, per year. [Footnote 1: Transcript of the December 16, 2003 meeting of the FDA Ctr. for Drug Eval. & Research, Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs, Dec. 16, 2003, 33, 37, available at <http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.DOC> (hereinafter, "Hearing Tr."). Duramed incorporates herein by reference the Hearing Transcript, which it presumes has been made part of docket number 2005N-0345.] This objective can only be achieved if women who need Plan B have timely access to the product.

Based on the scientific evidence regarding its safety and its benefit to the health of women, every relevant leading medical organization in the United States supports the efficacy and safety of Plan B as an OTC product. These organizations include the American Medical Association, the American Medical Women's Association, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Public Health Association, and the American Association of Family Physicians. [Footnote 2: A copy of each organization's statement is attached hereto at Exhibit ("Ex.") 1.]</37: 1.2>

<38: 6.6.1, 6.6.4>In September 2005, Massachusetts became the eighth State to permit enhanced access to Plan B, by allowing pharmacists to dispense Plan B. The others are Alaska, California, Hawaii, Maine, New Hampshire, New Mexico, and Washington. [Footnote 3: Alaska, see Alaska Stat. § 08.80 (2002) (Bd. ed. Feb. 2003), Alaska Admin. Code Title 12 § 52.240 (Bd. ed. Feb. 2003); California, see Cal. Bus

& Prof. Code §§ 4016, 4025, & 4050 - 4052; Hawaii, see Haw. Rev. Stat. § 461-1 ; Maine, 32 Me. Rev. Stat. § 13821 ; Massachusetts, see SB 2073/HB 1643 ; New Hampshire, see N.H. Rev. Stat. § 318 :47-e; New Mexico, see N.M. Stat. Ann. §§ 61-11-2, N.M. Reg. 16-19-26.9 ; and Washington, see Wash. Rev. Code 18.64, Wash. Admin. Code § 246-863-100.] Over thirty countries worldwide - including Britain, France, Australia, and Sweden -already permit such use.[Footnote 4: Center for Reproductive Rights, "Governments Worldwide Put Emergency Contraception into Women's Hands: A Global Review of Laws and Policies," 7 (Sept. 2004). Attached hereto at Ex. 2.] Most recently, in 2005, Canada and India approved emergency contraception for nonprescription sales. [Footnote 5: Morning After, The Toronto Sun, April 24, 2005 ; A Nod for Counter Sales of Emergency Contraceptives, The Hindu, Sept. 1, 2005. Attached hereto at Ex. 3.]</38: 6.6.1, 6.6.4>

<39: 1.2.1>After Duramed requested OTC status for Plan B, FDA jointly convened its Nonprescription Drugs Advisory Committee and FDA's Reproductive Health Drugs Advisory Committee to review the application. In December 2003, after reviewing extensive scientific evidence, the committees voted, by a margin of 28 to 0, that Plan B is safe. The committees voted, by a margin of 23 to 4, that Plan B should be made available OTC.6 [Footnote 6: Hearing Tr. at 349, 395.]</39: 1.2.1>

<6: 1.2.1>Reflecting strong public support for the switch to OTC status, editorials from across the country have urged FDA to accept the committees' recommendation. The New York Times called the committee vote "A Public Health Victory," The Pittsburg Post-Gazette called it "welcome news," and urged that "FDA would be wise to accept the [committees'] recommendation and authorize sale as soon as possible." The Denver Post "strongly support(ed) the recommendation." The Miami-Herald stated that, "[t]he two panels' lopsided vote for Plan B is encouraging. In the past, the FDA has followed its experts' advice. It should do so now." The Buffalo News urged that NDA 21-045 "deserve[d] quick approval." [Footnote 7: Editorial, A Public Health Victory, N. Y. Times, Dec. 18, 2003; Editorial, The FDA's Chance to Improve Contraception, Pittsburgh Post-Gazette, Dec. 21, 2003; Editorial, OK 'Morning After Pill,' The Denver Post Dec. 18, 2003; Editorial, Morning-After Pill Gets a Boost, The Miami-Herald, Dec. 18, 2003; Editorial, The Morning After Pill /Plan B Contraceptive Deserves Approval by FDA -And Quickly, The Buffalo News, Dec. 29,2003. These articles are attached hereto at Ex. 4.]

Notwithstanding the findings and recommendations of the two expert committees, by letter dated May 6, 2004; Dr. Steven Galson, then acting director of the FDA Center for Drug Evaluation and Research ("CDER"), informed Duramed that Supplement 011 was not approvable. In an interview, Dr. Galson acknowledged that his action was not the norm, and that in refusing to allow Plan B to be sold OTC, he rejected not only the judgment of a joint advisory panel, but also the recommendations of his own staff. [Footnote 8: Harris, Gardiner, Morning-After-Pill Ruling Defies Norm, N.Y. Times, May 8, 2004, at A13. Attached hereto at Ex 5.] A draft report by the Government Accountability Office agrees that the decision was highly unusual, that it was made with atypical involvement from senior agency officials, and that it was made months before it was formally announced. [Footnote 9: Kaufman, Marc, Decision on Plan B Called Highly Unusual, The Washington Post, Oct. 13, 2005, at A09 (reporting on draft GAO report). Attached hereto at Ex. 6.]

In its May 2004 letter, FDA stated that there was inadequate data to support that Plan B can be used safely by women under the age of 16 for emergency contraception without the supervision of a licensed practitioner. FDA did not cite any studies or data to support a concern that use of Plan B by younger adolescents is unsafe. Indeed, the advisory committees discussed and analyzed issues relating to OTC use of Plan B by adolescents, and did not vote to recommend against OTC use for that population. [Footnote 10: See, e.g., Hearing Tr. at 349-75.] In recent studies, access to emergency contraception did not lead teenagers to increase sexually risky behavior. [Footnote 11: See Tina R. Raine, et al., Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs, JAMA 293:54-62 (2005) (study of 2,117 young women ages 15 to 24 concluded that providing young women

with access to emergency contraception did not lead them teenage in more risky sexual behavior); Cynthia C. Harper, et al., The Effect of Increased Access to Emergency Contraception Among Young Adolescents, 106 Obstetrics & Gynecology 483-491 (2005) ("The Effect of Increased Access ") (finding that young adolescents with improved access to emergency contraception used the method more frequently when needed, but did not compromise their use of routine contraception or increase risky sexual behavior). These studies are attached hereto at Ex. 7.] There was also no increase in sexually transmitted diseases or decrease in the use of other forms of contraception. [Footnote 12: The Effect of Increased Access, at 489.]</6: 1.2.1>

<7: 1.2>FDA's May 2004 letter also suggested that Duramed could address the Agency's concerns by proposing a dual label for Plan B, with a prescription label for women under 16 and an OTC label for women 16 and older. On July 6, 2004, Duramed submitted to FDA a complete response to the Agency's May 6 not-approvable letter. Following FDA's suggestion, Duramed proposed OTC status only for the subpopulation of women age 16 or older while maintaining Rx status for women age 15 and younger. Duramed also proposed that both the Rx version and the OTC version of Plan B be marketed in the same packaging (with a place for prescription-related information to be added when the product is dispensed pursuant to a prescription). On August 11, 2004, FDA accepted the submission as a complete response to the May 2004 Not Approvable letter. The PDUFA action date for the resubmission was January 20, 2005. FDA informed Duramed on that date that the Agency would not then be taking an action on the supplement.

FDA's failure to take a final action on NDA 21-045 led Senators Hillary Rodham Clinton (D-NY) and Patty Murray (D-Wash.) to block a full Senate vote on Lester Crawford's nomination to be commissioner of FDA. In July 2005, the Senators agreed to lift their holds after Health and Human Services ("HHS ") Secretary Mike Leavitt wrote, in a letter to Senator Mike Enzi (R-Wyo.), who chairs the Senate Committee on Health, Education, Labor and Pensions, that FDA would act on Duramed's application by September 1, 2005.

By letter dated August 26, 2005, FDA informed Duramed that CDER had completed its review of Duramed's application and found that "the available scientific data are sufficient to support the safe use of Plan B as an OTC product" for women who are 17 years and older. Letter from L. Crawford to Duramed Research, Inc. of 8/26/05.

Notwithstanding this undisputed scientific finding and the fact that Plan B is also effective in OTC use under the same directions for use that apply when the drug is dispensed pursuant to a prescription, FDA refused to take final action on Duramed's supplement, and indefinitely delayed final action, FDA stated that the supplement presented the agency with the question of whether and how to market the same active ingredient to different populations for Rx and OTC use, and indicated that it would seek comments on whether to initiate rulemaking to resolve those issues. </7: 1.2>

<8: 1.2>One FDA official and a consulting member of an FDA advisory committee have publicly resigned in protest over the August 26 Plan B decision. Susan F. Wood, the Assistant Commissioner for Women's Health and Director of the Agency's Office of Women's Health, resigned shortly after the August 26 decision was announced. She stated that FDA's decision was contrary to the scientific evidence and resulted from unwarranted interference in agency decision-making. "I can no longer serve as staff when scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff here, has been overruled," she wrote in an e-mail to her staff and FDA colleagues. [Footnote 13: Marc Kaufman, FDA Official Quits Over Delay on Plan B, The Washington Post, Sept. 1, 2005, A08. Attached hereto at Ex. 8.] In early October, Frank Davidoff, a member of FDA's Nonprescription Drugs Advisory Committee when it voted to recommend approval of Plan B for nonprescription sales in 2003, also resigned his current consulting position with that committee in protest. He stated: "There wasn't any

observable scientific or procedural reason for [FDA] to first decline and then further delay the decision. I had to make the inference this was a decision that was made on the basis of political pressure, and it seemed to me that was unacceptable." [Footnote 14: FDA Advisor Resigns Over Plan B Handling, The Associated Press, Oct. 6, 2005. Attached hereto at Ex. 9.]

The relevant scientific and medical communities have almost uniformly concurred with Dr. Wood's and Dr. Davidoff's assessment. They have heavily criticized FDA's continued refusal to approve OTC status for Plan B. An editorial in The New England Journal of Medicine was typical of this response: "[T]he agency has previously resisted political pressure to reflect a particular social policy or ideology. The recent actions of FDA leadership have . . . squandered the public trust and tarnished the agency's image." Allastair J.J. Wood, et al., A Sad Day for Science at the FDA, 353:12 N. Engl. J. Med. 1196, 1198. Attached hereto as Ex. 10.

On October 7, 2005, a bipartisan group of 62 U.S. legislators wrote to FDA to urge acting Commissioner Andrew van Eschenbach to approve Plan B for OTC use. The legislators argued that, "[b]y further delaying the FDA's decision to expand access to emergency contraception, [FDA is] seriously hindering efforts to reduce abortions across the U.S." and it called on Dr. von Eschenbach to approve Plan B "without further delay." The legislators continued, "[w]e find it contradictory and disconcerting that the FDA's concerns are a direct result of the agency's own recommendations last May We believe this new delay does not truly reflect valid scientific or regulatory concerns" [Footnote 15: 15 U.S. Lawmakers Call for Morning-after Pill Approval, Reuters, Oct. 11, 2005. Attached hereto at Ex. 11.]</8: 1.2>

DISCUSSION

FDA's Notice seeks comment on the following questions:

1-A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

I.B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the FDCA?

1.C. If so, would a rulemaking on this issue help dispel that confusion?

2.A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

2.B. If it could, would it be able to do so as a practical matter and, if so, how'?

3.A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

3.B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

70 Fed. Reg. 52,050, 50,251 (Sept. 1, 2005). Duramed takes up each of these questions in turn below.

<9: 3.8.4>I. FDA'S INTERPRETATION OF SECTION 503(b) HAS NOT CREATED CONFUSION, AND THERE IS NO NEED FOR ANY RULEMAKING IN ORDER TO APPROVE NDA 21-04S/S011.

FDA need not, and should not, initiate a rulemaking to codify its interpretation of section 503(b) regarding when an active ingredient can be marketed simultaneously in both an Rx drug product and an OTC drug product.

As FDA acknowledges in the Notice, it has on a number of occasions permitted simultaneous Rx and OTC marketing of a product. Were FDA's interpretation of section 503(b) really in need of clarification, that need would have arisen well before now. The fact that the issue has not previously been raised is strong evidence that there is no need for rulemaking regarding FDA's interpretation of section 503(b).

Moreover, the issue presently before FDA is whether this drug product, Plan B, can simultaneously be marketed as both an Rx and an OTC drug product. Resolution of that issue need not, and ultimately does not, implicate FDA's long-standing interpretation of section 503(b). </9: 3.8.4>

<10: 3.9.2>A. UNDER THE FDCA AND FDA'S EXISTING REGULATIONS, PLAN B CAN PROPERLY BE AN OTC DRUG FOR ONE PATIENT SUBPOPULATION

Generally, new drug products that are indicated for different patient populations are different "new drugs." Where new drug products are different, one may be an Rx drug product, and the other an OTC drug product, without creating any problem under the FDCA or FDA's regulations.

The Manual of Policies and Procedures of the Center for Drug Evaluation and Research ("MAPP") expressly contemplates that an Rx version and an OTC version of a drug product may differ only in the population for which they are indicated:

Initial Marketing of a Drug Product OTC. This category of product could be one of two types: (1) OTC marketing of a product that was never previously marketed as a prescription drug product or (2) OTC marketing of a product in a strength, dose, route of administration, duration of use, population, indication, or dosage form different from ones previously approved for prescription use.

MAPP 60205 at 2 (Jan. 15, 1997) (boldface in original) (emphases added), available at <http://www.fda.gov/cder/mapp/6020-5.pdf>. [Footnote 16: The universe of OTC drug products consists of (i) those initially marketed OTC, and (ii) those switched from Rx to OTC status. As a matter of terminology, the term "Rx to OTC switch" "refers only to OTC marketing of a product that was once a prescription drug product for the same indication, strength, dose, duration of use, dosage form, population, and route of administration." MAPP 6020.5 at 2. The proposed Plan B subpopulation switch is an "Rx to OTC switch" with respect to the population of women age 16 and over; for that subpopulation, the drug product previously was available only as an Rx product, but would now be available OTC.] The use of the disjunctive "or" in the quoted passage makes clear that the passage expressly contemplates "OTC marketing in a . . . population . . . different from ones previously approved for prescription use," id.</10: 3.9.2>

<11: 3.9.2>There is no legally relevant distinction between the proposed subpopulation switch of Plan B and the scenario described in MAPP 6020.5. As applied to Plan B, the exact analogy would be a scenario in which Plan B had previously been approved only as an Rx drug for women age 15 and younger, and were now also to be approved as an OTC drug for women age 16 or over. In that scenario, the proposed OTC population would be "different from [the one] previously approved for prescription use." MAPP 6020.5 at 2.

It should make absolutely no difference, however, that Plan B previously has been approved as an Rx drug for women age 16 or over (as well as for women age 15 and younger), In both the scenario described

in MAPP 6020.5 and in the proposed scenario for Plan B, after approval of the drug for the specified OTC subpopulation, the drug would simultaneously be approved as an Rx drug for one subpopulation and as an OTC drug for another. Nothing in the discussion in MAPP 6020.5 suggests that, upon the approval of the OTC status for the new patient subpopulation, the Rx status for the remaining patient subpopulation would be withdrawn. Thus, MAPP 6020.5 demonstrates that there is no FDA policy that precludes the approval of a drug for simultaneous marketing as an Rx drug for one patient subpopulation and as an OTC drug for another. </11: 3.9.2>

<12: 3.3.3>The newness of a drug may arise from the newness of the "use " of the drug. 21 C.F.R. § 310.3(h)(4) (2005). Intended uses of a drug in different patient subpopulations constitute different uses of the drug, and thus create different new drugs, within the meaning of FDCA §§ 201(p) and 505(a), 21 U.S.C. §§ 321.(p), 355(a). The reason why a supplement is required for an additional indication for an approved new drug is that the additional indication constitutes a new use of the drug and therefore creates a different new drug. A manufacturer of an approved drug that promotes its product for a use different from or additional to the approved use(s) is subject to a charge of violating FDCA §§301(d), 21 U.S.C. § 331(d), as well as to a misbranding charge under FDCA § 502(f)(1), 21 U.S.C. § 352(f)(1). See Decision in Washington Legal Foundation v. Henney, 65 Fed. Reg. 14,286-01, 14,286-01 (Mar. 16, 2000) ("an approved new drug that is marketed for a 'new use' becomes an unapproved new drug with respect to that use").

FDA recognizes that persons age 15 and younger constitute a patient population ("the pediatric age group") distinct from patient populations consisting of persons age 16 or over. See 21 C.F.R. § 201.57(f)(9)(i) (2005). Generally, separate investigations are necessary to support an indication for that population, as distinct from an indication for an adult population. See generally, FDCA § 505A, 21 U.S.C. § 355a; 21 C.F.R. § 201.57(f)(ii) (2005).</12: 3.3.3>

<13: 6.3.1>Thus, for example, if a drug is indicated only for an adult population, but is promoted by its manufacturer for a pediatric population, the manufacturer would be subject to a charge under section 301(d) as well as to a charge under section 502(f)(1), The availability of a new-drug charge in this type of situation demonstrates conclusively that a drug intended for one patient population is a different new drug from the otherwise identical drug intended for a different patient population. In the language of section 310.3(h)(4), the difference between the intended patient population creates a different "use" of the drug - even though, in all other respects, the drug's physical qualities and its conditions of use (e.g., the medical condition it is intended to treat) remain the same. [Footnote 17: In the terms of FDCA § 201(p), 21 U.S.C. § 321(p), the difference in intended patient population constitutes a difference in "the conditions prescribed, recommended, or suggested" for the drug.]

Therefore, where intended patient populations are sufficiently distinct that FDA has concluded, on medical grounds, that one and the same product (i.e., same ingredients, dosage form, route of administration, strength, etc.) should be available OTC for one subpopulation of patients but only Rx for a second subpopulation, the uses of that product for the different subpopulations are different; and therefore the product, as intended for the different subpopulations, is, technically, two different new drugs. [Footnote 18: Patient populations can be differentiated on a variety of bases - including disease state, experience with other drugs, and gender, as well as age.]</13: 6.3.1>

<14: 3.9.2>"Sometimes the dose of a product to be marketed OTC may be lower than the previous prescription dose, or the proposed use may differ from the prescription use." FDA, Questions and Answers[:] Over-the-Counter Drug Products-Public Hearing June 28 and 29, 2000, at 3, available at <http://www.fda.gov/cder/meeting/otcqa-600.htm> (emphasis added). The FDA Questions and Answers expressly contemplate approval of a drug product for simultaneous marketing as an Rx drug for one use and as an OTC drug for another. As just explained, uses by different patient populations are different

uses.

The permissibility under the FDCA of approving the same drug product as Rx for one patient population and as OTC for another is valuable and important for protection of the public health. Such a pair of approvals enables the Agency to titrate the degree of intervention by healthcare professionals in patients' access to the drug product. Where FDA appropriately determines that a particular drug product can be safely, effectively, and appropriately used by one patient population with access QTC, but that another patient population needs the supervision of a physician, it would be inappropriate to make the drug product either entirely OTC (in which case the group for whom a prescription requirement is warranted would be put at risk) or entirely Rx (in which case the group for whom a prescription requirement is unwarranted would be subjected to unnecessary burdens and expense and, in this case, may experience unnecessary delay in obtaining the product, whose effectiveness diminishes with delay before use).</14: 3.9.2>

<15: 3.9.3>Further support for the permissibility under the FDCA and FDA's regulations of simultaneous dispensing to different patient populations of Rx and OTC versions of a drug is provided by FDA policy with respect to veterinary drugs. With respect to the Rx legend, veterinary drugs are subject to provisions very similar to § 503(b)(4). Compare FDCA § 503(b)(4), 21 U.S.C. § 353(b)(4) with FDCA § 503(f)(4), 21 U.S.C. § 353(f)(4). CVM Program Policy & Procedures Manual Guide 1240.2220 § 3.d (Mar. 9, 2000), available at <http://www.fda.gov/cvm/Policy-proced/2220.pdf>, states:

In the past, the same products used in varying routes of administration, dosage forms, and in varying species of animals may have been labeled prescription in one instance and non-prescription for other uses. The primary question is whether adequate directions for use can be written to assure safe and effective use. If an average food animal producer can safely and effectively administer a product, but a companion animal owner, regardless of label directions, cannot administer it safely and effectively, then the prescription status of the product must be different relative to these intended uses. If directions can be written for use for a particular route of administration (IV, IP, etc.) for one animal species but not for another, it is not inconsistent to grant OTC status for the one use and require the Rx legend for the other.

Id. This passage plainly contemplates that identical versions of a veterinary drug may be labeled in one instance (for one population) Rx and in another instance (for another population) OTC.

In sum, the proposed subpopulation switch of Plan B is consistent with existing written FDA policy. No further policy development is needed to support approval of the proposed subpopulation switch.</15: 3.9.3>

<16: 4.4.1>B. FDA'S INTERPRETATION SECTION 503(b) HAS NOT CAUSED ANY CONFUSION.

There has been no history of confusion regarding FDA's interpretation of section 503(b)(1i) of the FDCA as permitting simultaneous Rx and OTC marketing when some meaningful difference exists that makes the drug safe and effective for one patient population only under the supervision of a licensed practitioner but safe and effective for another patient population without such supervision.

There can be no genuine dispute that FDA has the authority to allow simultaneous marketing of the same active ingredient in Rx products and OTC products. In fact, approval of otherwise Rx drug products for OTC use in an appropriate subpopulation is not a novel concept. Whether a subpopulation is defined by a disease state (e.g., mild, moderate, severe), by prior experience with a drug (e.g., failed on first-line therapy), by gender, or by age (e.g., pediatric, geriatric) varies with particular products, but the principle is the same: different subpopulations for whom a drug is indicated create different "new drugs," for which separate approval is needed and which separately may be either Rx or OTC.

Although FDA has repeatedly found conditions under which an active ingredient may be marketed simultaneously in both a prescription drug product and an OTC drug product, and has presumably on occasion refused to find that such conditions exist, Duramed has been unable to locate any challenges to the interpretation of section 503(b)(f) that FDA utilizes to make such determinations. A review of the case law reveals that there is no published opinion addressing purported confusion regarding FDA's interpretation. Similarly, a review of the academic literature, including a review of the journals specific to issues relating to FDA and food and drug law, reveals that there has been no scholarly work identifying, or seeking to resolve, any confusion as to FDA's interpretation. In sum, neither the private nor public sector has been confused by FDA 's interpretation.</16: 4.4.1>

<17: 5.4.1>C. BECAUSE THERE IS NO CONFUSION REGARDING FDA'S INTERPRETATION, RULEMAKING IS UNWARRANTED.

Because there is no confusion regarding FDA's interpretation of section 503(b), there is no need for rulemaking to clarify FDA's interpretation.

Even if there were some circumstances in which confusion might somehow result from FDA's interpretation of section 503(b), there is no confusion regarding the application of FDA's interpretation to NDA 21-045/S011. Thus, no notice-and-comment rulemaking or guidance document is legally required or factually warranted in the circumstances here. The approval Duramed seeks from FDA is specific to NDA 21-045/S011 as amended, and does not raise broad issues potentially affecting other products.

If FDA is concerned that it has little prior experience with such use of an age restriction or its reflection in labels and labeling, the appropriate response is not to initiate rulemaking now. Instead, it is reasonable and appropriate for the agency to proceed case by case to accumulate experience before embodying a particular approach in a rule adopted in a notice-and-comment proceeding. See, e.g., SEC V. Chenery Corp., 332 US. 194, 202-03 (1947) (agency has discretion to proceed case by case or by notice and comment).

Since there is currently no court-created deadline, a rulemaking seeking to clarify FDA's interpretation of section 503(b), if initiated before approval of NDA 21-245/S011, could potentially delay such approval by years. FDA should not delay a decision on the pending supplement in order to conduct rulemaking to address concern over the clarity of its interpretation in some hypothetical future scenario. The delay that would necessarily accompany rulemaking in this instance would be particularly unjustified because it would deny women age 17 and over prompt and convenient access to a drug that FDA has already found is safe and effective for them when available OTC. Such delay would be flatly contrary to FDCA § 903(b)(1), 21 U.S.C. § 393(b)(1).</17: 5.4.1>

<18: 6.3.4>II. FDA CAN ENFORCE LIMITED SALE OF AN OTC PRODUCT TO A PARTICULAR SUBPOPULATION.

As the Notice highlights, there is nothing novel about an active ingredient that is marketed simultaneously in both an Rx drug product and an OTC drug product. FDA has repeatedly approved such simultaneous use where there is, as FDA states in its Notice, "some meaningful difference . . . between the two that makes the prescription product safe only under the supervision of a licensed practitioner." 70 Fed. Reg. at 52051. That the meaningful difference is in the population taking the drug, and not in the active ingredient, itself, has no impact on FDA's legal and practical ability to enforce the prescription requirement while permitting OTC sales of a drug with the same active ingredient. </18: 6.3.4>

<19: 6.3.1>A. AS A MATTER OF LAW, FDA CAN ENFORCE LIMITATION OF AN OTC

PRODUCT TO A PARTICULAR SUBPOPULATION THROUGH ENFORCEMENT OF SECTION 503(B)(1)(B).

Just as it has the legal authority to enforce a prescription limitation where the limitation applies to the entire population, FDA has the legal authority to enforce the prescription limitation of Plan B as to a subpopulation (i.e., women 15 and younger).

Section 503(b)(1)(B) of the FDCA provides:

A drug intended for use by man which . . . is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

21 U.S.C. § 353(b)(1)(B) (emphasis added).

In turn, section 301(k) provides that the following is a prohibited act: "The . . . doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded." 21 U.S.C. § 331(k).

Injunctive relief for violation of section 301(k) is available under FDCA § 302.21 U.S.C. § 332. Criminal penalties for committing a prohibited act under section 301(k) are available under FDCA § 303(a), 21 U.S.C. § 333(a).

Reading these three sections together, "the conclusion is inescapable . . . that one dispensing drugs . . . contrary to the provisions of Sec. 353(b)(1) shall be guilty of, and subject to the punishment provided by law for, an act of misbranding." *United States v. Carlisle*, 234 F.2d 196,199 (5th Cir. 1956). Thus, if FDA approves Duramed's supplement to NDA 21-045/S011, permitting OTC sale for those age 16 and over and requiring a prescription for sale to those under age 16, then selling to someone age 15 or younger without a prescription would constitute a prohibited act under section 301(k), for which civil and criminal remedies are available under the FDCA.</19: 6.3.1>

<20: 7.4.1, 7.4.4>B. FDA HAS EXTENSIVE EXPERIENCE IN ENFORCING PRESCRIPTION REQUIREMENTS.

The application of age restrictions to certain products is prevalent throughout our society. With respect to Plan B, the restriction could be enforced by requiring pharmacies to keep the drug behind the counter and dispense it only upon presentation of (i) a prescription or (ii) identification showing that the consumer is age 16 or over. These requirements and the age restriction can be enforced through a variety of mechanisms, all of which FDA has readily at its disposal and/or can employ in cooperation with state and local governments.</20: 7.4.1, 7.4.4>

<21: 7.4.2>First, in testimony before the Committee on Government Reform on September 13, 2005, Robert J. Meyer, M.D., Director, Office of Drug Evaluation II ("Meyer Testimony"), outlined many of the enforcement mechanisms FDA currently employs to curb prescription drug abuse. [Footnote 19: Dr. Meyer's testimony is attached hereto at Ex. 12.] FDA could use these mechanisms to enforce a

prescription requirement for women under age 16. For example, as it does in other matters, FDA can undertake joint investigative efforts with the Drug Enforcement Administration.</21: 7.4.2>

<22: 7.4.3>Second, FDA is authorized by FDCA § 704, 21 U.S.C. § 374, to conduct inspections of establishments that are subject to the requirements of the FDCA, which include pharmacies selling drug products. Anyone who refuses to permit such an inspection is subject to criminal penalties under FDCA § 301(f), 21 U.S.C. § 331(f), and § 303(a), 21 U.S.C. § 333(a). Under FDCA § 702, 21 U.S.C. § 372, FDA may conduct examinations and investigations, through officers and employees of the Department of Health and Human Services or through any health, food, or drug officer or employee of a state and local government, duly commissioned by the Secretary of Health and Human Services as an officer of the Department. Through use of its own, or state, investigators, FDA can conduct random, unannounced inspections of pharmacies or stores, to ensure that they are enforcing the prescription limitation of Plan B for women younger than age 15. </22: 7.4.3>

<23: 7.4.5>Third, FDA can deter persons from violating the subpopulation Rx requirement by aggressively pursuing criminal actions against known violators. FDA can use a number of means to pursue such enforcement. Cases can be developed, through FDA's network of field offices, reviewed by FDA headquarters, and then submitted to the Office of Consumer Litigation ("OCL") in the Department of Justice. OCL determines whether to pursue criminal or civil remedies, if any. FDA can also refer cases through the Office of Criminal Investigations ("OCI"). OCI can refer cases directly to United States Attorneys' Offices. </23: 7.4.5>

<24: 7.4.2>Fourth, FDCA § 909, 21 U.S.C. § 399, authorizes FDA to make grants to States for the purpose of conducting examinations and investigations. FDA can allocate grants to state and local governments to aid them in their own enforcement of such a restriction. State drug inspectors, in connection with local law enforcement, are involved in enforcing prescription requirements. President Bush's 2005 National Drug Control Strategy recognizes that state prescription drug monitoring programs are highly effective in curbing prescription drug abuse. [Footnote 20: The President's National Drug Control Strategy, The White House, 36-37 (2005). Attached hereto at Ex. 13.]</24: 7.4.2>

<25: 7.3.1.2>Fifth, FDA has the inherent authority to publicize the importance of strict adherence to prescription requirements, and could undertake a public education campaign to ensure that women under the age of 16 are aware of their need to obtain a prescription to buy Plan B. See also FDCA § 705, 21 U.S.C. § 375. For example, as Dr. Meyers testified, FDA has recently partnered in launching a "prescription drug abuse prevention education effort, with the primary goal of preventing and reducing the abuse of prescription drugs . . . by teens and young adults." Meyer Testimony at 4. FDA could launch a similar educational campaign regarding Plan B.</25: 7.3.1.2>

<26: 7.3.2>Sixth, FDA can also monitor the advertising and promotion of Plan B through its Division of Drug Marketing, Advertising, and Communications, which is responsible for regulating prescription drug advertising and promotion.</26: 7.3.2>

<27: 7.4.6>Seventh, FDA can monitor its enforcement success by making annual reports to the Department of Health and Human Services concerning the methods and effectiveness of enforcement efforts. For one example, the Substance Abuse and Mental Health Services Administration ("SAMHSA"), part of HHS, conducts an annual National Survey of Drug Use and Health on a random sample of U.S. households. This survey seeks to determine the prevalence of non-medical use of prescription drugs. FDA can work with SAMHSA to randomly sample, as part of its annual survey, the number of women under 16 who use Plan B without a prescription, report its findings, and thereby monitor the effectiveness of its enforcement efforts over time. </27: 7.4.6>

<28: 7.3.1.1, 7.3.1.2>Duramed will aid FDA's efforts through its proposed Convenient Access, Responsible Education ("CARE") program. Under the program, distribution of Plan B will be limited to retail operations with pharmacy services and clinics. The product packaging for Plan B will also include a 24-hour toll-free number and a supplementary patient leaflet that will describe available contraceptive methods, including abstinence, and information on sexually transmitted diseases. The program will also include educational and monitoring programs for physicians and pharmacists that clearly set forth, and evaluate the effectiveness of, the prescription age restriction.</28: 7.3.1.1, 7.3.1.2>

<29: 8.3.1>III. RX AND OTC DRUG PRODUCTS CAN LAWFULLY BE SOLD IN THE SAME PACKAGING.

A. FDCA § 503 CAN BE SATISFIED BY MARKETING THE Rx AND OTC VERSIONS OF PLAN B IN THE SAME INITIAL PACKAGING.

Under the FDCA and current FDA regulations, Rx and OTC products can lawfully be sold in the same packaging. Specifically, with respect to packaging of Plan B, FDCA § 503 can be satisfied by ensuring that all packages contain (i) adequate information and directions to ensure safe, effective, and appropriate OTC use, (ii) the legend "Rx only for women under age 17," and (iii) appropriate space for the traditional Rx label, to be affixed by a pharmacist when dispensing the product pursuant to a prescription. Issues relating to the label and labeling of Plan B have already been reviewed and addressed by the Reproductive Health and OTC Divisions of CDER during their review of Duramed's July 2004 submission. Appropriate labeling, including that on the tamper-evident seal, has been created and submitted to FDA.</29: 8.3.1>

<30: 8.3.1>1. The Label.

a. Compliance with General Requirements Applicable to the Label.

Plan B, when dispensed as an Rx drug, would need to comply, and would comply, with all requirements applicable to the label of an Rx drug and, when dispensed as an OTC drug, need to comply, and would comply, with all requirements applicable to an OTC drug. It would also need to comply, and would comply, with all requirements applicable to it during the period prior to dispensing.

It is proposed that Plan B have a printed label that includes all mandatory information for an OTC product. The proposed label and outer packaging comply with all the affirmative requirements applicable to OTC labels under FDCA §§ 502(b), 502(e)(1)(A), 502(f), 502(g), 21 U.S.C. § 352(b); 352(e)(1)(A), 352(f), 352(g); 21 C.F.R. §§ 201.1, 201.5, 201.10, 201.15, 201.17, 201.60- 62 (2005).</30: 8.3.1>

<31: 8.3.1>In addition, when Plan B is dispensed pursuant to a prescription, its label would be subject to all the requirements applicable to labels of Rx drugs under FDCA §§ 502(b), 502(e)(1)(B), 502(g), 21 U.S.C. §§ 352(b), 352(e)(1)(B), 352(g); 21 C.F.R. §§ 201.50, 201.51, 201.100(b) (2005).

Even though Plan B, as an OTC product, would bear adequate directions for use by consumers who, in accordance with the approved labeling, may buy the product without a prescription, it would not {in legal contemplation) bear adequate directions for use by patients who, in accordance with the approved labeling, may buy the product only with a prescription. [Footnote 21: The legal theory justifying prescription status as to those patients is that adequate directions for use by them cannot be written.]

Therefore, when dispensed to a patient who may obtain the-product only pursuant to a prescription. Plan B must comply, and would comply, with all the conditions, set forth in 21 C.F.R. § 201.100 (2005), for exemption from the requirement of adequate directions for use by the prescription population, FDCA §

502(f)(1), 21 U.S.C. § 352(f)(i).</31: 8.3.1>

<32: 8.3.1>There is no obstacle to simultaneous compliance with all these requirements. Indeed, because the product information, including all directions for use are exactly the same for the Rx and the OTC users of Plan B, the presence of the OTC information and directions on the packages dispensed to Rx users would tend to enhance their safe, effective, and appropriate use of the product. Neither subpopulation of patients would be in any way adversely affected by the presence on the package of any information placed there in order to comply with a regulatory requirement for the protection of the other subpopulation.

FDCA § 503(b)(2), 21 U.S.C. § 353(b)(2), exempts an Rx drug from many of the requirements of § 502, 21 U.S.C. § 352, if its label contains (i) the name and address of the dispenser; (ii) the serial number and date of the prescription or its filing; (iii) the name of the prescriber, (iv) if stated in the prescription, the name of the patient; and (v) the directions for use and cautionary statements, if any, contained in such prescription. The information required by section 503(b)(2) would appear on the Rx label attached to the package by the pharmacist when dispensing the product pursuant to a prescription. </32: 8.3.1>

<33: 8.3.1>b. Compliance with Section 503(b)(4).

FDCA § 503(b)(4) provides:

(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

21 U.S.C. § 353(b)(4).

Whether a drug product is subject to section 503(b)(4)(A) or 503(b)(4)(B) depends entirely on whether it falls under paragraph (1) of section 503(b). Under the proposed subpopulation switch, Plan B would remain an Rx product for women under age 16. Therefore, it would remain "[a] drug that is subject to paragraph (1)" of section 503(b). Consequently, at all times, it would remain subject to section 503(b)(4)(A), and would not be subject to section 503(b)(4)(B), which applies only to drug products that are not subject to any prescription requirement under section 503(b)(1) at all. Even the units of Plan B ultimately dispensed OTC to women age 16 or over would be subject to a prescription restriction under section 503(b)(1) against their being dispensed OTC to women under age 15, and so would be subject to section 503(b)(4)(A), rather than to section 503(b)(4)(B).

Duramed proposes that Plan B comply with section 503(b)(4)(A) by bearing on its label the legend: "Rx only for women under age 15 and younger." Section 503(b)(4)(A) requires that "the symbol 'Rx only'" appear on Plan B's label. The symbol "Rx only" would appear on the label as part of the statement "Rx only for women age 15 and younger." Nothing in section 503(b)(4)(A) precludes the appearance of the symbol on a label as part of a truthful and non-misleading statement of the prescription limitation applicable to the labeled product under its NDA. Indeed, the expression "at a minimum" in section 503(b)(4)(A) expressly contemplates that the words "Rx only" may appear with other words on the label. The proposed Rx legend would comply literally with the text of section 503(b)(4)(A). It also would fully serve the purpose of section 503(b)(4), which is to make clear to pharmacists and the public when a drug product is to be dispensed OTC or only by prescription.</33: 8.3.1>

<34: 8.3.1>2. Labeling.

a. OTC Labeling.

The Plan B package would also need to contain, and would contain, labeling that complies with the labeling requirements applicable to OTC products, 21 C.F.R. § 201.66 (2003).

b. Rx Labeling.

There would also need to be Rx labeling with respect to the class of patients to whom the product may be dispensed only pursuant to a prescription. See 21 C.F.R. §§ 201.50, 201.56; 201.100(c), 201.100(e) (2005). Thus, it would be necessary to revise the current Rx labeling. Plan B would comply with these requirements.</34: 8.3.1>

<35: 8.3.2>c. NDC Number.

There would not be separate NDC numbers for the (Rx and OTC) versions of Plan B. There is no need for separate numbers because all purposes of the NDC system would be fully served here by a single number.</35: 8.3.2>

<36: 9.1.1>B. IN LIMITED CIRCUMSTANCES NOT APPLICABLE TO PLAN B, TWO PRODUCTS COULD NOT BE SOLD IN THE SAME PACKAGING.

It would be inappropriate to sell two products in the same packaging if different doses, different strengths, or different directions for use were needed for the safe and effective use of the OTC produce as compared to the safe and effective use of the prescription product. None of these circumstances, however, applies to the marketing and sale of Plan B. </36: 9.1.1>

CONCLUSIONS

For the foregoing reasons, (i) FDA should not initiate rulemaking with regard to its interpretation of section 503 of the FDCA; (ii) FDA has the legal authority and practical ability to enforce an age-related prescription limitation applicable to Plan B; and (iii) FDA can permit the marketing of the Rx and OTC versions of Plan B in the same packaging.

FDA has determined that Plan B is safe and effective for OTC use in women age 17 and older. Therefore, FDA should give final approval to NDA 21-045/S011 without further delay.

Respectfully submitted,

Richard M. Cooper
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November 1, 2005

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November 1, 2005

BY HAND DELIVERY

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0345/RIN No. 0910-AF72
Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in
Both a Prescription Drug Product and an Over-the-Counter Drug Product

Dear Sir or Madam:

Enclosed please find one original and three copies of comments, and exhibits
attached thereto, submitted by Duramed Pharmaceuticals, Inc. and Duramed Research, Inc. in response to
the above-referenced Advance Notice of Proposed Rulemaking.

Sincerely,

Ana c. Reyes

Enclosures

COMMENT NUMBER - 2005N-0345-C443

2005N-0345-C443 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: National Association of Boards of Pharmacy

2005N-0345-C443 - TEXT

November 1, 2005

Division of Dockets Management
Food and Drug Administration

5630 Fishers Ln, Room 1061
Rockville, MD 20852

Re: Drug Approvals; Circumstances Under Which an Active Ingredient May be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product [Docket No. 2005N-0345]

The purpose of this correspondence is to provide the comments of the National Association of Boards of Pharmacy (NABP) to the United States Food and Drug Administration (FDA) in response to its request for public comments on whether to initiate a rulemaking to codify its interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.) regarding when an active ingredient may be simultaneously marketed in both a prescription drug product and an over-the-counter (OTC) drug product.

As you may know, NABP, founded in 1904, represents all of the pharmacy regulatory and licensing jurisdictions in the US, Guam, Puerto Rico, the Virgin Islands, eight provinces of Canada, two states in Australia, New Zealand, and South Africa. NABP's purpose is to serve as the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

<1: 3.8.2, 7.3.1.1, 7.4.2>Specifically, the following comments address NABP's position regarding the most effective method by which FDA, with the assistance of the state boards of pharmacy, may safely allow and easily enforce the limited sale of nonprescription drug products to a particular subpopulation, particularly emergency contraceptives.

We believe the best way to do this is via a third, transitional class of drugs, also known as a "counseling" class of drugs. Since 1995, NABP has advocated a counseling class of drugs dispensed, without a prescription, only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs. That year, during NABP's 91st Annual Meeting, the NABP delegation passed the following Resolution, 91-3-95, "Establishment of a Transitional Class of Drugs;"

Whereas, there are a number of prescription-only drugs that are being converted to over-the-counter status; and

Whereas, there are strong economic forces that are encouraging this change in status; and

Whereas, many of the drugs have serious side effects and need proper patient education for their effective use;

Therefore Be It Resolved that such drugs be placed in a special class requiring sale only by health care professionals authorized by law to prescribe and/or dispense prescription drugs; and</1: 3.8.2, 7.3.1.1, 7.4.2>

<2: 7.3.1.4>Be It Further Resolved that health care professionals authorized by law to prescribe and/or dispense be required to counsel patients regarding the proper use of drugs in this class; and</2: 7.3.1.4>

<3: 3.8.2>Be It Further Resolved that NABP support the introduction of legislation into the US Congress to create this new transition class of drugs.

NABP believes that a counseling class of drugs could significantly contribute to the overall safety of the public health as more drugs are transitioned from "prescription drug" status. A counseling class of drugs

would serve as a beneficial adjunct to FDA's plan to reclassify prescription drugs by ensuring that patients are properly educated in medication use. In addition, it would serve as a means to implement any subpopulation requirements to risk manage specific drugs. </3: 3.8.2>

<4: 7.3.1.2>In the case of an emergency contraceptive, for example, a patient's thorough understanding of the drug's indication, directions for proper use, and adverse effect is vital to appropriate patient care and safety. If emergency contraceptives are placed in a new counseling class of drugs, pharmacists, the nation's most accessible health care professionals, will be able to provide such necessary information and assistance. </4: 7.3.1.2> <5: 7.4.1, 7.4.4>Additionally, this classification would provide a mechanism for the verification of the patient's age, if necessary, or any other subpopulation requirements. </5: 7.4.1, 7.4.4> <6: 3.8.2>Overall, the implementation of a counseling class of drugs would not decrease the accessibility of newly reclassified prescription drugs, but would ensure that appropriate patients are using medications in a safe and effective manner.

In closing, NABP hopes that FDA will consider the counseling class of drugs as an approach to ensure patients' proper and safe use of specific, identified prescription drug products.</6: 3.8.2>

If I can provide any additional information, please contact me. Thank you for the opportunity to address this important issue.

Sincerely,

Carmen A Catizone, MS, RPh, DPh
Executive Director/Secretary

COMMENT NUMBER - 2005N-0345-C453

2005N-0345-C453 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Aventis Pharmaceuticals, Inc and Sanofi- Synthelabo, Inc.

2005N-0345-C453 - TEXT

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November 1, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0345

Dear Madam or Sir:

We submit these comments on behalf of Aventis Pharmaceuticals Inc. and Sanofi-Synthelabo Inc., members of the sanofi-aventis Group, in response to the advanced notice of proposed rulemaking published by the Food and Drug Administration ("FDA" or "Agency") on September 1, 2005, regarding the circumstances under which an active ingredient may simultaneously be marketed in both a prescription and an over-the-counter ("OTC") drug product. [Footnote 1: 70 Fed. Reg. 52050 (Sept. 1, 2005).] The sanofi-aventis Group is the world's third largest pharmaceutical company, The sanofi-aventis Group is a dynamic organization that is working to meet the healthcare needs of physicians and their patients and is committed to researching, developing and bringing to market new and innovative healthcare products.

In its September 1, 2005 Federal Register notice, FDA solicited comments as to whether it should commence rulemaking to codify its interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act") regarding when an active ingredient can be marketed as both a prescription and OTC drug product. [Footnote 2: *Id.* at 52050-51.] Specifically, FDA requested comments on whether there is "significant confusion regarding FDA's interpretation" of section 503(b) and if so, whether a rulemaking on the issue would resolve the confusion. [Footnote 3: *Id.* at 52051.]

<1: 3.10>FDA has consistently interpreted section 503(b)(1) as permitting the marketing of the same active ingredient in products that are both prescription and OTC only if there is "some meaningful difference" between the two, for example in conditions of use, strength, route of administration, or dosage form. [Footnote 4: *Id.*] FDA has never permitted the same active ingredient to be marketed simultaneously as both a prescription and OTC product for identical conditions of use. </1: 3.10>

<2: 3.8.6, 4.1>Nevertheless, sanofi-aventis believes that there is indeed significant confusion over the Agency's interpretation of section 503(b) - confusion created by the Agency's October 1999 Draft Guidance for Industry regarding "Applications Covered by Section 505(b)(2)." [Footnote 5: FDA, Draft Guidance for Industry: Applications Covered by Section 505(b)(2) (October 1999) (hereinafter "1999 Draft Guidance" or "Draft Guidance").] However, sanofi-aventis believes that FDA need not initiate rulemaking to dispel this confusion. Rather, the Agency can simply withdraw or amend its 1999 Draft Guidance. In addition to noted confusion, the Draft Guidance raises issues of the Agency's unauthorized "taking" of confidential data belonging to the pioneer manufacturer and the Agency's authority under section 505(b)(2), which are beyond the scope of these comments, </2: 3.8.6, 4.1>

<3: 4.3.1>An application under section 505(b)(2) of the FDCA is one for which the investigations of safety and effectiveness on which the applicant relies for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use" [Footnote 6: FDCA § 505(b)(2), 21 U.S.C. § 355(b)(2).] In its 1999 Draft Guidance, FDA advanced for the first time its unsupported interpretation of section 505(b)(2) as permitting reliance on proprietary data contained in another manufacturer's application. FDA also asserted in the Draft Guidance that a section 505(b)(2)

application could be used to obtain a switch in product indications from prescription only to OTC.
[Footnote 7: 1999 Draft Guidance at 5.]

Insofar as it suggested that a section 505(b)(2) application is a suitable vehicle for obtaining approval of a switch from a prescription indication to an OTC indication for another applicant holder's product, the Agency's Draft Guidance does not account for the potential for Durham-Humphrey misbranding issues. Under the Draft Guidance, the Agency could theoretically approve an OTC product in reliance on a pioneer's data for an approved prescription product. That prescription product would continue to be covered by the pioneer's NDA. The pioneer with an approved NDA for its product is entitled to -indeed must - sell that product in conformity with the terms of its NDA, including selling it only as a prescription product. Through its Draft Guidance, the Agency thus opened the door to the same active ingredient being simultaneously marketed for the same conditions of use as both a prescription and an OTC drug product, thereby creating an unworkable tension with section 503(b) of the FDCA. </3: 4.3.1>

<4: 4.3.1>Significantly, any attempt to remedy the inherent confusion of the Agency's Draft Guidance by forcing the innovator company to take its product OTC upon approval of another applicant's section 505(b)(2) application would raise serious legal concerns. Among other things, section 503(b) of the FDCA does not anticipate such broad-based OTC switches absent rulemaking. [Footnote 8: FDCA § 503(b)(3); 21 U.S.C. 8 353(b)(3).] In addition, questions of constitutional rights must be addressed. </4: 4.3.1>

<5: 3.8.6>FDA need not initiate rulemaking to clarify its interpretation of section 503(b) of the FLEA as to when the same active ingredient may be simultaneously marketed in both a prescription and OTC product. Rather, the Agency can do so simply by withdrawing or amending its 1999 Draft Guidance. By withdrawing that guidance or striking any reference to OTC switches in that document, FDA will affirm its practice (1) of permitting switches through the original applicant's initiative or the Agency's own rulemaking and (2) of allowing the same active ingredient to be marketed simultaneously as a prescription and OTC counter product only where a meaningful distinction between the two products exists. </5: 3.8.6>Sanofi-aventis appreciates the opportunity to comment on this advanced notice of proposed rulemaking.

Sincerely,

Peter O. Safir
Kelly A. Falconer

Counsel for Aventis Pharmaceuticals Inc. and Sanofi-Synthelabo Inc., members of the sanofi-aventis Group

COMMENT NUMBER - 2005N-0345-C489

2005N-0345-C489 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Women's Bar Association of the State of New York

2005N-0345-C489 - TEXT

Women's Bar Association of the State of New York

November 1, 2005

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0345
RIN No. 0910-AF72

Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-The-Counter Drug Product

The Women's Bar Association of the State of New York ("WBASNY") is a statewide organization with over 3,500 members across the State. Our mission is not only to promote the status of women in the legal profession, but also to promote the fair and equal administration of justice for all women at the state, national and international level. We submit this letter in response to the request of the Food and Drug Administration ("FDA") for comments in its Advance Notice of Proposed Rulemaking. The FDA requested comments after receipt of the application of Duramed Research, Inc. The Company's application requested permission to market emergency contraception ("Plan B") over the counter to women who are 16 years of age and older, and by prescription to women under 16 years of age.

Women's health issues are a primary focus and concern to our bar association. <1: 1.2.1>We believe that proper and safe access to emergency contraception to avoid unwanted pregnancy is crucial. WBASNY therefore supports making Plan B as widely available at the counter as possible to women of childbearing age with appropriate safeguards and instructions as to use.

It has been estimated that emergency contraception could prevent over a million unwanted pregnancies and thousands of abortions annually in the United States alone. </1: 1.2.1><2: 3.8.2, 7.4.1>WBASNY has supported legislation proposed in New York State (A. 116 Paulin/ S.3661 Spano, currently tabled) that would allow New York State pharmacists (and registered nurses) to dispense emergency contraception to women of childbearing age without a patient specific prescription. This legislation requires that, in dispensing emergency contraception, a licensed pharmacist who has been trained about emergency contraception follow written procedures and protocols. It also requires that the patient be provided with a fact sheet containing clinical considerations, methods for use, the need for follow up care, and referral information. We suggest the development of comparable or equivalent safeguards to the extent possible on the federal level for over the counter use of Plan B by women. Such safeguards might address many of the FDA's concerns about inappropriate use by teenagers. This would allow the FDA to consider permitting access by teenagers to Plan B over the counter as a means of reducing unwanted pregnancy and abortion rates among teenagers.</2: 3.8.2, 7.4.1>

<3: 1.2.1>With regard to the specific pending application of Duramed Research, Inc., we believe that the FDA should take whatever actions are necessary to deal with the legal and practical problems involved in approving the application.</3: 1.2.1> <4: 7.4.4, 10>We caution against imposition of requirements as to age identification or sworn statements verifying age at the counter. Since studies have shown that the health risk involved in use of emergency contraception pills ("ECP's") by adolescents is small, we believe that the theoretical danger of a few adolescents potentially obtaining the drug without a prescription would be far outweighed by the advantages of adult women's ability to access it promptly in an

emergency. [Footnote 1: See Melissa Schorr, Emergency Contraception Safe for Use in Teenage Girls, Medscape Medical News (Nov. 18, 2003) cited by Planned Parenthood at <http://www.plannedparenthood.org/pp2/portal/files/portal/medicalinfo/ec/fact-emergency-contraception.xml> : "ECPs can also be safely used by adolescents. One study designed to evaluate the safety of ECP use in teenagers enrolled 55 teens between the ages of 13 and 16. ECPs were found to be safe and well tolerated by the teens. The teens took the medicine properly, and they returned to their normal menstrual period at the same rate as adult women taking ECPs."]

In summary, we recommend the approval of the proposal made by Duramed Research, Inc. as a positive first step toward allowing Plan B to be marketed with appropriate safeguards and instructions as to use to women of childbearing age without a prescription. Should you have any questions or concerns, please do not hesitate to contact me. Thank you for considering our comments.

Respectfully submitted,

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President, WBASNY

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Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Micro ICU Project

2005N-0345-C5 - TEXT

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Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0345 and RIN 0910-AF72 ("Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-The-Counter Drug Product")

To Whom It May Concern:

The Micro ICU Project is an interdisciplinary project in micro-biomedical engineering working to create neonatal-type incubators for pre-implantation infants using microfabrication technology, a field that has considerably advanced in recent years. [Footnote 1: Californiaa, E. Method of monitoring the body temperature of human embryos and hatchlings. U.S. Patent No. 6,694,175. Feb. 17, 2004. Prior to this teaching practitioners failed to grasp the biophysical distinction between an incubator thermostat reading and the patient's own body temperature!] [Footnote 2: Californiaa, E. Thermoregulation of human embryos and hatchlings in a prenatal incubator using infrared microthermography. Trends in Reproductive Biology. 2005; 1:63-67 (in press). A preprint of the article is available online at <http://www.juridic.org/images/preprint.pdf>. This is the founding paper on the subject of competent incubator care for pre-implantation infants, and it offers ethically relevant insights.] Such incubators have been dubbed "micro ICUs" (micro intensive care units). As the world leader in developing incubator systems for the patient care of pre-implantation infants using microfabrication technology, the Micro ICU Project opposes products such as the morning-after pill that may harm a pre-implantation infant.

In a statement of Aug. 26,2005 ("FDA Takes Action on Plan B"), FDA Commissioner Lester M. Crawford raises important questions concerning the impact that liberalized distribution of the morning-after pill "Plan B" will have on public health. <1: 2.2>The Commissioner is thanked for the opportunity to comment on these questions. </1: 2.2>

In the language of the FDA, a "molecule" refers to a composition of matter comprising a drug treatment. The FDA has approved two different molecules for prescription use as a morning-after pill. The molecule known by the brand name Preven consists of a combined estrogen and progestin composition. The molecule known by the brand name Plan B consists of a progestin-only composition.

The two molecules differ widely in their side effects and effectiveness. The short term side effects of Preven are significantly more unpleasant than those of Plan B. Regarding differences in effectiveness, according to Dr. James Trussell and colleagues at Princeton University, using no other method if women made perfect use of Preven after every act of intercourse, 38% would experience a post-implantation pregnancy in the first year of use, compared to half as many (19%) using Plan B. [Footnote 3: "How effective is emergency contraception ?" <http://ec.princeton.edu/questions/eceffect.html>]

Barr Laboratories, which owns marketing rights to both molecules in the United States, quietly withdrew Preven from the U.S. market approximately one year ago. The exact reasoning behind this decision has not been publicly disclosed.

The FDA is cautioned to recognize that whatever the reasons Barr Laboratories may have had for withdrawing prescription use of Preven, the FDA's own analysis failed to anticipate these reasons in allowing prescription use of Preven in the first place. For unlike the FDA, it appears even Barr Laboratories eventually realized that Preven should non be on the U.S. market. In view of these developments the importance of caution should not be underestimated because the FDA has a responsibility to avoid making the same mistakes with Plan B such as were evidently made with Preven.

Although questions raised by Commissioner Crawford in his recent statement do recognize the need for caution, they do so only in minor part. For those questions do not make available for comment the major determination by the Center for Drug Evaluation and Research (CDER)-namely, that Plan B is safe as an over-the-counter product for women who are 17 years of age and older-as if that finding were a done deal. In an effort to promote thorough responsibility, and to invite recognition for the possibility of oversight, the Commissioner is strongly urged to open up a lengthy period of comment so as to enable an open,

public process to respond to the credibility of this finding.

The criticism that may be offered for such a finding is so strong and certain that one is wary that its expression may be mistaken for an ad hominem attack. For this reason, it seems preferable to introduce the possibility of such criticism indirectly in the form of a couple of questions.

- 1) Would it be unprofessional for a medical body to employ the brand name of one molecule as a generic name for two different molecules?
- 2) As consumers begin to learn that one molecule is more effective than another, would it serve to defraud consumers for a medical body to employ the brand name of the more effective molecule as a generic name for both?

In this case, the medical body in question is the American Medical Association (AMA) House of Delegates. Though integrity demands that both of these questions be answered in the affirmative, the AMA demonstrated unprofessional resolve by employing the brand name "Plan B" as a generic name to refer to both the combination and progestin-only molecules of the morning-after pill. In evidence of this act of consumer fraud, AMA House of Delegates Resolution 443 (A-04) reads in part: "The Plan B pill is a post-coital contraception method which transiently provides a high dose of (1) combined estrogen and progestin or (2) progestin-only.. ." [Footnote 4: American Medical Association House of Delegates. Resolution 443 (A-04) Re: FDA Rejection of Over-The-Counter Status for Emergency Contraception Pills. June 12, 2004. <http://www.ama-assn.org/meetings/public/annual04/443a04.rtf>] Note that Barr Laboratories voluntarily withdrew Preven from the U.S. market shortly after the AMA resolution. From the perspective of social analysis, it stands to reason that the members of the AMA House of Delegates did not make credible analysis of either morning-after pill regimen, else presumably they would not have made the mistake of equating the two different molecules using the brand name of the least ineffective of the two. If the credibility of a medical body as distinguished as even the AMA can be drawn into question, certainly the conclusions of the CDER should not be made exempt from public comment.

<2: 3.9.1>At any rate, the questions raised by the Commissioner in his recent statement are pertinent, and he should be commended for bringing them to our attention. But his approach to the question of whether the same molecule can exist in both prescription and over-the-counter forms for the same indication still deserves a note of criticism. For in accepting the finding of the CDER that Plan B is safe as an over-the-counter product for women who are 17 years of age and older, he appears to have contradicted his own question by overlooking the fact that Barr Laboratories' Plan B is the same molecule as Wyeth's prescription-only brand Ovrette, but in a different dosage. For this reason the question should be broadened to address whether prescription and over-the-counter forms of the same molecule can exist to straddle different dosages and/or ages.

Each of two tablets in the Plan B regimen contains the active progestin equivalent of 20 tablets in the Ovrette regimen-a 40 tablet total. Both regimens are indicated by their labels to reduce unplanned pregnancy. Both regimens suggest suppressing ovulation as a mode of action. The molecular equivalence is confirmed by Dr. Trussell and colleagues at Princeton University, who recommend substituting 40 tablets of Ovrette for the two tablets of Plan B. [Footnote 5: "Twenty-one brands of oral contraceptives that can be used for emergency contraception in the United States." <http://ec.princeton.edu/questions/dose.html>] So why would the FDA accept the finding of the CDER that the same molecule is safe in high dosage form as an over-the-counter product for women who are 17 years of (age and older, but not in low dosage form? Since it is particularly odd to conclude that the higher dosage of the same molecule should exist in over-the-counter form and the lower dosage in prescription form, by circumstances alone one must conclude that the determinations of the CDER are highly questionable. For although the FDA might consider whether different dosages can be straddled, it

is hard to believe that the higher dosage would be the one relegated to over-the-counter status! </2: 3.9.1>

It is noted that important clarification is needed regarding the Commissioner's recent statement. The statement reports that the CDER determined that Plan B is safe as an over-the-counter product, "but only for women who are 17 [sic] years of age and older." If this is not a misprint, then the Commissioner appears to have independently concluded that Plan B is safe for women who are specifically 16 years of age. For according to the Commissioner's statement, the FDA is now considering whether to allow over-the-counter use of Plan B for women as young as 16 years of age and older, rather than for women at least 17 years and older.

In considering whether Plan B should be made available in age-straddled prescription and over-the-counter forms, the reasoning the FDA appears to have used is that 1) the research on Plan B has left out women of the younger age group, 2) the CDER is satisfied with the research regarding the older age group, and 3) the line between the younger and older age groups should serve to distinguish prescription and over-the-counter forms. Of note, comments C 2044 and C 2092 of the Micro ICU Project in Vol. 300 of Docket No. 2001P-0075 demonstrate with absolute certainty the invalidity of the CDER's finding. But even aside from this paramount issue, an unqualified assumption is made in presuming that the age differences between research groups should automatically draw the line between prescription and over-the-counter forms.

This is an extremely important but subtle point. The CDER did not specifically validate the safety of Plan B for women who are, for example, 17, 18, and 19 years old. Instead, these women were included in an overall group, and the CDER was satisfied with the results for the group as a whole. But the CDER failed to investigate the possibility that unacceptable values for the lower aged women in the group (e.g., women aged 17-19) may have averaged in with better values for older women in the group. For this reason, even if the results for the overall group had been acceptable, there would still be the possibility that the age limit used to distinguish prescription and over-the-counter forms may still need to be set higher (e.g., to 20 years of age) than the age of the youngest members of the group. This means even if the FDA were to accept the CDER's finding that liberalized distribution of Plan B is safe for older women, it would still be scientifically premature to define a specific age range of safety.

Yet if the FDA is to consider age-straddling the availability of a given molecule between prescription and non-prescription forms, then the issue of age specificity is of critical importance. However, at present the CDER lacks sufficient age-specific data to make such a determination regarding Plan B. Instead, for the most part the CDER only has data to rely upon that has been averaged over a range of ages regarding women in the group 17 years and older. No age cutoff has been scientifically established within the group of women 17 years and older. It is spurious to rely on the lowest aged members of that group as the cutoff point without detailed, age-specific data to back it up.

As a word of extreme caution, it may be recalled that after Sweden introduced liberalized distribution of the morning-after pill in 1995, teen abortions rose an epidemic 32% between 1995 and 2001. As reported by a researcher at the Karolinska Institute in Stockholm, "Teenage abortion rates have gone up, from 17/1000 in 1995 to 22.5/1000 in 2001. Genital chlamydial infections have increased from 14,000 cases in 1994 to 22,263 cases in 2001, 60% occurring among young people, and with the steepest increase among teenagers." [Footnote 6: Edgardh, K. Adolescent sexual health in Sweden. *Sex Transm Infect.* 2002;78:352-356. Online at: <http://sti.bmjournals.com/cgi/content/full/78/5/352>] As the American Association for Pro-Life Obstetricians and Gynecologists (AAPLOG) points out in comment C 2042 in Vol. 295 of Docket No. 2001P-0075, "It would seem to us that the association of an increased induced abortion rate among teens corresponding to the availability of OTC EC [over-the-counter emergency contraception] in Sweden is a very red flag." The basis for the predictable effect of liberalized distribution is examined statistically in the above-stated Micro ICU Project comments. In a nutshell, the morning-after

pill is ineffective in a liberalized atmosphere. This problem appears especially evident in teenagers, and not just in women under 16 years of age. Though the average typical use patterns of women may improve with age, women of any age group are not immune to the ineffectiveness based on statistical reality.

<3: 6.6.1>Even if the FDA were to attempt age-straddled distribution of the morning-after pill between prescription and over-the-counter forms, there is no doubt that some of those eligible for non-prescription Plan B would in effect become the prescribers to ineligibly young women. Consequently, the FDA must question the ability of these would-be physicians to assess the risks to their would-be patients. The enforceability of discipline in this regard is evidently very low, for even a number of states have disregarded the process of drug evaluation by going ahead of the FDA, on their own incentives, and allowing over-the-counter distribution of Plan B to women of any age. If even a number of states have disregarded discipline, the same problem can certainly be expected from individuals, especially since public opinion is volatile in the United States when it comes to reproductive rights issues. </3: 6.6.1>

[See original comment for figure: Pregnancy Reduction Totem Pole]

Col. I: Pregnancies per 100 women in the first year of use are paired with given methods of reducing pregnancy. Data from the Alan Guttmacher Institute and Not-2-Late.com.

Col. II: Percentage of possible pregnancies reduced by the given method in the first year of use, assuming 85 pregnancies per 100 women in the first year using no method of reduction.

Important: These percentages calculated for the first year of use are not to be confused with reduction percentages determined with respect to a single act of intercourse.

Note: The totem pole has been truncated. At the bottom of the full totem pole is "No method" with its corresponding 85 pregnancies per 100 women in the first year—a 0% reduction.

In considering whether would-be physicians will be able to assess the risks to their would-be patients, it suffices to show that even distinguished medical bodies have been unable to appreciate the risks correctly. In other words, if even top medical bodies throughout the world have been unable to appreciate the risks, then clearly street physicians will be unable to appreciate the risks for their ineligibly young patients. To give an example, the Karolinska Institute is Sweden's top medical institute and is highly respected throughout the world. As a notable distinction, members of the Institute determine who will receive the Nobel Prize for medicine. But tragically, the Institute decided in favor of what became Sweden's policy in 1995 of instituting liberalized distribution of the combined estrogen and progestin molecule of the morning-after pill, which in the United States is marketed under the brand name Preven.

Examining the "Pregnancy Reduction Totem Pole" on the previous page, given that the molecule branded as Preven in this country is at the low end of the totem pole even with perfect use, it is not surprising that liberalized distribution resulted in an epidemic of unplanned pregnancies in Sweden. This is especially true since typical use rates will be much worse than perfect use rates. In 2001 Sweden liberalized distribution of the progestin-only molecule marketed in this country as Plan B. Yet unlike the voluntary actions of Barr Laboratories in this country regarding its brand Preven, Sweden did not remove the combined estrogen and progestin molecule from the Swedish market despite its greater ineffectiveness. This goes to show that even a medical body as distinguished as the Karolinska Institute did not appreciate the risks that liberalized distribution of either morning-after pill would have on public health. The miserable consequence, as is now known, was an epidemic of unplanned pregnancies and sexually transmitted diseases that proper discipline in this country would do well to avoid.

In assessing the epidemiology of this tragedy, a strong driving force was provided by none other than the admirably strong intentions of Swedish teens to take responsibility for their fertile capacity by listening to authorities who offered them the morning-after pill as if a respectable new means. But like a dog being cruelly made to chase its own tail in a miserably humiliating fashion, the more they relied upon the

morning-after pill the higher their rates of unplanned pregnancy and abortion went up-and as their rates went higher, their authorities became all the more determined to impose the morning-after pill on them. Because this is truly one of the cruelest tragedies in world memory, even though it did not transpire in this country the U.S. Congress should investigate it.

Other countries, such as England, have experienced similar results, though such experiences have been largely damped compared to the Swedish tragedy due to relatively tight controls on the over-the-counter distribution. Noted is that concerned citizens have been similarly bewildered by the results. For example, as one bewildered advocate of the morning-after pill writes for a British periodical, "Astonishingly, the greater availability of the morning-after pill over the past five years has had no real impact on teenage conception or abortion rates . . . And in the 13 local authorities with the highest rates, 11 have seen the numbers of teenage pregnancies increase." [Footnote 7: The Observer Magazine, Guardian Unlimited, "Waking Up to the Morning After Pill", by Geraldine Bedell. May 15, 2005.] So clearly if the FDA were to allow older women to get Plan B over-the-counter, they would be unlikely to understand the tragic risks posed in giving it to ineligibly younger women, since even distinguished medical bodies and concerned citizens remain bewildered.

At the heart of the bewilderment appears to be an inability to appreciate three considerations: 1) the exponential (i.e., non-linear) distinction between first year rates and per act rates, 2) the distinction between perfect use and typical use, and 3) the problem of substituted reliance. In addition to these considerations, it is also helpful to appreciate the meaning of acquiescence and coitivity ("co-it-TIV-it-t").

Coitivity is the rate at which a sexually active woman experiences coitus. Acquiescence is the rate at which non-sexually active women become sexually active. To understand the importance of coitivity, suppose Method X reduces a greater percentage of possible pregnancies per act than Method Y, but Method X seems so sophisticated and wonderful that users increase their coitivity in relationship to its use. On this basis, first year pregnancy rates, for users of Method X could actually be higher than rates for Method Y. When it comes to teen sexuality, this problem presents a special concern because individual teenagers may be especially subject to increases in coitivity inasmuch as their comparatively low coitivity rates leave them plenty of room for increase. To understand the importance of acquiescence, suppose Method 1 reduces first year pregnancy rates for its users to a greater extent than Method 2 does. But the boys hear about Method 1 and think science has solved everything, so they put more pressure on the girls to acquiesce. Even though Method 1 has lower first year pregnancy rates per user than Method 2, popularization of Method 1 could actually result in an increase in the total number of pregnancies in the population, based on increased acquiescence.

When it comes to the problem of substituted reliance, even the brand name "Plan B" is cleverly suggestive in the marketing sense of substitution for traditional "Plan A" methods of pregnancy reduction. However, advocates note that studies submitted to the FDA on this subject found no decrease in the use of traditional methods. Actually, what those short studies found was a tremendous increase in the use of traditional methods. Obviously, what is happening here is that researchers have failed to distinguish between the short term effects of counseling on the use of traditional methods from the impact of Plan B on the problem of substituted reliance. For by introducing a variable that will not be present in over-the-counter use, namely, counseling, researchers failed to control the variable they attempted to study. However, since literacy tests show clearly that many women fail to grasp the suggestion that Plan B should not be relied upon in place of "Plan A" methods, there can be no question that substituted reliance is a major problem with Plan B. The rate of sexually transmitted diseases experienced in Sweden is clearly a "red flag" as to what can be expected from liberalized distribution. But even the literacy studies mask the overall problem, because in many situations it is actually the male's impression that is most controlling, not the female's. For this reason, the literacy of males should also have been tested, to learn their thoughts on reliance possibilities.

In a table entitled "Pregnancy Rates for Birth Control Methods", the FDA defines "typical use" to include non-use after planned use. [Footnote 8: U.S. Food and Drug Administration. Center for Devices and Radiological Health. Uniform Contraceptive Labeling. CDRH Facts on Demand Document Shelf No. 1251. Issued July 23, 1998. Table prepared by FDA: 5/13/97, revised 9/17/98.

<http://www.fda.gov/cdrh/ode/contrlab.pdf>] Noted is that perhaps "typical reliance" would be better, since in some cases there is no actual use. Perfect use includes times of correct use and excludes times of non-use and times of incorrect use, whereas typical use includes all of these times. Non-use means couples and individuals who consider themselves users of a method may lapse in its use. Typical use rates have not been estimated for either Plan B or Preven.

Suppose every time a woman seeks Plan B her doctor administers it to her according to the prescription label and makes a house call to ensure she takes the two doses. It would be a mistake to assume this woman will necessarily experience the rate of pregnancy associated with perfect use. For example, suppose the woman lets her boyfriend skip condom use thinking she will go to the doctor the next day. But the next day she forgets about her plans. In such a case she exhibits non-use after planned use, even though on other occasions she follows through and goes to her doctor. This means her rate of pregnancy will be higher than the perfect use rate. We cannot assume prescription use necessarily implies a perfect use scenario. Instead, even prescription use can include non-use after planned use. Thus, the FDA is faulted for allowing even prescription use without an estimate of typical use rates; moreover, it is unconscionable to consider over-the-counter use without a typical use estimate.

Comments C 2044 and C 2092 of the Micro ICU Project in Vol. 300 of Docket No. 2001P-0075 have explained the exponential difference between first year pregnancy rates, known elsewhere as "first year contraceptive failure rates", versus "per act" rates of pregnancy reduction, meaning per act of intercourse. For example, the difference between an 89% per act rate and a 75% per act rate is actually a two-fold increase in terms of first year pregnancy rates; the difference between per act rates of 99% and 97% is a three-fold increase in first year rates; and the difference between per act rates of 99% and 75% is a nineteen-fold increase in first year rates. The following graph depicts this exponential relationship using the data of Table 1 in comment C 2092. As explained in comment C 2044, the form of this graph differs from Chart 1 in comment C 2092 in that the first year rate is expressed as a percentage of pregnancies reduced, on the basis of an expected rate of 85 pregnancies per 100 women in the first year of using no method.

[See original comment for figure: Pregnancy Reduction Curve]

It may be noted that the typical use rate for the withdrawal method of 27 pregnancies per 100 women in the first year of use is taken from the Alan Guttmacher Institute, which relied on a report from Fu et al. [Footnote 9: Fu, H., Darroch, J.E., Haas, T., and Ranjit, N. Contraceptive failure rates: new estimates from the 1995 National Survey of Family Growth. *Fam Plann Perspect.* 1999;31:56-63.] In contrast, Dr. James Trussell, whose work the FDA relied upon to compile its table entitled "Pregnancy Rates for Birth Control Methods", states a typical use rate of 19 pregnancies per 100 women. [Footnote 10: Trussell, J. Contraceptive efficacy. In Hatcher, R.A., Trussell, J., Stewart, F., Cates, W., Stewart, G.K., Kowal, D., and Guest, F. *Contraceptive Technology: 17th Rev. Ed.* New York, NY: Ardent Media, 1998.] Trussell's own rate for typical use of the withdrawal method is identical to the perfect use rate he and his colleagues have determined for Plan B and which the FDA relied upon. Typical use rates for Plan B will be worse than perfect use rates.

In contemplating the extent to which typical use rates will worsen compared to perfect use rates, the rate of non-use after planned use L ("L" is for lapse) and incorrect use M ("M" is for misapplication or misuse) must be considered. With relatively straightforward methods such as the condom or withdrawal

methods, it may be valid to presume that M is relatively small. This may also be the case with methods such as the diaphragm, given that patients are instructed to proficiency on correct use. In contrast, the use of a method such as Plan B is not so straightforward and therefore may involve higher rates of M, particularly in the context of over-the-counter use. This appears to have been confirmed by literacy studies and other experience. Another problem is that uneducated women with over-the-counter access may fail to propagate accurate information about use when in effect "prescribing" Plan B to ineligible younger women. Thus, in estimating the typical use rate, it is reasonable to expect that the value for M will be unusually large for the morning-after pill compared to a method like the condom.

Comment C 2092 of the Micro ICU Project in Vol. 300 of Docket No. 2001P- 0075 has considered the increasing trend of the lapse rate L associated with a comparison of pre-coital, inter-coital, and post-coital methods of pregnancy reduction. Inter-coital means the practice of the method takes place during intercourse. Noted is that the lapse rate for the withdrawal method-an inter-coital method-is roughly twice as high as that for the condom-a pre-coital method. Even without having the results from Swedish experience before us, it stands to reason that the lapse rate for a post-coital method will be even higher still, simply because behaviors after intercourse can differ widely compared to behaviors planned for before intercourse, based on a large variety of circumstances, some of which are not under individual control. Thus, in estimating the typical use rate, values for both M and L will likely be much larger for a post-coital method such as Plan B compared to values for other methods. This means Plan B's typical use rate will fall back dramatically compared to the perfect use rate, which is already on the low end of the scale.

In addition to failure to estimate the typical use rate, it appears the FDA has not fully applied the meaning of typical use. For example, it has been mistakenly reported that the high price of Plan B will inhibit reliance. On the contrary, what the high price means is that women planning to rely on Plan B will be less likely to experience actual use. One thing is reliance; another thing is the experience of use. The high price will serve to increase the typical use occurrence of non-use after planned use. Another factor concerns negative reinforcement. Since Plan B and Preven offer unpleasant side effects as well as problems of conscience, past users may be inhibited from following through on future plans of use. This highly important area has not been investigated.

In addressing the issue of safety, it is imperative to apply a coherent standard. For example, it would not be "safe" for teens to be unwittingly exposed to increases in unplanned pregnancy and sexually transmitted diseases after being misled to believe that Plan B is effective. It may be noted that FDA research on sexually transmitted diseases has been obscured by the short term effect of counseling, which not only showed an increase in the use of traditional methods, but preference for the condom. For this reason, unlike the real-life results experienced in Sweden, it is not surprising that these studies appear to indicate no increase in sexually transmitted diseases.

In addressing the issue of safety, it is imperative to apply a coherent standard. Some contend that Plan B is as safe as aspirin. But if anything is "as safe as aspirin" it must be aspirin itself. So in consideration of the drug safety issue, suppose a woman visits her doctor and says, "Sometimes I have trouble with my partner and he gives me a headache. So I decided to take 20 aspirin, followed by another 20 aspirin 12 hours later- not because I had a headache, but because I had contact with him and I was afraid I might get a headache later on." Obviously it would not be reasonable for the FDA to conclude that this practice is safe for women simply because millions of women have used aspirin safely. Yet the FDA has adopted the similar assumption that Plan B is safe simply because it believes many users of Ovrette have been largely free from safety problems. However, to review the above comparison, each tablet of Plan B contains the active progestin equivalent of 20 tablets of Ovrette-a 40 tablet total.

To review the analogy further, women are instructed to take this phenomenal dosage of progestin, not

because they know they have an impending pregnancy to avoid, but simply out of fear that a possible pregnancy might be on their horizon after contact with their partners. Comment C 2053 of the Micro ICU Project in Vol. 300 of Docket No. 2001P-0075 examines the inefficiency of this practice, and Comment 2092 of the same docket elaborates on it further. In a nutshell, with perfect use limited to the two mid-cycle weeks, 93% of the time a woman will take Plan B for nothing. Looked at another way, with perfect use limited to the two mid-cycle weeks, for every 14 times women take Plan B, one pregnancy will have been reduced. This does not mean one pregnancy in net; it simply means to reduce a single pregnancy at all. By comparison this total represents the progestin equivalent of taking 1-1/2 years worth of Ovrette. Outside the two mid-cycle weeks, when fertility is greatly decreased, the figure of inefficiency will be even higher still, and the sky is the limit regarding women who are infertile to begin with. With typical use, the inefficiency will climb even further due to misapplication or misuse. Despite this phenomenal use of progestin, net pregnancy rates will actually increase due to the typical use ineffectiveness of the regimen under liberalized distribution.

Notably, AMA Resolution 443 (A-04) begins by saying that widespread use of the morning-after pill could reduce 1.7 million unplanned pregnancies in the United States annually. According to the Alan Guttmacher Institute, there are about three million unintended pregnancies in the U.S. annually. So reducing 1.7 million unplanned pregnancies would mean a 57% annual reduction. But even with perfect use of Preven, assuming no increase in coitivity or acquiescence, only 55% of pregnancies would be reduced annually—a very low value compared to perfect or even typical use of other methods. In other words, even if the definition of "widespread use" meant that all women who are not planning to get pregnant will make perfect use of Preven after every act of intercourse in addition to their usual methods, with absolutely no increase in coitivity or acquiescence, the AMA's expectations still would not be fulfilled!

Instead, as has been evidenced in Sweden, something along the lines of the complete opposite happens. Women do not use the morning-after pill in addition to their usual methods, they substitute it for their usual methods. Instead of making perfect use, they exhibit non-use after planned use in a typical use scenario. Also, the rates of coitivity and acquiescence increase. And so with liberalized distribution the predictable result is an epidemic of unplanned pregnancies, with no net reduction in unplanned pregnancies at all. So clearly the members of the AMA House of Delegates did not make a credible analysis of the morning-after pill in offering us their consensus.

The bias physicians have for presuming the effectiveness of pills predates the double-blind study. Indeed, it is with great irony that the logic of the double-blind study still escapes the medical community even today. For example, a research director at a psychiatric medical association, responding to researcher claims that antidepressants do not work, was recently quoted in the news as saying, "The interesting issue is that it is now medical malpractice not to treat major depression with medication. If in fact there were nonsignificant differences (between antidepressants and placebo), that would not be the standard of care." [Footnote 11: Reuters Health, "Antidepressant Efficacy May Be Overblown -Experts", by Karla Gale. Jul. 15, 2005 (correction Jul. 19, 2005).] But contrary to this assumption, if a trial medication can be distinguished from a placebo based on its spectrum of side effects, doctors may single out the trial medication and apply the biased presumption that the pill works.

Identifying positive results for a trial medication as often as a placebo signals problems in a study of its effects on a condition unlikely to improve spontaneously. But logically the reverse is not true: Choosing a trial medication over the placebo does not imply it works! For example, doctors may have been alerted to the trial medication's identity based on the side effects it produces; in turn they may have associated positive results with it, due purely to their biased belief that the "real" pill works.

A breed of psychotropic drugs has capitalized on this design flaw in drug tests, which allows various

useless drugs to pass their clinical trials. These psychotropics have withdrawal patterns, the symptoms of which are relieved by re-administering the drug. Mental illnesses, anxiety disorders, and learning difficulties have been targets because the symptoms of withdrawal mimic the disorder under treatment. Unaware that this is the case, doctors, patients, and their families may become loyal to the drug once they witness its apparent power to relieve symptoms. In other words, it appears to them that the drug is relieving symptoms of the disorder under treatment, when really it is relieving symptoms caused by an attempt to withdraw from the drug. This side note underscores the need for the medical community to review its undisciplined infatuation with pills.

No doubt, many a young man would be infatuated with the notion that science had somehow created the chemical equivalent of the "undo" button on your computer in pill form-and that it sends the stork packing back to the cabbage patch, with no pregnancy or abortion to worry about. Two weeks away from his high school graduation, a young man with right-wing roots responded with a gleam in his eye to let it be known where even he departs from traditional conservatives, saying, "But the morning-after pill--I think that's a really good thing." It did not take much to remember what it was like to be 18 years old, nor did it take much to realize that the morning-after pill is poised to create an epidemic of unplanned pregnancies. More so than any data on the morning- after pill, the gleam in his eye provided the best tip on the epidemic to come.

The infatuation with pills is so strong in our medical community that it may be virtually impossible, psychologically, to break the biased belief that the pills work very well and that a whole consensus of experts has already validated them. [Footnote 12: If one reviews *Sell v. United States*, 539 US 166 (2003) it is evident that our legal system has had such an infatuation with pills and those who prescribe them that one may even be forced to take them.] So to get the point across concerning the dangerous ineffectiveness of Plan B in a liberalized scenario, it may be necessary to use a different example of a post-coital method-namely, one that does not involve any kind of pill. For example, Casanova's lovers are reported to have used a lemon juice douche post-coitally to reduce pregnancy.

In general, if people have intercourse independently of their knowledge of a given method or its availability (i.e., knowledge of the method does not increase coitivity or acquiescence), then the use of the method will-under controlled circumstances-serve to reduce some amount of pregnancy compared to using nothing at all. The slight of hand played on the mind in considering a post-coital method is that the notion that intercourse has already occurred creates a sense of comparison to using nothing at all. For example, if a woman experiences condom breakage, and then she uses a lemon juice douche in response to the problem, some might conclude, "It's better than nothing at all." But what happens when the method, like the morning-after pill, is ineffective compared to other methods on the totem pole? And what happens if the method is advertised like something really great-something that even Casanova would use?

What happens is that when the boy forgets his condom, and the girl does not want to give him a hard time, she will think it is okay just to use "that lemon juice thing" after sex. In pill form, this is what happened in Sweden. Teens started relying on "that morning-after pill thing". They thought it was something great that doctors and scientists had recently invented to keep them from getting pregnant. Instead, they ended up with an epidemic increase in unplanned teen pregnancies and sexually transmitted diseases.

If one is not to be terribly naive it must be admitted that there are those among us who reap their fortunes of social, political, and financial currency based on women's dependency on abortion. Looked at from a business perspective, the most significant statistic relating to the abortion industry is the annual number of abortions. According to the Centers for Disease Control and Prevention (CDC), "Overall, the annual number of legal induced abortions in the United States increased gradually from 1973 until it peaked in 1990, and it generally declined thereafter." [Footnote 13: Strauss, L.T., Herndon, J., Chang, J., Parker,

W.Y., Levy, D.A., Bowens, S.B., Zane, S.B., and Berg, C.J.; CDC. Abortion surveillance-United States, 2001. MMWR Surveill Summ. 2004;53: 1-32.] As one can imagine it would for any business, a downward trend in abortion may have sounded the alarm for those whose very fortunes rely on the dependency women have on abortions. This consideration may provide insight into what otherwise might seem like a puzzling contradiction.

Namely, reproductive choice advocates like Planned Parenthood waited until 1994-amid declining abortion rates-to push for urgent FDA backing of the morning- after pill, as if America's best kept secret. But the "secret" was known since the 1960s. So if reducing unplanned pregnancies was truly their aim, and they truly believed the morning-after pill would have this effect, why didn't they push for it back when abortion rates were increasing? But on the other hand, if they knew the morning-after pill would actually increase abortion rates like it did in Sweden, this might solve the puzzle, For if they knew deploying the morning-after pill would actually reverse falling abortion rates, this might explain why the abortion industry's support for it is now so adamant.

A recent news story attributed to Jim Sedlak, director of STOPP International, a group that monitors Planned Parenthood, alleges that documents made public in a court trial have revealed a "sweetheart deal" between Planned Parenthood Federation of America, Inc. (PPFA) and Barr Laboratories (Barr). The story reads: [Footnote 14: Lifenews.com, "Planned Parenthood Turns Sweetheart Deal on Morning After Pill Sales", by Jim Sedlak. Aug. 24, 2005. <http://www.lifenews.com/nat1563.html>]

One of the documents is a February 9, 2004 e-mail from the PPFA vice president of medical affairs, Vanessa Cullins, M.D., to all Planned Parenthood affiliate CEOs. The executives were told that Planned Parenthood was "in the midst of confidential discussions" with Barr and that Planned Parenthood's "immediate interest is to develop and protect our market base."

According to Sedlak's allegations, Barr Laboratories agreed to sell Plan B to Planned Parenthood at \$0.25 less than the \$4.50 price given to the public sector. The average sale price, Sedlak noted, was \$25 at Planned Parenthood clinics-hardly a "sweetheart deal" for women seeking help to reduce unplanned pregnancy.

No doubt, maintaining women's dependency on abortion would indeed protect the "market base" of the abortion industry. But it would be unwise to allow the abortion industry to "develop" this market base by promoting a method of pregnancy reduction that with liberalized distribution will have the unwitting effect of actually increasing abortion rates, and to allow the abortion industry to profit additionally by selling women the very pills that in effect make the dog chase its own tail, as in Sweden.

Presumably Barr Laboratories realized that the liabilities of the two morning-after pill regimens would be more easily exposed, by comparison of the differences in their ineffectiveness for liberalized distribution, if Preven, the more ineffective of the two, were allowed to stay on the U.S. market. This would explain the product's removal from the U.S. market, even despite the support Preven received from authorities such as the AMA House of Delegates. The remaining question is whether Barr Laboratories felt it could somehow gain protection from the liabilities associated with Plan B by maintaining a "sweetheart" relationship with the powerful abortion industry lobby.

The FDA should be cautioned to reflect that unlike real medical procedures, it is not mandatory to report abortions to the CDC. Voluntary reporting to the CDC is largely under the control of the abortion industry. Although the CDC has enumerated the importance to public health of accurate reporting of abortions, the reliability and completeness of voluntary reporting has been limited. Additionally, CDC reports on abortion surveillance become available only several years after the year for which the data has

been collected. Consequently, this means that the FDA would have to wait years before assessing the impact of Plan B on abortion rates. Because abortion rates are notoriously subject to underreporting in this country, it is plausible to believe that the rates may even be tampered with to mask the true impact of Plan B. Alarming, California, the nation's most populous state, and one of the states that decided to abandon the FDA's drug evaluation process by instituting over-the-counter access on its own to Plan B for girls and women of all ages, does not even report abortions at all. Similarly, teen pregnancies are only casually monitored in this country. Thus, the FDA's real ability to assess Plan B's effect on pregnancy and abortion will be badly limited.

Comments C 2044 and C 2092 of the Micro ICU Project in Vol. 300 of Docket No. 2001P-0075 underscore the statistical reasons why post-coital methods, being subject to a large lapse rate L, are contraindicated for popularization in a typical use scenario, no matter how effective they may be with perfect use. So when someone says, "The condom broke," we must have the discipline not to fall prey to the presumption that a post-coital approach to the problem should be liberally popularized. Instead, looking ahead, a pre-coital discipline should always be emphasized. This might include engineering better standards for condoms. It also means teaching people that the technology best suited for those who wish to completely separate sex and responsibility is abstinence.

Because it will be administered in a controlled setting, a method of preventing fertilization post-coitally would be desirable for rape victims, provided the method does not have a concepticidal component. Concepticide is the taking of the life of a conceptus. Methods with a concepticidal component would be especially problematic for women who have been actively seeking pregnancy, because the method would be more likely to harm a child conceived by her partner than by the offender. In cases where conception by rape does occur, and the victim is unable to continue her pregnancy, the technology is now feasible to 1) detect and locate the conceptus prior to implantation, 2) separate him or her from the victim, 3) transfer the conceptus to an incubator (micro ICU), and 4) transfer her or him to an adoptive or surrogate mother within the timeframe associated with pre-implantation events. Importantly, this separation procedure is medically distinct from an abortion in which no effort is made to preserve the life of the child.

If preventing fertilization post-coitally would be desirable for rape victims, why not for women with other reasons? The tough answer is that life is not based on what is desirable. You have to take real life into account. In the case of rape, use of a post-coital method would satisfy the condition that the act of intercourse took place independently of knowledge of the method. Without this condition being satisfied, women will substitute the post-coital method for other methods, and sometimes they will not even follow through on their plans of reliance. The former problem is of special importance when the post-coital method is inferior to the other methods. The latter problem will be true of any post-coital mechanism that is not permanently in place or otherwise independent of the woman's actions. It takes discipline to account for these factors. Like sex, life is not always based on what is desirable; instead you have to take practical considerations into account. Otherwise, you will end up with a tragedy like Sweden did.

When people dream unrealistic figures it is good to take out a calculator and do a quick reality check. For example, did Barr Laboratories ever tell the FDA it has plans to sell in excess of 23.8 million units of Plan B per year? At minimum, 14 units of Plan B will be taken on average for every one pregnancy reduced. So to fulfill the AMA's morning-after pill fantasy of reducing 1.7 million pregnancies annually, it would take no less than 23.8 million units. At \$25 per unit, this would put revenues for Plan B at \$595 million per year, with Planned Parenthood taking a piece of the cake. Recall also that this lavish expenditure to reduce pregnancies will not reduce pregnancies in net, since in net liberalized access to the morning-after pill serves to increase pregnancies. Instead, it simply means that to reduce 1.7 million pregnancies, on an individual basis, it would take 23.8 million units of Plan B at absolute minimum.

The figure of 14 units of Plan B per pregnancy reduced is determined by first multiplying the odds of

pregnancy (0.08) by the fraction of them reduced (0.89) per use of Plan B, which gives the odds of actual pregnancy reduction per use, and then taking the reciprocal. This minimum figure is based on the unrealistic assumption that all women will make perfect use of Plan B during the two mid-cycle weeks and will not combine it with other methods that have some effect. Otherwise, the likelihood that an instance of use will actually have the effect of reducing a pregnancy will be less, because the odds of pregnancy are less at other times of the cycle as well as when women are simultaneously using other methods that have some effectiveness.

In a subtle way, Plan B's prescription label actually serves to mask the overall rate at which women will be taking the drug for nothing. To be clear, "for nothing" means times of taking Plan B when either they would not have gotten pregnant anyway, or when Plan B does not reduce a pregnancy anyway because they ended up with one even despite taking the drug. The label is faulted for masking the problem of the overall rate at which women will be using the drug for nothing because it quotes a value for natural pregnancy expectation of 8% that is only valid during the two mid-cycle weeks, when pregnancy expectation is highest. But the label does not limit the indications of use to specific weeks of the cycle. Yet women who take Plan B during the infertile portions of their cycles, like women who are infertile, will always be taking it for nothing.

According to MedlinePlus drug information, a service of the U.S. National Library of Medicine and the National Institutes of Health, "Combined estrogen and progestin oral contraceptives may increase the risk of getting breast cancer, endometrial cancer, and liver tumors. It is not known whether progestin-only oral contraceptives also increase the risks of these conditions." [Footnote 15: "Progestin-only oral contraceptives" <http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a602008.html>] Recalling that one unit of Plan B contains the active progestin equivalent of a 40-day supply of Ovrette—an enormously large dosage—one seriously questions the epidemiological impact that taking Plan B may have on women's risk of getting cancer. Especially alarming is that women will be taking Plan B for nothing at such a high rate, and that Plan B's net effect of increasing unplanned pregnancies with liberal access will be counterproductive to begin with.

Unfortunately, the medical community behaves in an odd way when it comes to an evaluation of the health effects of matters that implicate concepticide. For example, the unqualified claim persists that abortions are safer for women than birth. The claim is unqualified because it does nothing to rule out the possibility that abortions, whatever their risks, present a compounding risk factor. Women who have abortions do so predominately before they complete their lifetime number of births. For this reason, abortions may largely tend to forestall the completion of a woman's desired birth pattern, thereby subjecting her to added risks by enabling her to balk at the child-bearing process via abortion. In other words, abortion risks may largely be additive.

Another example concerns evaluation of the impact abortion has on breast cancer. For example, contrary to general assumption, the famous study of Melbye et al. did not eliminate recall bias, because the study failed to "recall" abortions for some of the older women. [Footnote 16: Melbye, M., Wohlfahrt, J., Olsen, J.H., Frisch, M., Westergaard, T., Helweg-Larsen, K., and Andersen, P.K. Induced abortion and the risk of breast cancer. *N Engl J Med.* 1997;336:81-85.] In other words, as far as figures go, the numbers do not care who is failing to do the recalling, whether it is the researchers or the women under study. This makes it seem all the more amazing that the study managed to pull a one-point-zero-zero figure for relative risk out of its hat. Analysis of the range of uncertainties associated with crude and adjusted figures also suggests that the latter's range is too narrow to have undergone proper error propagation in adjusting the former's value of 1.44. [Footnote 17: Brind et al. state the value of the crude figure but not the corresponding range of uncertainty. In response Melbye et al. manage to give a partially adjusted figure with an upper range that is narrower (in parts per million) than that of the corresponding crude figure on which it is based! Brind, J., Chinchilli, V. M., Senghas, R. E., Dolan, M. F., Melbye, M., Wohlfahrt, J.,

and Andersen, P. K. Induced abortion and the risk of breast cancer. *N Engl J Med.* 1997;336:1834-1835.] Yet as with support for Plan B, we are told everything has been validated by an expert consensus.

Evidently some element of reform is needed in our medical community, which seems to be living in a time warp. Even new medical students are not receiving the most up-to-date education. For example, despite being introduced by the Medical Students Section, AMA House of Delegates Resolution 443 (A-04) makes reference to "ovum implantation", underscoring the problem that even our new students of medicine are not being familiarized with the fact that ovum implantation is known to be a complete myth. Instead, human babies must literally hatch from their eggs before implantation.

Of medical concern, Plan B may have a concepticidal ("conceptus-killing") component, particularly during the pre-implantation stages of life. These stages include what are properly known as the embryo and hatchling stages. As shown in the photo below, the transition between embryo and hatchling stages occurs at hatching time, taking place about 5-6 days after fertilization. The baby below is hatching in the two o'clock direction through a hole in the eggshell. The baby's body is surrounded by a fluid-filled precursor of the birth sac in primordial form, which serves as a protective spacesuit. Despite the ignorance of our medical profession, these babies hatching are every bit as important as the ones you see crawling across the floor.

[See original comment for figure: A Human Baby Hatching]

Because of the problem of concepticide, legality presents a consideration regarding over-the-counter status for Plan B. Notably the definitions of "pregnancy" and "abortion" used in Dorland's Illustrated Medical Dictionary are broad enough to include the conceptus during the pre-implantation stages of gestational life. Although some authorities may beg to differ with these definitions, it appears nonetheless that the U.S. Supreme Court has traditionally relied upon Dorland's. In *Roe v. Wade*, 410 U.S. 113 (1973), the Supreme Court made expressly clear that a woman may neither decide nor effectuate an abortion on her own; instead, as stressed in *Roe*, "the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician." 410 U.S., at 164. Yet based on its concepticidal potential, over-the-counter distribution of Plan B would violate that ruling by enabling a woman to decide and effectuate an abortion herself. Similarly, section 503(b)(1)(A) of the Federal Food, Drug, and Cosmetic act does not limit the concerns of a drug's "toxicity or other potentiality for harmful effect" to the woman herself, thus providing further indication that unsupervised use of Plan B is strictly illegal based on the adverse implications the drug may have for her conceptus.

As a technology, if Plan B did not have a concepticidal component, but instead only prevented fertilization, an application for over-the-counter status would still face the broad standards of inquiry posed by the Commissioner's notable questions. But Plan B presents additional legal complexities based on its concepticidal potential. For it would be unprecedented for the FDA to enable a woman to decide and effectuate her own abortion, in any form, apart from the medical judgment of an attending physician. For example, birth control pills and intrauterine devices, which some believe may have a concepticidal component, require an attending physician because they are only available as prescription products. Notably, all concepticidal products would be banned outright if the Government were to protect the person by outlawing concepticide altogether.

From the photo on the previous page, it is clear that hatching is a very intelligent human behavior, and one that defies the traditional neurological paradigm. Instead, we have to think of brain power based on molecular computing inside the cells, and that the neurons formed later represent specific interconnects. Understandably, many users of Plan B would be shocked to learn that they may have caused the demise of an intelligent human baby engaged in behaviors such as hatching prior to implantation.

Early pregnancy tests are evolving to detect conception prior to implantation. However, apart from an early pregnancy test, there will be uncertainty as to whether or not a given use of Plan B prevented fertilization, destroyed a conceptus, or was taken for nothing due to infertility at the time of use. From an emotional and psychological perspective, uncertainty about the possible destruction of a conceptus may present cause for morbidity. Consequently, states require abortion providers to perform a pregnancy test in advance of an abortion. But with Plan B this compliance will generally be lacking, particularly with over-the-counter use. In this regard, the FDA has an obligation to research and consider the facts thoroughly in an effort to protect a woman's conscience from serious harm. Though some would keep women in the dark under the pretense of protecting them, the potential for awareness about the lives of pre-implantation infants is rapidly evolving thanks to medical programs like the Micro ICU Project.

Obviously the application to liberalize access to Plan B should be denied. But most of all, the FDA should evaluate the concepticidal potential of its regulated products and reject their approval accordingly.

Sincerely,

Mr. Eurica California, Amb.
Juridic Embassy, Micro ICU Project

ATTACHMENT:

Dockets Management Branch HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Dockets Management Branch Food and Drug Administration

Re: Docket No. 2005N-0345

I am infuriated that the Food and Drug Administration (FDA) has refused to make Plan B emergency contraception available over the counter. The latest delay is an unnecessary road block in what should have been a clear path to FDA approval of the Plan B application. An unprecedented medical and scientific consensus - both inside and outside the FDA - shows that women of all ages can use Plan B emergency contraception (EC) safely and effectively without a prescription.

The FDA continues to use the unfounded and specious argument that Plan B would promote promiscuity among teenage girls. The FDA's job is to judge the safety and efficacy of drugs rather than impugn the morality of people who use them. The FDA has a legal obligation to act on the scientific evidence and promote public health. There is absolutely no justification for denying women over-the-counter access to this safe and effective method of contraception

Contraceptive use has led to dramatic declines in maternal and infant mortality rates and has been the driving force in reducing national rates of STDs, unintended pregnancy and abortion. However, America isn't where it should be in guaranteeing access to contraception. The U.S. continues to have the highest rate of unintended pregnancy In the industrialized world - almost half of all pregnancies are unintended and half of those end in abortion.

Emergency contraception (EC) is an effective way to prevent unintended pregnancy after unprotected sex

or a contraceptive failure. Widespread use could prevent as many as half of the three million unintended pregnancies each year, including as many as 700,000 that now end in abortion. However, speed is most important in maximizing the effectiveness of EC which is why over-the-counter access is so critical. If taken within 72 hours of intercourse, EC can reduce the risk of pregnancy by as much as 89 percent and efficacy is greatest if the drug is taken within 24 hours. The American College of Obstetricians and Gynecologists (ACOG) noted that the need to obtain a prescription from a doctor is one of the biggest barriers to EC use.

By endlessly delaying a decision on Plan B, the FDA is failing to be part of public health effort to reduce our nation's staggering rates of unintended pregnancy I strongly urge the FDA to approve the application to make Plan B available over-the counter without further delay.

COMMENT NUMBER - 2005N-0345-C54

2005N-0345-C54 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: LaChance, Robin

2005N-0345-C54 - TEXT

September 30, 2005

Food and Drug Administration, HHS
Division of Dockets Management
Docket No. 2005N-0345
RIN No. 0910-AF72
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To whom it may concern:

We object to the over-the-counter sale of Plan B for the following reasons:

<1: 1.2.3>Plan B is a powerful hormonal drug that can prevent a developing embryo from attaching to the uterine wall, causing an early abortion.

Plan B has not been tested for its effects on under-age girls. If the FDA approves the drug for over-the-counter sale, 16- and 17-year-old teenage girls will be able to purchase it without a prescription and without the knowledge or consent of their parents. </1: 1.2.3>

<2: 7.5.3>Girls under 18 who are sexually active are often victimized by predatory adult (over 18) males. Allowing over-the-counter sale of "Plan B" would allow men to procure the drug with the intention of using it to ensure that their victims, willing or not, never show the consequences of their behavior. Remember, sexual activity on the part of an adult with a minor is statutory rape. In that case, "Plan B" conceals the crime. </2: 7.5.3>

<3: 1.2.3>"Plan B" gives a false sense of security while leaving a young girl or woman open to the transmission of sexually transmitted diseases including HIV. Between the years 1995 when Plan B became available over-the-counter in Great Britain, and 2000, diagnosis of genital Chlamydia went up 77%, gonorrhea by 57%, and syphilis by 56%, according to the British Health Service. (Paul Caprio, Family- PAC Federal - 9/9/05)

"Plan B," according to the website of its manufacturer Barr Labs, "may inhibit implantation by altering the endometrium. " In other words, "Plan B" can work to abort a developing human baby by preventing him from attaching to the wall of the uterus. Plan B kills.

I urge the FDA to NOT approve the sale of the Morning after pill (Plan B) (without a prescription) to girls 16-years-old and above. </3: 1.2.3>

Sincerely,

Robin L. LaChance
2825 Lexington Rd. SBTS 80-388
Louisville, KY 40280

COMMENT NUMBER - 2005N-0345-C61

2005N-0345-C61 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Family Planning Advocates of New York State

2005N-0345-C61 - TEXT

Family Planning Advocates of NYS
17 Elk Street
Albany, New York 12207-1 002
Phone: (518) 436-8408
Fax: (518) 436-0004
Website: www.fpaofnys.org

October 7, 2005

Food and Drug Administration, HHS
Division of Dockers Management
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: RIN 0910-AF72
Docket No. 2005N-0345

Dear Acting Commissioner von Eschenbach;

Family Planning Advocates (FPA) is a nonprofit organization that represents family planning providers in New York State, including the state's thirteen Planned Parenthood affiliates. As an organization, we are committed to the goal of reducing the rate of unintended pregnancy in New York State. Increasing access to emergency contraception (EC) is important to achieving that goal, and we therefore support making Plan B an over the counter medication for women of all ages.

<1: 3.2, 4.2, 5.2>In response to the questions posed in RIN 0910-AF72, FPA believes the first three questions (1A, 1B and 1C) should be answered in the negative, making it unnecessary to address the remaining questions. We do not believe there is any confusion over the interpretation of section 503 of the Federal Food, Drug, and Cosmetic Act.</1: 3.2, 4.2, 5.2> <2: 2.3>We feel it is clear that the delays in approving the application to classify Plan B as an over the counter medication, and request for information these comments address, are the result of inappropriate political interference as opposed to "significant confusion" over section 503's interpretation. The questions over how to label, market and enforce an age-restricted medication are the end result of a process that has allowed politics and ideology to interfere with decisions that should be based on medical fact and reason. </2: 2.3>

<3: 3.2>The mission of the FDA is to protect "the public health by assuring the safety, efficacy, and security of human and veterinary drugs. . .," not to pander to politically motivated opposition where objections have no grounding in medical or scientific research. Because the questions posed in the Request for Information are not the result of medically supportable facts that necessitate placing age restrictions on the medication's USC, it is simply inappropriate for the questions to be considered in conjunction with the FDA's consideration of the Plan B application. We do not support initiating a rule-making process in relation to Plan B. </3: 3.2>

<4: 3.5.2>EC approval process diverges from FDA mission

We are concerned that the FDA has diverged from its role of determining whether a medication that is the subject of an application seeking exemption from prescription-dispensing requirements, is "safe and effective for use in self-medication . . .," [Footnote 1: 21 C.F.R. §310.200(b).] FPA has watched with dismay as politics has interfered with the application to make Plan B available as an over the counter medication. Despite the recommendation of two FDA advisory committees that the application be approved, the application was denied. Similarly, the pending application has now been deferred for reasons that have no grounding in science.

It is not the role of the FDA to limit access to a medication because some factions of society are morally opposed to its use. If limiting access to a medication, which has been shown to be safe and effective, is not necessary to protect public health, then it should be exempted from prescription-dispensing requirements. [Footnote 2: See 21 C.F.R. § 310.200(b).] The FDA exists to protect public health by making evidence-based decisions; on drug safety; the agency should not allow political agendas to substitute for science in making health decisions. </4: 3.5.2>

<5: 1.2.1>Evidence shows EC is suitable for OTC use

The FDA has received substantial documentation that offers clear and convincing evidence that EC is a safe and effective drug suitable For self-medication.

Overwhelming evidence shows chat EC is a safe and effective medication whose benefits are best realized by removing unnecessary barriers to access. This evidence has caused the American Medical Association and the American College of Obstetricians and Gynecologists to support making EC an over the counter medication. This support would not have been forthcoming if there were valid evidence showing it would be inadvisable or dangerous to public health if EC could be obtained without a doctor's

prescription. </5: 1.2.1>

<6: 1.2.1, 10>EC benefits

Unintended pregnancy is a public health issue that has long-ranging health impacts. Women with unintended pregnancy forego the opportunity to receive pre-conception counseling to improve the health of the fetus and are more likely to have low birth weight babies and experience a higher rate of neonatal mortality. [Footnote 3: R, Bonoan and J. Gonen, "Promoting Healthy Pregnancies; Counseling and Contraception as the First Step," Washington Business Group on Health, August 2000.]

Increasing access to emergency contraception would play a significant role in reducing the incidence of unintended pregnancy—a goal that would not only serve to improve the health of women and children, but would also save money for state, federal and private insurance plans who must bear the costs of health problems related to unintended pregnancy. A study published by New York State Comptroller Alan Hevesi found that increasing access to EC, including making it available over the counter, would result in 122,000 fewer unintended pregnancies and 82,000 fewer abortions every year in New York. [Footnote 4: New York State Office of the State Comptroller, "Emergency Contraception in New York State; Fewer Unintended Pregnancies and Lower Health Care Costs," November 2003.] The study projected that Medicaid costs would be cut by \$254 million a year, and private insurers would save nearly \$200 million.

Making EC available over the counter would enable women to obtain the medication in a timely manner. EC is a time-sensitive medication that is most effective the sooner it is taken after unprotected intercourse. Making the medication available over the counter will enhance women's ability to prevent unintended pregnancy by allowing them to obtain the medication when it has the greatest potential for effectiveness. </6: 1.2.1, 10>

<7: 1.2.1, 10>Use of EC by teens

Although concern about 'the use of EC by teens has been stated as the reason for denying the original application and then delaying a final decision on the application to make Plan B available to women aged 16 and over, widespread support among mainstream medical organizations for making emergency contraception available over the counter makes that assertion untenable. [Footnote 5: We note that the most recent decision to defer a final decision on Barr Labs' application contained a reference to making the medication available to women aged 17 and over, however, the application was for women aged 16 and over.] Claims by EC opponents that easier access to EC will cause teens to engage in increased or unprotected sexual activity are not supported by evidence-based studies.

Medical research shows that enhanced access to emergency contraception does not lead to increased rates of unprotected intercourse or pose a risk to minors. A study published in the January 5, 2005 edition of JAMA found that women with enhanced access to EC are no more likely to engage in unprotected sex or abandon use of other contraception methods than women who do not have easy access to the pills. [Footnote 6: Raine TR et al. (2005) Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs. Journal of the American Medical Association, 293(1):54-62.] The article's findings are based on a study of over 2000 sexually active women aged 15-24. A similar study also found that increased access to emergency contraception did not cause minors to engage in unprotected intercourse. [Footnote 7: See, Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraceptive on adolescent women's sexual and contraceptive behaviors. J Pediatr Adolesc Gynecol. 2004;17:87-96.]

In addition, the American Academy of Pediatrics (AAP) is supportive of increasing the availability of emergency contraception, including over the counter access for teens. [Footnote 8: See, American

Academy of Pediatrics Policy Statement on Emergency Contraception, Pediatrics 2005; 116:1038-1047.] In its position paper on emergency contraception, AAP states, "An increase in awareness and availability of emergency contraception to teens does not change reported rates of sexual activity or increase the frequency of unprotected intercourse among adolescents." [Footnote 9: American Academy of Pediatrics Policy Statement on Emergency Contraception, Pediatrics 2005; 116:1038-1047.] This medical support should dispel any myths that the medication is somehow dangerous to a minor's health. </7: 1.2.1, 10>

<8: 1.2.1, 2.3>Conclusion

Because there is no scientific basis for restricting access to teens, it would be inappropriate to consider the questions posed in the Request for Information in conjunction with the application to approve Plan B as an over the counter medication. In the interest of women's health and the application of scientific data, we strongly believe the pending application to allow Plan B to be sold over the counter should be approved without any age restrictions,</8: 1.2.1, 2.3>

Sincerely,

JoAnna M. Smith
President and CEO
Family Planning Advocates of New York State

COMMENT NUMBER - 2005N-0345-C71

2005N-0345-C71 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Ruckdeschel, Diana

2005N-0345-C71 - TEXT

I would like to share some serious concerns I have with regard to making the morning after pill available without a prescription. Please take the following items into consideration: With regard to requiring a prescription for those under 16 only, I worry about some very real possibilities and even probabilities that need to be addressed. Please consider the following seven areas of concern.

<1: 1.2.3>a. What about turning 16 eliminates the need for a prescription? There have not been enough tests showing the absolute safety of the drug for anyone, especially after repeated use. It would not be a smart precedent to establish that prescription medication can be dispensed *without medical consent because of age. This will open the flood gates for law suits on all kinds of drugs because people will say, "I am old enough to decide what medications I want regardless of medical implications." You only have to living and breathing in America to see those lawsuits on the horizon. </1: 1.2.3>

<2: 7.5.3>b. How can we be sure an older friend will not purchase the drug and give it to a minor? How can we know there will not be an older boyfriend (as is often the case) who purchases the drug for a minor girlfriend? What's worse, once a boyfriend has the drug in his hands, the pressure for a young girl to take it can be absolutely overwhelming to her. Mark my words, there will be young girls who take it because they are pressured by their boyfriends who will have serious regrets, There will undoubtedly be

girls who take it against their own true wishes and against their own better judgment. Can this be prevented by allowing only females to purchase the drug?...Not unless the FDA wants a sexual discrimination lawsuit on its hands. </2: 7.5.3>

<3: 1.2.3>c. What about sexual predators who purchase it and force women and girls to take it? What about men who will use it in conjunction with the date rape drug to eliminate the consequences of potential child support bills? As tragic as the whole issue of rape is, we need to consider the fact that terminating a pregnancy is not in itself a solution to the problem. There are women who, even if raped, would not chose to terminate their pregnancies. I can say with all sincerity that even under those terrible conditions, if I were raped, my grief would only be compounded immeasurably by the fact that a new life who was dependent on me were taken without my consent. </3: 1.2.3>

<4: 1.2.3>d. We know that some will chose to rely an it as a form of birth control, considering every sexual encounter to be an "emergency" because it will inevitably cause a decline in responsibility with other forms of birth control, Some, especially young girls, will rely on this and discontinue using condoms, because of this back-up plan, thereby eliminating what little protection condoms can offer. What do we know about the effects of repeated use on women's reproductive abilities? What do we know about the effects of repeated use on the heart? What do we know about the effects of repeated use on all bodily systems? Excessive use could be curtailed by medical intervention. </4: 1.2.3>

<5: 8.6.2>e. Using different packaging would not be helpful at all. In all practicality, what it will do is give the medically illiterate the impression that there are two different drugs, and obviously the OTC version is safer as it does not require a prescription. </5: 8.6.2>

<6: 3.8.8>f. With regard to the FDA defining a regulation to allow for drugs to be available with and without a prescription....bad idea because of the precedent it will set. Consumers will want that option available for every drug. They will want it because of criteria other than age. Through lawsuits and judicial action, consumers will slowly start to interfere with the FDA's ability to do its job without "checking inn with the public. It will also undermine the FDA's credibility and authority..."Can't the FDA decide for itself?" "Is this drug safe for OTC use or not?...It either is or it isn't!" "Can't they make up their minds?" </6: 3.8.8>

<7: 6.5.4>g. Additionally girls, under 18 are still minors. 16 and 17 year old girls should still have their parents included on major medical decisions. The 14th Amendment's Right to Privacy is clearly inclusive of parental tights to parent their children which includes intervention in medical areas. For this very reason schools and day cares are not allowed to administer Tylenol without notifying and receiving permission from parents. Making this available to minors is a violation of the 14th Amendment where parents are concerned. </7: 6.5.4>

Diana Ruckdeschel

COMMENT NUMBER - 2005N-0345-C83

2005N-0345-C83 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Alterton, Faith

2005N-0345-C83 - TEXT

October 10, 2005

Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Dear Sir or Madam:

I am a registered nurse with emergency room experience and am concerned that the Food and Drug Administration is considering making RU-486 also known as Plan B or "the morning after pill" available to the public with out a medical doctor's prescription or supervision, Docket Number 2005N-0345 or Regulatory Information Number (RIN) 091 0-AF72. I would like to respond to the FDA's request for public comment regarding this upcoming decision.

The FDA has asked for comment on three issues:

1. Should the FDA create and define a regulation to allow for a drug to be available both with a prescription and without?

<1: 3.2>NO.</1: 3.2> <2: 1.2.3, 7.5.3>Limiting unsupervised access to Plan B to a certain population based on age would NOT be an effective way to stop underage adolescents from getting the drug. It would be far too easy for an older person to purchase Plan B for a minor. Furthermore, I have serious concerns whether Plan B should be marketed and prescribed to adolescent females at all. There is very little research on long-term effects of this drug on adolescent patients, and particularly with those who take it repeatedly for birth-control. Plan B is meant to be an "emergency" birth control only, and from personal experience, I find that many patients view it as something to be used multiple times. These patients often do not understand how Plan B actually works, only that it "takes care" of an unwanted pregnancy. If most patients do not even retain information explained with a prescription, the public would be greatly at risk if offered the same drug without a doctor's advice or guidance The FDA should NOT create or define a regulation allowing Plan B to be available both with a prescription and without. </2: 1.2.3, 7.5.3>

2. Does the FDA have the authority or ability to enforce restricting a drug from a subpopulation when it would be available to the larger population?

<3: 6.2, 7.2>NO.</3: 6.2, 7.2> <4: 7.5.3>The FDA would not have the authority or ability to restrict a drug from one subpopulation while making it available to another. Plan B might be available for SALE without a prescription to only a certain subpopulation, but enforcing who actually takes the drug would be impossible. It would be very easy for an 18 year old to purchase the drug herself and then give it directly to a minor. ALL patients prescribed Plan B, need to be under the direct supervision of a medical doctor. </4: 7.5.3>

3. Can a drug that is approved both with a prescription for some and without a prescription for others have the same packaging, or would it require different warning labels and instructions?

<5: 1.2.3, 8.2, 8.6.2>A drug that is marketed and sold both with and without a prescription MUST have different packaging, labels, and instructions. The general public does not have the training to understand important information such as side effects, contraindications, and warnings on a standard drug label. tf

made available over the counter, Plan B needs very detailed labeling and instructions written in a simple, easy to understand manner. However, this drug is not safe to be making available without a prescription to ANYONE. There is simply too little research into long term effects. </5: 1.2.3, 8.2, 8.6.2>

<6: 1.2.3>Please consider my thoughts on this issue. They are well intention⁴ and from a desire to keep the general public safe. The FDA, made a responsible decision in 2003 when it declined to make Plan B available without a prescription. I hope that the FDA will remain firm on it's decision and continue to make Plan B a prescription-only drug. </6: 1.2.3>

Very Sincerely,

Faith Alterton, RN

COMMENT NUMBER - 2005N-0345-EC1009

2005N-0345-EC1009 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Rose, Demian

2005N-0345-EC1009 - TEXT

2 A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 7.5.3>not without severely restricting access to the "legal" population.</1: 7.5.3>

COMMENT NUMBER - 2005N-0345-EC1032

2005N-0345-EC1032 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Ladd, Judy

2005N-0345-EC1032 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.8>To use an ingredient in both OTC and by prescription only muddies the water as to who will receive what and in what form and intensity (dosage). It should be OTC only to assure that if someone wants it, it's available. </1: 3.2, 3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product? <2: 4.1>This is unclear and opens a pandora's box of abuses by the pharmaceutical companies. </2: 4.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1>Completely. </3: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 5.5>It depends on whether the ruling was in favor of the population as a whole or was it to knuckle under to the pharmaceutical companies. </4: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law? <5: 7.2, 7.5.3>It would be impossible to regulate something that is readily available to every other person OTC. </5: 7.2, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.6>One would incur higher costs to receive the same ingredient by prescription because they would need a doctor's visit to get the prescription. Why would anyone want to raise the price of getting something unless it was in some way 'improved' by the interference of a health official? </6: 8.6>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so? <7: 8.9> If another more restrictive drug were included that had side effects that needed monitoring by a health official would be the only way that that would be feasible.</7: 8.9>

GENERAL

GENERAL

<8: 1.1>The FDA has shown itself to be a patsy for the drug companies rather than a protector of the American public. It's time they did the job they were formed to do.</8: 1.1>

COMMENT NUMBER - 2005N-0345-EC1041

2005N-0345-EC1041 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Speight, Thomas

2005N-0345-EC1041 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.1>The FDA should clarify all regulations so that they can be understood by the layman, and possibilities for abuse may be minimized. </1: 3.8.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 3.8.1>To the extent that the same ingredient may be present in different combinations and different proportions in prescription and OTC medications, yes the FDA should evaluate existing regulations to ensure that the public good is protected. </2: 3.8.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1, 4.3.4>Yes, if the FDA has finally gotten around to realizing that it needs to be rulemaking. </3: 4.1, 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.5>If such a rulemaking would not in any way change the intent or action of the section's language, yes. </4: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.5.3>It does not appear possible or cost-effective for the FDA to attempt to enforce such a law, nor would it be in the interests of the public good to do so. There is, simply put, no good legal reason in current federal case law or constitutional law to restrict the OTC sale of contraceptive products (broadly defined), allergy medication, antibiotics, or other products in such a manner. Doing so would intrude

heavily onto the issue of doctor- patient privilege and would also bring up the question of the right to privacy as determined in Griswold V. Connecticut. </5: 6.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.5.1>Restricting such a product's availability would probably require new case law or revisitation of existing precedents to determine the legality of restricting such products, as well as the FDA's authority to do so. Given the current erosion of support for broad interpretation of the Commerce Clause, it appears unlikely that the FDA would be able to do so in the current legal environment. Such a move would also likely be very unpopular with the population as a whole.</6: 7.5.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 9.1.1>As the same ingredient may be present in different combinations and very different proportions in prescription and OTC medications, it would be extremely unwise to allow identical packaging. Use of the wrong product due to mistaken identity, or the assumption that the products are the same, could lead to adverse reactions, injury, or death.</7: 9.1.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

see 3A

GENERAL

GENERAL

<8: 11>As a general comment, I would like to remark that the current environment of medical costs increasing well ahead of the rate of inflation and the prevailing average wages is not sustainable for the long term, and that both drug companies and medical providers will have to drastically restructure their arrangements if the current economic decline continues. </8: 11>

COMMENT NUMBER - 2005N-0345-EC1044

2005N-0345-EC1044 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Pruis, Trisha

2005N-0345-EC1044 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2>In regards to Emergency Contraception, I think having the same ingredients in birth control pills, which are prescription-only, and EC, which is up for release OTC, is that birth control pills are long term commitment, while EC is one time use. A person only needs to understand swallowing 1 or 2 pills at the correct time, not everyday. </1: 1.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 7.4.1>I think if a law were created, it would have to be enforced at the level of the pharmacy or doctor.</2: 7.4.1> <3: 1.2.1>In reference to Emergency Contraception, I don't think their should be sub-population restrictions.</3: 1.2.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.4.4, 7.5.3>If there were sub-population restrictions, I suppose people would have to ask for identification with the age on it before dispensing the product. The problem with that is that not everyone over 16 will necessarily have identification with their age on it. Many people don't get driver's licenses at 16 and would therefore not be likely to get an ID. This would create problems getting the product to people that need it. Additionally, doctors and pharmacists are not going to want to add an extra step to their work. Doctors in particular tend to be very busy. Overall, asking for identification would probably not be practical.</4: 7.4.4, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.9>In reference to Emergency Contraception, I don't see why this is an issue. It would not make sense to sell birth control pills and EC in the same package because EC is usually one or two pills and birth control pills are usually 21 or 28. A person wouldn't need something with 21 or 28 holes for 1 or 2 pills. I think the nature of the product themselves preclude the same packaging. </5: 8.9>

GENERAL

GENERAL

<6: 1.2.1>I think safety is a first priority for any drug released OTC. Emergency Contraceptives have been proven safe and effective for use over the counter. I think questions like how to package it are just details. If it's safe, it should be an easy matter to package it. In regards to EC, I personally think that there should not be an age restriction of 16 placed on it. Like it or not, people younger than 16 have sex and are raped, and they need unrestricted access to EC as well. </6: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC106

2005N-0345-EC106 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Shaffer, Kathleen

2005N-0345-EC106 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.3.2>It is a contradiction to sell an active ingredient simultaneously as a prescription drug and an OTC drug product. Therefore the FDA has no authority to attempt to codify its interpretation of section 503(b), thereby allowing it. </1: 3.2, 3.3.2>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes. </2: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.2>No.</3: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.5.4>The FDA would risk profuse litigation by angry parents, such as myself! </4: 6.5.4>

GENERAL

GENERAL <5: 1.3>That an organization would attempt to allow general use of a drug with so many dangerous medical side effects as the birth control pill, is incomprehensible! Surely the FDA would be doing society a disservice.</5: 1.3>

COMMENT NUMBER - 2005N-0345-EC107

2005N-0345-EC107 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: White, Molly

2005N-0345-EC107 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

What is 503(b)?

<1: 3.1, 3.8.1>Sure. Rules are great. Everyone knows the game plan when regulations exist, provided they are short, clear and to the point.</1: 3.1, 3.8.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

Sure, provided a regulation is short, clear and to the point.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

I'm not in a position to respond to this one. See above. What is 503(b)?

C. If so, would a rulemaking on this issue help dispel that confusion?

What is "dispel"?

<2: 5.5>Rules can alleviate confusion or they can make it worse. The nice thing about rules is they provide grounds for further action.</2: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.1, 6.3.5>Why not? Other agencies do. Examples: Only people who have completed medical school are permitted to practice medicine. Only people of a certain age are permitted to vote or drive. Only people born in the US can be president. Just because the FDA has not tried it to date doesn't make it a particularly original or difficult problem.</3: 6.1, 6.3.5>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.1, 7.4.4>Yes. Just like other agencies assure that specific criteria are met before the

rights/privileges/responsibilities associated with a certain activity are conferred upon any given individual, the FDA should have no problem requiring, for example, that persons purchasing a molecule show proof of identification including age and whatever else is felt to be relevant. If the local Quick Trip can do it for me to purchase beer, then the drug store can do it for me to purchase drugs. Heck sometimes drugs and beer are sold in the same places!</4: 7.1, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.1>Who cares? Yes. It's as legal as you want to say it is.</5: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 9.2.2>None.</6: 9.2.2>

GENERAL

GENERAL

<7: 1.2.1>My casual observation is that governments which preside over wealthy, healthy, well-educated populations tend to encourage rational family planning. Such governments tend to act in a manner that preserves and encourages a wide choice of family planning options. As a matter of sound economic policy, all people should have unfettered access to whatever forms of family planning they prefer and family planning should be highly encouraged.

Governments which restrict access (directly or implicitly) to family planning options tend to preside over poor stupid populations. I don't want to live in a poor stupid country.

I'm aware that some people opposed to the sale of Plan B without a prescription (to anyone, let alone women 16 or older) feel that such freedom would lead to various abuses. A person over 16 could purchase Plan B and give it to a woman under 16, and such a purchase could occur in abusive or otherwise unsafe situations. However, I believe that restricting the freedom of all is not the way to cope with the unacceptable behavior of a few. </7: 1.2.1>

<8: 7.4.6>All freedom comes with the potential for abuse. In the case of OTC Plan B, it seems to me that a variety of methods are available to society to address the type of abuse that Plan B critics fear. For example, make the purchaser provide identification and take the first dose of the drug right there in the store. </8: 7.4.6>

<9: 1.2.1>Another criticism is that Plan B itself is a form of abortion. My opinion is that life is a privilege, not a right. The fact of conception does not automatically confer the right to live. The human body destroys fetuses naturally all the time. In addition, I know too many people that have no business bringing children into this world or attempting to raise them. By all means, allow these people to abort their pregnancies! Parenting should not be a privilege either!

If the science indicates no sign of significant harm or inefficacy, then the FDA should allow unfettered access to Plan B without a prescription for any person of any age. Persons who do not want to access this family planning option may certainly make that decision for themselves. Such persons do not have the

right to make that decision for others.</9: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC1080

2005N-0345-EC1080 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Rucker, Gwendolyn

2005N-0345-EC1080 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.3.2, 3.8.8>No. No drug should be both prescriptive & over the counter at the same time. The idea is a contradiction and dilutes the definition of both terms. Prescription drugs indicate caution is required. Over-the-counter items indicate public consumption. That is the mindset of the public and if you allow an item to be both prescriptive & over the counter, then people will automatically assume the lower degree of over the counter and assume it is for public consumption.</1: 3.3.2, 3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 3.3.2>Yes. The only time this should be allowed is when the active ingredients harmful properties are made unharmed in the drug that is over the counter. If it can not be made unharmed for public consumption, then it should be prescriptive. </2: 3.3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1, 4.3.4>yes. there is the confusion in terminology as to the ingredient (which is the raw drug) and the medicine (which is the compound drug). There needs to be clarification as to when you are discussing the ingredient drug versus the medicine drug</3: 4.1, 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

not sure

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2, 7.5.3>No. You would wind up with the exact same issues we have with alcohol & cigarettes. Adults will purchase and give to underage people. With the issue of the Morning-After-Pill, you would additionally have the issue of Male Sexual Predators using it as an illegal and unknown to the women method of birth control.</4: 6.2, 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 6.6.3, 7.4.1, 7.4.5>I think cigarettes & alcohol are the items that society has done this with and what we have found out is that restricting certain types of items to adults only, only makes youth want it more and allows those who do not care about others to profit from the youth's desire (illegal drivers licenses, buying for minors if they pay you more). If you must do it, the way would be to follow the alcohol & cigarettes policy. You would need to have a commission to oversee it & then the police would have to periodically setup up sting operations at stores to make sure they are only selling the items to adults. The stores would have to have the items behind the counter & only certain people at the store would have access. More regulation & more money for something that could be simply regulated by making it a prescriptiononly item. </5: 6.6.3, 7.4.1, 7.4.5>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.6.3>Legally sold in the prescription package, but not in the OTC package. Selling it in the OTC package would remove all restrictions on the prescriptive ingredient.</6: 8.6.3>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 8.5.4>Selling them in OTC packages would be inappropriate. That would essentially remove all restrictions on the prescriptive ingredient.</7: 8.5.4>

GENERAL

GENERAL

<8: 1.2.3>The Morning-After-Pill should never become an OTC item. First, it should never be distributed, but if we must distribute, as a prescription is the only way. If this drug has the power to abort a baby that has been conceived, it is too potent for public consumption. Public consumption of the Morning After Pill as an OTC opens the doors to allow not only women to use it as a birth control option, but men also. Public consumption of the Morning After Pill as an OTC would allow male sexual predators to purchase it and for those whose minds are already disturbed to rationalize that it is okay to take advantage of a women because they can give her the Morning After Pill and she will not be pregnant. Public consumption of the Morning After Pill as an OTC would cause an increase in rapes, and child molestation because it would allow those whose minds are disturbed enough to do those things to have a measure of protection. Public consumption of the Morning After Pill as an OTC would cause an increase in STD's in youth; because they often see the only consequences of having sex as getting pregnant - this would allow them to overlook the serious consequences of STD's. Public consumption of the Morning

After Pill as an OTC would cause an increase in pregnancies in youth; because they would intend to take the Morning After Pill, but would forget to actually take it due to the immaturity and irresponsibility of youth. Public consumption of the Morning After Pill as an OTC would ultimately cost society money to maintain the regulations, to monitor criminals, to provide for the children born to teenage mothers. While it may seem that Public consumption of the Morning After Pill as an OTC would be freeing women to take charge of their lives, it would actually be stunting the advance of women in society by opening the door for women to be even more taken advantage of by sexual predators, by allowing those females and males who are irresponsible to maintain a level of irresponsibility, by causing public funds to be spent to enforce the OTC law of underage --- when restricting the item to prescription only would resolve all of these issues and would be less expensive for society. </8: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC1086

2005N-0345-EC1086 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: McCormick, Michelle

2005N-0345-EC1086 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.8>It makes very little sense, if the drug is necessary to the welfare of thousands of American women, to limit and restrict the access to said drug. The FDA needs to base rules on the health & well being of Americans, not politically motivated "interpretations" of sections and codes.</1: 3.2, 3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product? See above

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Definitely, because I am certainly confused.</2: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.5>Maybe so, but more than likely it will restrict the process of issuing drugs even further. </3: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1, 6.6.1>Sure. In California, the sale of over the counter sinus medication (used in the production of methamphetamine) is restricted to people with an ID stating that they are over 18 years of age. This seems to be working. </4: 6.1, 6.6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.1, 7.4.4>By restricting access based on IDs and age, or the presence of an adult, unless prescribed by a doctor. </5: 7.1, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1, 8.4.1>Yes, because it would be necessary to ease confusion over the two options.</6: 8.1, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.2.2>I am not sure if I can think of a situation.</7: 9.2.2>

COMMENT NUMBER - 2005N-0345-EC109

2005N-0345-EC109 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Burometto Jr, Charles

2005N-0345-EC109 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes</1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 3.8.2>Yes, by creating a third class of drugs, those sold by a pharmacist without requiring a prescription.</2: 3.8.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1>Yes.</3: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.1>Yes, a rule would clarify the confusion by stating what actions are to be taken.</4: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 3.8.2, 6.1>Yes, by creating a third class of drugs for sale by a pharmacist. By restricting the sale of a drug by a pharmacist without a prescription, the pharmacist would be held accountable to enforce the limitation on the sale of the product.</5: 3.8.2, 6.1>

B. If it could, would it be able to do so as a practical matter and, if so, how?

<6: 7.1, 7.4.1>Yes, Pharmacies and pharmacists are required to abide with multiple other rules and regulations pertaining to the dispensing of drugs.</6: 7.1, 7.4.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1, 8.3.1>Yes if the labelling is adjusted appropriately.</7: 8.1, 8.3.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.1.1>When the directions for use are so vastly different that confusion could occur when reading the instructions leading to inappropriate use.</8: 9.1.1>

GENERAL

GENERAL

<9: 1.1, 3.8.2>Multiple other industrialized nations have more than 2 classes of drugs. In this day and age when patients are being empowered to take a proactive role in their health, safeguards need to be in place to make sure patients are not harmed by taking inappropriate drugs. With more drugs being switched from prescription to OTC status, having drugs available without a health care practitioner can lead to adverse

outcomes. Some of the labeling on current OTC drugs is very confusing to a lay person. </9: 1.1, 3.8.2>

COMMENT NUMBER - 2005N-0345-EC110

2005N-0345-EC110 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Roye, Carol

2005N-0345-EC110 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 10>There is no reason to do this in the case of Plan B. There have been well-done studies that show that Plan B does not promote irresponsible sexual behavior by teenagers. In fact, several studies found that giving Plan B to sexually active teens at routine visits actually encourages more responsible condom use. I refer you to (among others):1) Raines T et al (2005, Jan. 5). Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: A randomized clinical trial. JAMA, 293, 54-62; 2)Gold, M.A. et al. (2004). The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. Journal of Pediatric and Adolescent Gynecology, 17, 87-96; 3)Roye C. & Johnsen, J. (2001). Routine provision of emergency contraception to teens and subsequent condom use: A preliminary study. Journal of Adolescent Health , 28, 165- 166.</1: 3.2, 10>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 1.2.1>Not really relevant to a discussion of EC. This drug can safely be used by all women of childbearing age.</2: 1.2.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 7.5.3>It is difficult. Think about how many teens buy alcohol and cigarettes. </3: 7.5.3>

COMMENT NUMBER - 2005N-0345-EC111

2005N-0345-EC111 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Black, Jerrold

2005N-0345-EC111 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes</1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

yes

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>no</2: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

na

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.2>no</3: 6.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 6.3.4>It seems to me that we will actually encourage disdain for the law as those selling the product would be faced with crying 15 year-olds begging for the morning after pill to cashiers with little idea of

what is at stake. Also, how many 17 year olds will act as a surrogate to purchase the product for a minor? I predict the ACLU would love to make an issue about any prosecution that was attempted. An age related ban is an unenforceable "fig-leaf".</4: 6.3.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.5>I don't know about the legality, but I certainly wonder about future litigation when users of the product sue for injury. Will the judge and jury look at it differently? Should they? What if it was sold OTC to an underage patient? Does that affect liability?</5: 8.5>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

see above

GENERAL

GENERAL

<6: 1.2.4>This is an end-run around the FDA regulatory function. The health concerns in teens must be completely addressed before this drug can be released. If this is made OTC, be prepared for school nurses to be giving it out in large numbers with little idea of who will actually be using it. This is a litigation disaster waiting to happen.</6: 1.2.4>

COMMENT NUMBER - 2005N-0345-EC1117

2005N-0345-EC1117 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Ahmed , Stephanie

2005N-0345-EC1117 - TEXT

GENERAL

Please see attachment.

2005N-0345-EC1117-Attach-1.DOC

ATTACHMENT:

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Agency: FDA
Docket Number 2005N-0345

Dear Acting Commissioner von Eschenbach:

<1: 1.2.2>As an obstetrician-gynecologist I am deeply concerned about the FDA's repeated delay on a decision regarding over-the-counter approval of Plan B emergency contraception. I urge you to approve Barr Laboratories' EC application immediately.

Currently, half of all pregnancies in the United States (about 3 million) are unintended and about 1.3 million of these will end in abortion. Widespread availability of emergency contraception could prevent many of these unplanned pregnancies, and dramatically reduce abortion rates in the United States.</1: 1.2.2>

<2: 3.7.2>Under the Durham-Humphrey Amendment of 1951, the default option for all new drugs is OTC unless the drug is addictive or dangerous when self-administered. Plan B meets all the criteria for OTC use: low toxicity; no potential for overdose or addiction; no risk of causing birth defects; no need for medical screening; self-identification of need; uniform dosage; and no important drug interactions. In short, no medical reason exists for prescription status of Plan B.</2: 3.7.2>

<3: 2.1>In 1999, the FDA approved Plan B for the "prevention of pregnancy." In April 2003 Barr Pharmaceuticals filed an application with the FDA to make the drug available over the counter. The FDA's Advisory Panel overwhelmingly recommended OTC approval of Plan B by a 23-to-4 vote, after reviewing more than 15,000 pages of clinical data from approximately 40 studies submitted with the OTC application. Since receiving Barr Pharmaceutical's application, the FDA has at every opportunity delayed making a decision. HHS Secretary Leavitt, who oversees the FDA, assured the Senate that the FDA would make a decision by September 1, 2005. Instead, the FDA delayed its decision and initiated a 60-day public comment and rulemaking process with no timetable for making a decision.

Again, I urge you to approve the Plan B EC application today-providing women with safe and effective contraception that will reduce unintended pregnancies and abortions.</3: 2.1>

Sincerely,
Stephanie Ahmed, MD

COMMENT NUMBER - 2005N-0345-EC1121

2005N-0345-EC1121 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: White, Alan

2005N-0345-EC1121 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.9.1>There is no sufficient reason to distinguish the issue of legalizing OTC Plan B over and above that of OTC Loperamide on the basis of 503(b). Since the same general issues apply in both cases, and OTC Loperamide was approved without raising these issues, it is unclear why these issues should be pertinent to this case except for irrelevant moral/social/theological/political reasons.</1: 3.9.1>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 1.2.2, 2.1, 5.2>If there is confusion about what constitutes a safe and effective OTC drug in some circumstances, a ruling in this particular case (Plan B) is not one that could dispel the confusion in any significant way. Studies show that Plan B is safe and effective for the suggested target OTC population (17+ year-old females), and thus poses no significant risk to that population (except, perhaps, in the estimation of those commentators who import questionable and possibly unconstitutional moral or religious assumptions about danger to embryos, as suggested above, and clearly the FDA may not seriously entertain such concerns in its decision-making).</2: 1.2.2, 2.1, 5.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.4.3>Since there is no reason to believe that the FDA has heretofore interpreted section 503(b) in a confused way, and the case of Plan B introduces no novel issues of safety and efficacy for the target OTC population, then there is no reason to use this case to further refine interpretation of that section. In fact, any ruling on Plan B that further restricts the interpretation of 503(b) may well lead by parity of law to further unintended consequences, such as rescinding the current practice of allowing equivalent-dosage OTC drugs such as Loperamide.</3: 5.4.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.4.1>2. A./B. Since the FDA has previously ruled on OTC drugs that cannot be vended to minors (e.g., nicotine patches), and entrusted the enforcement of said rulings to local authorities without major incident, it is reasonable to conclude that similar enforcement of the availability of OTC Plan B is equally feasible.</4: 6.4.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 6.6.1, 8.6.4>3. A./B. Similarity of packaging for prescription and OTC Plan B is purely a practical matter with regard to issues of distribution of the drug, including inventory of the two modes of dispensing the drug and the potential for illegal marketing. Some of these same problems currently are

involved in the case of OTC pseudoephedrine, and are being resolved by local and state legislative action to regulate that drug appropriately. Since the FDA has not seen fit to involve itself in this kind of regulation directly, and the case of Plan B does not raise many of the serious issues of public policy that pseudoephedrine does, there is no reason, again except for irrelevant moral/social/theological/political reasons, that the FDA should view this case differently. </5: 6.6.1, 8.6.4>

GENERAL

GENERAL

<6: 3.9.1>It is significant that the commentary on this case is solicited only in terms of the above general questions that cover the specific issue of whether Plan B contraception should be acceptable as an OTC drug. That implies that this case is the first such case considered by the FDA that brings these questions forward. However, for example, the case of Loperamide, which the agency has approved for treatment of diarrhea and is cited in the FDA's list of dual prescription/OTC-dispensable drugs, completely undercuts this implication. Though the FDA very finely distinguishes the prescription/OTC indication for diarrhea in these two uses as respectively chronic/acute, each occurrence of that condition is in fact an individual medical event, and the prescribed/OTC medication is in fact dispensed in equivalent dosage to prevent a recurrent episode of that condition, whether diagnostically chronic or acute. Logically and medically the use of prescription/OTC Plan B to prevent pregnancy, interpreted merely as an undesirable episodic biological condition, is not different. Should the FDA care to challenge this claim on the basis that potential pregnancy cannot be a medical condition comparable to diarrhea, it should equally consider more carefully the current medical acceptability of procedures such as breast augmentation and rhinoplasty, which are often pursued wholly on the patient's subjective assessment of somatic undesirability. Clearly both potential pregnancy and potential diarrhea are equivalently undesirable for some patients, and the relevant medications are indicated chiefly for these reasons. Furthermore, if the prevention of possible pregnancy is interpreted by the FDA as something other than an issue of patient-assessed undesirability of a somatic condition, then the FDA would import moral, social, religious, or political assumptions about possible early pregnancy that are of dubious scientific or logical merit to this argument, and might well constitute an unconstitutional basis for any ruling issued by the FDA. </6: 3.9.1>

COMMENT NUMBER - 2005N-0345-EC1129

2005N-0345-EC1129 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Paslawsky, JoAnn

2005N-0345-EC1129 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC

drug product?

<1: 3.8.5>As a chemist, I am all too familiar with the exceptions that occur despite the industry's best pre-marketing testing and post-marketing surveillance. Thus, I believe that it is virtually impossible to codify interpretation of section 503(b). I believe strongly that simultaneous marketing of an active ingredient in both prescription and OTC form must be assessed on a case-by-case basis. Otherwise, I believe both patient safety and industry's liability are placed at major risk.</1: 3.8.5>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

As a chemist, I am all too familiar with the exceptions that occur despite the industry's best pre-marketing testing and post-marketing surveillance. Thus, I believe that it is virtually impossible to codify interpretation of section 503(b). I believe strongly that simultaneous marketing of an active ingredient in both prescription and OTC form must be assessed on a case-by-case basis. Otherwise, I believe both patient safety and industry's liability are placed at major risk.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2, 4.3.2>I do not believe there is confusion on this point. The FDA has worked diligently to ensure clarity of its interpretations whenever it makes a decision. I believe the media can and often do create confusion in the manner it reports on scientific matters in general and health topics in particular.</2: 4.2, 4.3.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.2>No, I believe a rulemaking would simply provide additional opportunities for clouding the issue when it is conveyed to the public.</3: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.3.5>For those bent on obtaining a drug (whether prescription or OTC), there is ALWAYS a way to get the drug, regardless of legal restrictions. Examples abound in this area.

However, since legal restrictions on pharmaceuticals exist largely to prevent patient harm, and such restrictions have historically been successful, I think it would be quite logical and generally effective to enact and enforce a prescription only requirement for a subpopulation on an OTC product.</4: 6.3.5>

B. If it could, would it be able to do so as a practical matter and, if so, how?

<5: 7.4.4>If, for example, the OTC product required a prescription for minors (i.e., under age 18), the pharmacy could simply require photo ID showing DOB, such as on a driver's license. It is currently done for cigarettes, why not a drug?</5: 7.4.4>

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 9.2.1, 9.3>Since prescription medications are provided with complete instructions, including warnings related to possible AEs, drug interactions, etc., the OTC product should provide the same information. In addition, if there is no difference in the formulations, including amount of the active ingredient, then they should not require different packaging.</6: 9.2.1, 9.3>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.1>Different packaging should only be needed when formulations differ, including but not limited to active ingredient.</7: 9.1.1>

GENERAL

GENERAL

<8: 1.2.3>As this relates to Barr Labs Plan B, I strongly believe that a decision to make this drug available OTC creates unnecessary risk to women's health and safety. This is especially true for females under age 18, those who cannot read or read poorly, and those for whom English is a second language. In other words, those women already victimized and most at risk.

By approving Plan B for sale OTC, the agency, which bases its guidance and decisions on patient safety, would place these women at even greater risk.

As an OTC drug, anyone would have access to it. This would include those trading sex with children for drugs, those holding children in abusive relationships, and adult men (age 18 or over) preying on minor girls. Please do not open a new door for sexual predators.

Women still suffer a stigma when reporting rape. It is even more difficult to successfully prosecute rape, incest, and sexual abuse. Do not offer another tool to these criminals.

Those who truly care for women and their health (physical as well as emotional) would NEVER allow Plan B to become an OTC drug for the reasons I've cited.

Studies, including those by Barr Labs itself (Jan. 2004 JAMA) have shown that easy access to the morning-after-pill has not decreased abortions or pregnancies.

The main driver for seeking this approval is greed. Planned Parenthood stands to make \$100 million profit over a 5-year period on the sale of the morning-after-pill, provided the FDA approves its OTC sale. Even without the OTC approval, Planned Parenthood has already made significant profit from the drug, thanks to a partnership with Women's Capital Corporation. A year after FDA's approval of the prescription sale, Planned Parenthood had already sold 100,000 units. When Women's Capital Corp. asked the FDA for OTC status for the drug, Barr offered to buy the Corporation, and did so in February 2004, for nearly \$21 million.

Before you make the decision, please send people to Planned Parenthood locations around the country. See who the clients are. You will realize they are the women I mentioned earlier - poor, uneducated,

victims.

As a woman, I ask you to PLEASE do NOT allow OTC sale of the morning-after-pill. To do so means that the agency is ignoring the risks posed for greater sexual exploitation. I am angered by the so-called 'women's groups' who support this approval while ignoring the growing abuse of women. These same 'women's groups' NEVER use the media as widely or vehemently to demand greater funding for breast, ovarian, or uterine cancer research, or for greater protection and assistance for single mothers and abused women and girls.

I trust the FDA will continue to guard patient safety as its primary and highest goal. Please act to protect women and their health - not the sexual and corporate predators. </8: 1.2.3>

Thank you!

COMMENT NUMBER - 2005N-0345-EC11670

2005N-0345-EC11670 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Farren, Wanda

2005N-0345-EC11670 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.9.1>FDA has precedent for simultaneous prescription and OTC usage, whether at the same or at different doses. The nicotine patch and ibuprofen are two examples. The patch is restricted to buyers ages 18 and older. </1: 3.9.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.4.1>Nicotine replacement products available OTC are "restricted" to persons 18 and older. </2: 6.4.1><3: 7.5.2>As a practical matter, enforcement appears to be up to vendors. I don't see local drugstores listed in the paper as being in violation of underage sales, and given FDA's personnel shortages, "enforcement" that would single out emergency contraception would reflect bias in the agency's priorities.</3: 7.5.2> <4: 6.7>Either science dictates an age cutoff, or it doesn't. </4: 6.7><5: 6.3.5, 6.4.1>In the case of nicotine replacement products, the legal age for purchase of nicotine is 18, so

conforming labeling only makes sense. If the rule of law is cited for limiting distribution of an OTC product, it should be consistent with relevant statutes. In the case of EC, relevant statutes might be age of consent laws. These laws vary significantly from state to state, with the average age of consent being 14, but as low as 11 or 12, and as high as age 18. Nonetheless, this should not stop availability to persons who have aged out of those covered by these laws, and age 18 would be an appropriate cutoff age nationwide. </5: 6.3.5, 6.4.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.4.1>Leaving the product behind the pharmacy counter would ensure only certain persons get the product, but it would also pose a barrier.</6: 7.4.1> <7: 6.5.4>Condoms are available OTC; there is no age verification.</7: 6.5.4> <8: 7.5.3>Cigarettes are available only behind the counter, but this has not stopped underage purchase, or purchase by older persons on behalf of those under age. Beer (and wine) in some states is available "OTC"--and while there are requirements for age verification, it is inconsistently done.</8: 7.5.3> <9: 7.4.6, 7.5.3>For a product that could be sold single-dose (or "use"), and for which the adverse effects are exceedingly rare, it makes no sense to try to screen every possible purchaser. As a practical matter, a purchaser under a state's legal age of consent should be reported to child protective authorities. I seriously doubt that retailers are prepared to do this. </9: 7.4.6, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<10: 8.1>There would be no obvious reason why this would not be the case.</10: 8.1> <11: 8.4.1>The burden on the manufacturer would be less. There would be no particular reason a pharmacist could not dispense the individual product (dose of pills, whatever it is) via usual packaging for that pharmacy, however. </11: 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<12: 8.4.1>It would be inappropriate to charge any additional fee for either package; the price should be the same. </12: 8.4.1><13: 9.2.2>I can't imagine why it would be inappropriate to have simultaneous distribution channels, under any circumstances. This would be regulation run amok. </13: 9.2.2>

COMMENT NUMBER - 2005N-0345-EC117

2005N-0345-EC117 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Dorn, Kellie

2005N-0345-EC117 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.3, 6.3.5, 7.5.3>I agree with the FDA's initial long-standing decision that a drug should not be used simultaneously both by prescription and used over-the-counter. It would be too difficult to enforce this decision to make Plan B OTC only to individuals 16 or older. Many teenagers don't have a driver's license until 17 or 18 years of age, so proof of age in itself is a problem. Also, even if the individual purchasing the contraception is 16 or older, what is to prevent these individuals from diverting Plan B to teens who are under 16 years of age? What is the magic age of 16 that makes this medication suddenly safe? I don't see a huge difference in judgement between a 15 year-old and a 16 year-old or 17 year-old for that matter. Finally, I feel that by making this emergency contraception available over-the-counter to anyone, it will replace a visit to a doctor, which provides a valuable service. In a single visit, a doctor can screen for STD's, pregnancy, HIV, and give a pap-smear. A patient could conceivably purchase a Plan B pack every time that this person has sexual intercourse and never see a doctor in her entire lifetime. This will raise the number of undetected STD's, increase the rates of undetected ovarian, endometrial, breast, and uterine cancers, increase the number of undetected HIV cases, and prevent patients from using conventional monthly contraceptive methods which require thought before engaging in sex and which require a yearly physical exam. I strongly urge you to consider the points I have made and retain Plan B as available by prescription only.</1: 1.2.3, 6.3.5, 7.5.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 3.8.4>I agree that if a medication is unsafe for some, it should remain as prescription only.</2: 3.8.4>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 7.5.4>I don't feel that this law is enforceable, as not every teenager has state-issued identification, and significant diversion would occur to teenagers under 16 years-of-age.</3: 7.5.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.2, 8.5.1>No these products could not be sold in the same package, as the law requires OTC products to comply to specific labeling requirements which are explicitly different than prescription labeling requirements. The labeling requirements for an OTC product are designed to educate the patient on safe use of the product, and the prescription packaging is designed to assist the health professional in education of the product.</4: 8.2, 8.5.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<5: 9.1.2>It would never be appropriate. </5: 9.1.2>

COMMENT NUMBER - 2005N-0345-EC12

2005N-0345-EC12 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Reynolds, Charles

2005N-0345-EC12 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.1>Yes, this is an important decision for the future of health care in the US.</1: 3.8.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes, this is an important decision for the future of health care in the US.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 3.8.1, 4.5>The issue is not one of confusion. The question becomes one of establishing defined criteria for which a drug may be used and marketed both OTC and Rx.</2: 3.8.1, 4.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.7>Unknown if the FDA has the ability to regulate this under its jurisdiction.</3: 6.7>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.4.1>Yes. By creating a class of drugs that can be directly sold only by a licensed pharmacist. This makes a specific person responsible for effectively implementing what the FDA wants. It also protects the health and safety of US citizens by making them interact with a health care professional who can assess the request for appropriateness as well as potential problems.</4: 7.4.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.1>Assuming there is no specific legal prevention, this would be acceptable.</5: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 8.5.3, 9.1.1>Can't think of any problems, unless regulatory action would require special record keeping to separate OTC use from Rx use... then separate packaging (and thus NDC code) would be important.</6: 8.5.3, 9.1.1>

GENERAL

GENERAL

<7: 1.1>This question, prompted by 'Plan B' product will become more prominent as time goes on unless the US deals with its health care crisis. </7: 1.1>

COMMENT NUMBER - 2005N-0345-EC121

2005N-0345-EC121 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Slee, April

2005N-0345-EC121 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.8>No. There are two reasons to have a drug available by prescription. One is so insurance covers it, like blood glucose test strips. The other is that a reasonable person can't be expected to take it safely and correctly without the direction of a doctor. On this second part, either a drug is safe enough or it isn't. Besides, anyone who is 15 is smart enough to get a 16 year old friend to buy it for them.</1: 3.2,

3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No. Same reason. By the way, there's a typo here.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No, I think the interpretation is reasonable and correct.</2: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.2, 6.3.4>No way. As a teenager, you need an 18 year old friend to by you smokes, a 21 year old friend to by you booze, and now you'd just need a 16 year old friend to buy you emergency contraception.</3: 6.2, 6.3.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.2, 8.6.2>No. Obviously you are worried that the population needing the prescription can't be trusted to take it without the prescription, so you need warnings that address these concerns.</4: 8.2, 8.6.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<5: 9.1.1>If the risks are different, you need different warnings. </5: 9.1.1>

COMMENT NUMBER - 2005N-0345-EC12379

2005N-0345-EC12379 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Mershon, Claire-Helene

2005N-0345-EC12379 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.1, 3.1, 3.8.5>Yes. Plan B should be available OTC, and while I disagree that it should be split between OTC and prescription, I understand the concerns of the FDA in taking the action for women under 16. However, this should not keep the FDA from keeping it off of the shelves completely. If an active ingredient is judged to be safe for use OTC by women, it should be sold that way. If it is necessary to make the drug prescription for one population in order for that to happen, then the FDA should review its rules and allow the drug to be available in both forms.</1: 1.2.1, 3.1, 3.8.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.6.3>Yes. If the age of a person buying cigarettes or alcohol is subject to legal enforcement, why would this limitation not be enforceable?</2: 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.4.1>One possible way to enforce this, if the FDA is worried about the populations purchasing the drug, is to keep it behind the pharmacy counter. The only stipulation would be that there must be one pharmacist available at all times who could not refuse to sell the drug to a customer because of its intended use. If the pharmacy were to control this sale or distribution, they could check identification in an area that is somewhat more private than the cash register, and they would also be available to answer any questions a woman might have about how to use the product.</3: 7.4.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.1, 8.4.1>Yes. This would remove the burden on the part of the manufacturer to create different packaging. In addition, the current packaging is extremely straightforward, and they have made it easy to understand. If the current packaging works, as was ruled by the advisory committee, why complicate it further?</4: 8.1, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<5: 9.2.1>I don't know what circumstances would make it inappropriate, but I don't believe that this is one of them.</5: 9.2.1>

COMMENT NUMBER - 2005N-0345-EC126

2005N-0345-EC126 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Dougherty, Anne

2005N-0345-EC126 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes</1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

Yes

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Most consumers do not understand section 503(b)</2: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.3.2>It might, yes. Consumers look only at the availability and price of health care items. In an era where health care is available to far fewer people at an affordable price it is vital that the patient feel he or she is involved in healthcare decisions.</3: 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.6.3>Limiting the sale of the "Plan-B" drug over the counter is no different under the law than limiting the sale of tobacco to people over 18 or alcohol to people over 21.</4: 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 6.6.3>Yes, I believe so. Requiring proof of age is in no way an infringement on the right to privacy. As long as it is only proof of age, in the form of a government issued identification, that is required,

enforcement of such a regulation could be turned over to the same agency that enforces alcohol and tobacco regulations.</5: 6.6.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.4.1>Unless there is a dosage difference, I believe that marketing exactly the same product in different packaging would cause undue stress to the consumer of the product. Anyone considering using the "Plan-B" contraceptive is already facing a tough decision; packaging and marketing should not add to any already existing impediments.</6: 8.4.1>

COMMENT NUMBER - 2005N-0345-EC13

2005N-0345-EC13 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Clague, Alexander

2005N-0345-EC13 - TEXT

Issue Areas/Comments

2

B. If it could, would it be able to do so as practical matter and, if so, how?

<1: 7.4.4>There are two obvious circumstances where products are limited for purchase on the basis of age: alcohol and tobacco. If a pharmaceutical product were to be sold based on age-related criteria, similar protocols from what are in existence today should suffice to ensure compliance with the laws. In addition, since Plan B is not habit forming, the way alcohol & tobacco products are, some of the restrictions on advertising which exist for tobacco would not be necessary in the case of Plan B.</1: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<2: 3.9.1, 8.3.1, 8.7>This is an odd question, since omeprazole (brand name Prilosec) is currently being sold both as a prescription and as an OTC product. The distinction that the OTC product is a different salt than the prescription product has no biologic significance. Accordingly, the same package may be used so long as the "OTC" product contains whatever required language the "prescription" product would require so that there would not be any problems where a pharmacy were "out of stock" of the prescription product while still having an inventory of the OTC product.</2: 3.9.1, 8.3.1, 8.7>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<3: 9.3>only if the "package insert" information is not available for the "prescription" sale.

</3: 9.3>

GENERAL

GENERAL

<4: 1.2.2>Plan B is safe and should be sold over the counter. If young girls are required to obtain a prescription for it, the packaging should be created to ensure flexibility regarding the type of sale so that there are no inventory "shortages" for either the OTC or prescription sale. </4: 1.2.2>

COMMENT NUMBER - 2005N-0345-EC13026

2005N-0345-EC13026 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Thomas, Tiffany

2005N-0345-EC13026 - TEXT

Tiffany N. Thomas
Paper Assignment
Political Science 3700
October 31, 2005

ANPRM published in the Federal Register vol 70 no. 169, pages 52050-52051;
Docket No. 2005N-0345 and/or RIN number 0910-AF72,

<1: 7.5.3>In response to the Advance Notice is Proposed Rulemaking, about what types of drugs should be sold simultaneously both by prescription and over the counter, and it has major implications for the so-called "Plan B" emergency contraception. I think that all drugs should only be available through prescription or over the counter and not both. In my opinion it is absurd to have both. Like many others I think there is no point in going to the doctor and when one could just go to their local CVS or Eckerd and buy the same thing they are getting with a prescription over the counter.</1: 7.5.3> <2: 3.11>Another issue I have with having both is will the dosage be the same. If you are going have both, then the amount of the active ingredient should be less in the over the counter drugs. </2: 3.11>

<3: 3.8.4>According to Lester M. Crawford at one time the Federal Drug and Administration "used to prohibit products from being sold both over the counter and prescription at the same. The idea was if an active ingredient was safe and effective with out practitioner's supervision it had to be over the counter." I think that is a major reason that drugs should only sold either over the counter or by prescription no simultaneously. Prescriptions have physician advisory; your doctor can control the amount of the drug you receive and how often you receive it. Whereas, with the over the counter you are only consulting your pharmacist, who does not know you medical history and can not adequately make sure that it is safe

for someone's particular body type. This could be dangerous and harmful to your health. Also, with prescriptions somebody can keep track of how much you receive and you can only get the amount that your doctor has prescribed. When a drug is sold over there is no way for you to keep track of who gets what and how much. With drugs such as the "Plan B" drug there would need to be some sort of data base to keep track of who purchases, so that people could not abuse the system, and go from store to store every other day and be like I need this pill. There should a limit on how much you can receive with in a certain time frame.</3: 3.8.4>

<4: 3.11>Another big factor in determining whether drugs should be sold in both prescription and over the counter is the amount of the active ingredient that is in the drug. If the drugs are going to be sold simultaneously then the dosage should be different in the over the counter drug than it is the prescription drug. That way people could not abuse the drug. In regards to the "Plan B" drug lowering the dosage and selling it in a single package would be essential in making sure that women do not act irresponsibly and try to take multiple dosages of the drug. </4: 3.11>

<5: 7.5.3>One of the questions regarding the "Plan B," drug is "should age by a criterion on which we decide whether a drug is sold as a prescription product, or an over-the-counter product...how as a practical matter, would such a limitation be enforced." This is a big question and is one that is difficult to answer; we can not fully enforce keeping kids from smoking and drinking so how can someone enforce keeping underage girls from gaining access to this drug. I think that if the "Plan B" pill is sold by prescription only then it would make it harder for underage girls to get. With a prescription the girls will have their doctor's supervision and it will adequately prescribe to their particular body type. When it is sold over the counter to older girls the younger teens will just ask their friends who are of age to go and buy it for them the same way in which they do other things they are to young to buy for themselves. Another major reason that it drug should be sold by prescription only is there would be no way to really enforce the age limit, girls could get fake identification and then what would be the point, with a prescription then the pharmacist knows who the person is and what their real ages. </5: 7.5.3>

<6: 7.6>Furthermore, how would this affect insurance? If the drug is sold over the counter how would this affect your insurance; would your insurance provider tell you to buy the over the counter version instead of the prescription version of the drug? If you sold the drug both over the counter and by prescription, then I think the over the counter version should be more costly than the prescription this would also prevent people from misusing the drug. If the over the counter drug cost more than the prescription then people would be more careful and would take the time out to go to the doctor and get a prescription instead of just going the pharmacist.</6: 7.6>

<7: 3.11>There is no reason for a drug to be sold over the counter and by prescription simultaneously, it is absolutely pointless. It should be sold either by prescription or over the counter not both, there is no way that you could regulate how much a person receives and how often if it is sold both ways. When a drug such as the "Plan B" pill is sold both ways there would be no physician advisory for the people who received the drug over the counter there would be no way to tell what the effects were on their bodies this could possibly be dangerous to our society. Many may argue that this is a good idea especially in special circumstances like rape, because then the drug will be very assessable in a limited amount of time. However, I do not think that it is even a good idea in special circumstances such as rape, because once again this would cause people to not to see their physicians who can adequately tell what is right for a particular body type. When something is sold over the counter it can be misused easier than prescription drugs and there is no way to limit and record who takes it and how much, therefore all drugs should be sold either by prescription or over the counter.</7: 3.11> <8: 1.2.3>The "Plan B" is one of those drugs that should be sold only by prescription and not over the counter. </8: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC13197

2005N-0345-EC13197 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Chihane, Ziad

2005N-0345-EC13197 - TEXT

GENERAL

See Attachment

2005N-0345-EC13197-Attach-30.DOC

ATTACHMENT:

Ziad Chihane
3027 Henderson Mill Rd.
Atlanta, Ga 30341

Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product.

Agency: Food and Drug Administration, HHS
Action: Advanced notice of proposed rulemaking.
Docket No. 2005N-0345
RIN: 0910-AF72

<1: 3.1, 4.1, 5.1>The rulemaking in question is of utmost importance in regards to health and safety of citizen of the United States. The FDA should absolutely initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product. The act in itself is unclear and with the high degree of importance that medicine serves to citizens it is imperative that there be rulemaking in regards to this issue. The confusion that occurs with the FDA's interpretation of section 503(b) is that they have set limits in the amount of dosage that something can have depending if it is OTC or a prescription drug. But this is not very clear this is why I believe that FDA should go into a more effective rulemaking process to better regulate this issue. The way that the rule is currently setup I believe leaves a lot of room for speculation, which is not something that needs to be done with prescription or OTC drugs. If we don't put a more effective rule on the section 503(b) it could eventually get out of control. So yes I do believe that rulemaking on this issue would dispel the confusion that is along with this section 503(b).</1: 3.1, 4.1, 5.1>

<2: 6.1, 7.3.1.1>The FDA like other Federal administrations has many processes to ensure that the rules that they make and administer are followed. So if the FDA does continue with rulemaking in respects to the section 503(b) they would certainly be able to enforce the rules that have been made. As long as the FDA makes the law so that it is constitutional then there should not be a enforcement problem in respects

to the rules made. I think that this would be somewhat of an easy thing to control because the enforcement would be on a broad level. The FDA would have to regulate the pharmaceutical companies by telling them how the product will be distributed and then the pharmacies that distribute the drugs will only do so if a licensed practitioner prescribes it. Although this would be more difficult if the rulemaking affected drugs that were previously OTC and then they become prescription drugs. This I believe would cause a problem in regards to enforcement because people will be upset over the new rule but in the end the new rule will be more effective. The rulemaking enforcement would be practical from a forward perspective clearly it would take a while for companies and pharmacies to change in respects to the new rules but it would be done and it will be affective.</2: 6.1, 7.3.1.1>

<3: 8.2, 8.9>With the new rulemaking if the prescription and OTC product are going to be allowed to be sold they should not be sold in the same package. Depending on what you need the medicine for if they are packaged together this may lead to abuse of the product and that would clearly not be the purpose of the rulemaking. I don't agree with the being sold in the same package but if it was to do so I believe that it would be inappropriate if the packaging didn't clearly state the differences between the two different levels of drugs that would be contained inside the packaging. I also think that it would be inappropriate to package the two drugs if they had side effects that may be different depending on the dosage cause I feel that this would also lead to abuse.</3: 8.2, 8.9>

<4: 4.1, 8.2, 8.6.2>Overall I don't believe that drugs should be packaged together or that there should be higher doses that could be taken without a practitioner to determine the level of drug that is needed. Drugs are a serious problem in the United States and if the FDA loosens up the restrictions on higher dosage drugs then this will lead to a more abusive situation in regards to prescription and OTC drugs. Also I do believe that if this was done it will take away some of the professionalism from the health professionals and people will self medicate without the proper knowledge and this could lead to serious side affects. Clearly there needs to be a more clear interpretation of the section 503(b) so that it is more effective clear and most importantly that it will have safe rules for people. If this can be done the FDA has done their job on this matter.</4: 4.1, 8.2, 8.6.2>

COMMENT NUMBER - 2005N-0345-EC132

2005N-0345-EC132 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Peters, Jeanette

2005N-0345-EC132 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.3, 3.8.5>It is logical to update codes to include provisions for the simultaneous marketing and

selling prescription and OTC drugs. This is especially clear in a case where age is the deciding factor: adult users should not have road blocks put in their way when they seek to buy safe, legal medication. Consider: we do not need a prescription or other form of authorization to buy alcohol, though its selling is age-based. In the case of medication, the issue of accessibility can be much more critical: patients rarely have a chance to get a prescription over the weekend, for example, and some medications are heavily time-sensitive.</1: 3.8.3, 3.8.5>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

It is logical to update codes to include provisions for the simultaneous marketing and selling prescription and OTC drugs. This is especially clear in a case where age is the deciding factor: adult users should not have road blocks put in their way when they seek to buy safe, legal medication. Consider: we do not need a prescription or other form of authorization to buy alcohol, though its selling is age-based. In the case of medication, the issue of accessibility can be much more critical: patients rarely have a chance to get a prescription over the weekend, for example, and some medications are heavily time-sensitive.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1, 4.3.4>Significant confusion exists, especially in light of concerns that section 503(b)'s criteria may unfairly and negatively impact accessibility to legal and scientifically-validated medications.</2: 4.1, 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 3.7.1, 5.1, 5.3.1>Rulemaking, in accordance with ADA section 553, is needed as a matter of public health via increasing accessibility to safe, legal medications and removing the unfair burdens currently upon consumers.</3: 3.7.1, 5.1, 5.3.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.6.3>Analogously to the ATF and tobacco/alcohol regulations, a limitation on availability to a subpopulation could be enforced.</4: 6.6.3>

B. If it could, would it be able to do so as a practical matter and, if so, how?

<5: 6.6.3, 7.4.4, 7.4.6>Inasmuch as any other law may be practically enforced, the FDA would be able to enforce regulation concerning availability to a subpopulation. As with other agencies' laws, a large pool of enforcement possibilities exist. On the front end, consumer regulations can require that customers prove their age, as with alcohol and tobacco purchases. On the back end, penalties including but not limited to fines and eventual closure of offenders' operations have been used to enforce agency laws.</5: 6.6.3, 7.4.4, 7.4.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.6.2, 8.6.4>Assuming that it is legal to market the same active ingredient in both a prescription and OTC product, product labeling remains an issue very distinct from the allowing for availability of a product to a subpopulation. The FDA should seek a removal of barriers on consumers that impede their access to safe, legal medications, especially when these medication are time-sensitive in nature. While diverse labeling costs the manufacturer somewhat more, labeling OTC products differently from prescription products when both are simultaneously available will facilitate in avoiding customer and seller confusion, and allow for easier enforcement of regulations concerning sale to a subpopulation.</6: 8.6.2, 8.6.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 8.5>As discussed previously, ease of enforcement and concerns about vendor and/or customer confusion would warrant selling the products under different labeling.</7: 8.5>

COMMENT NUMBER - 2005N-0345-EC135

2005N-0345-EC135 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Severance, Peter

2005N-0345-EC135 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.8>No. Why are you complicating this? The FDA is supposed to regulate drugs based on clinical evidence, not make social policy.</1: 3.2, 3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Is this a mistake? You have two Issue Areas marked 1 A -- with slightly different wording...both of which seem to be grammatically incorrect and/or contain spelling errors?

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1, 4.3.4>Yes. Unfortunately, it is the FDA which has created the confusion. If there is clinical evidence that a significant portion of the target population may be adversely affected by dispensation under non-prescription protocols, then the drug should only be dispensed as a prescription drug.</2: 4.1, 4.3.4>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.2>No</3: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.5.4>Irrelevant. The FDA would be creating an overly-complicated system of enforcement.</4: 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.5.4>Irrelevant. The FDA would be creating an overly-complicated system of enforcement. </5: 7.5.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

Irrelevant. The FDA would be creating an overly-complicated system of enforcement.

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

Irrelevant. The FDA would be creating an overly-complicated system of enforcement.

GENERAL

GENERAL

<6: 3.8.4, 3.8.7>You should not be growing a government bureaucracy in order to achieve someone's idea of social policy. If a drug carries clinically proven risks to the affected population, it should be dispensed only by prescription. Period. End of story. Don't play games with drug regulation. The agency's credibility is already on shakey ground.</6: 3.8.4, 3.8.7>

COMMENT NUMBER - 2005N-0345-EC13643

2005N-0345-EC13643 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Kwak, Eugene

2005N-0345-EC13643 - TEXT

GENERAL

see attachment

2005N-0345-EC13643-Attach-33.TXT

ATTACHMENT:

Eugene Kwak
3078 Devauden CT
Duluth, GA 30096

Comment on Notice of Proposed Rulemaking

FDA

Docket #: 2005N - 0345

The benefits that may arise from selling some prescription only medicines over-the-counter as well to the end-user consumer are greater than any possible affliction it may cause upon society. For instance it allows for better accessibility, raised competition amongst businesses, and promotes the idea of free choice and personal accountability. There are, however, many possible drawbacks if this were to happen, but the benefit makes it a greater need.

<1: 3.9.1>One may argue that if pharmaceuticals were placed as an over-the-counter drug, it would allow abusers to gain easier access to a substance. Well, naturally the FDA would be drawing a line as to what is and what isn't going to be sold in both market areas. Drugs such as hydrocodone, a powerful painkiller and opiate, would not move from its prescription-only status, naturally due to its potency and highly abusive properties. There are already drugs being in both areas, even today. Acetaminophen, Tylenol's active ingredient, is sold in its original non-prescription form and in prescription strength. What is the difference between the two and why is Tylenol given such treatment? Acetaminophen, unlike hydrocodone, is not highly addictive and doesn't have a likelihood of being abused. Also, the non-prescription form is roughly one-third the amount of acetaminophen per pill. So, if we were to avoid the problem of abuse, then a line should be drawn as to what can and what cannot be moved to the shelves.</1: 3.9.1>

<2: 3.8.3>Accessibility would be such an advantage to almost every person there is. Not everyone can go to a doctor at 12am midnight to get a prescription for some powerful nasal decongestant when that person needs it. If the prescription strength nasal decongestant was moved down to the over-the-counter level, it would be available to the person at all times. Also, the less fortunate low-income families would be allowed greater access to medicines as well. Doctor fees are expensive and many of the country's poor are unable to pay these fees and receive proper treatment or medication for their problems, simply due to

being unable to pay the costs. If some medicines moved over-the-counter, even these people would benefit for having access to the drugs without the hefty doctor fee.

Moving medication to the shelves can also heighten the level of business competition. It would increase the market size that these companies can sell to. This would make more companies strive harder to reach this market at even further horizons. An initial effect and end effect would be the lowering of costs for medications for the end-user consumer as well. Also, if companies are doing better here, that shows in the status of the country's economy as a whole, so I cannot see where we are being hurt on this matter by going through with this process.</2: 3.8.3>

<3: 3.8.3>America's governing principle is that of liberty, which is also being able to choose and take accountability and responsibility in your actions and the choices you decide to make. So how would moving medicines over-the-counter promote this ideology? Well, if the people aren't able to choose what they can and cannot do for themselves, then isn't that a lack of liberty? Currently, the liability and accountability, for the use and sales of prescription medicines is placed largely on the doctors who prescribe them. If they were to prescribe a patient the wrong medicine, then that doctor would be facing some form of punitive measure. If people were allowed to choose for themselves what is best for them, they would simply be taking liability and responsibility for their own actions. This is the first fundamental step to liberty. People should be able to choose whether or not to take some medicines if they felt the need to be treated.</3: 3.8.3>

<4: 3.8.3>What should the FDA do? I believe the FDA should follow through with this rule, but make sure there is some form the threshold in place to insure that highly abusive substances, such as hydrocodone, be kept out of the open market and behind the counter as it is today. However, going through with the process would enhance accessibility of the medicines to anyone in need, business competition would be heightened, the idea of personal liberty and accountability would be nothing but promoted to a greater degree. These are but a few of the reasons as to why the FDA should follow through with this rule.</4: 3.8.3>

COMMENT NUMBER - 2005N-0345-EC13845

2005N-0345-EC13845 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Rahl, Michael

2005N-0345-EC13845 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

There is sufficient reason for the FDA to initiate a rulemaking to codify its interpretation of Section

503(b) as to when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product because the lack of legislation has created interpretations that have had some success but whose scope is not broad enough to address concerns that arise outside of their margins that focus primarily on the safety to the consumer. In the absence of such codification we find misspent FDA resources, delay on the marketing of certain drugs, a consequent profit loss by pharmacies and pharmaceutical companies, and specific needs of members of our society have been put on hold while the FDA balks in this decision making process. In codifying the aforementioned interpretation of section 503(b), the FDA could maximize its procedural efficiency and increase its service level output to the nation which would generate broader levels of satisfaction to society's needs.

2005N-0345-EC13845-Attach-34.TXT

2005N-0345-EC13845-Attach-35.DOC

ATTACHMENT:

Michael Rahl
7931 Roswell Road Apt. F
Atlanta, GA 30350
Food and Drug Administration
Docket: 2005N-0345

<1: 3.1, 3.8.1>There is sufficient reason for the FDA to initiate a rulemaking to codify its interpretation of Section 503(b) as to when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product because the lack of legislation has created interpretations that have had some success but whose scope is not broad enough to address concerns that arise outside of their margins that focus primarily on the safety to the consumer. In the absence of such codification we find misspent FDA resources, delay on the marketing of certain drugs, a consequent profit loss by pharmacies and pharmaceutical companies, and specific needs of members of our society have been put on hold while the FDA balks in this decision making process. In codifying the aforementioned interpretation of section 503(b), the FDA could maximize its procedural efficiency and increase its service level output to the nation which would generate broader levels of satisfaction to society's needs.</1: 3.1, 3.8.1>

<2: 3.9.1>The FDA has deemed it appropriate to market the active ingredient in both formats under four conditions: indication, strength, form of dosage, and the manner of product administration. The impetus for these four criteria and the permission to market dual forms of an active ingredient that has varying formula constitutions have been based on the relative safety of the individual that is using the products. A drug such as Meclizine, which in its prescription form is used to treat vertigo and nausea in its OTC form, was tested and deemed to be safe for public consumption in either of the two forms. If one were to examine several of the other drugs that have been evaluated in a similar fashion by the FDA, they would witness the development of a theme which binds this accepted category together: these drugs are not ethically, morally, or normatively questionable to society. </2: 3.9.1>

<3: 1.2>Why should social values be mentioned at all? There are new classes of drugs that are emerging whose utilization challenges the moral consciousness of an influential and conservative sector of America. A case in point is the drug Levonorgestrel, or Plan B, that was created by Barr Laboratories. After The Center for Drug Evaluation and Research (CDER) completed its review of Barr's amended application, it scientifically concluded that the drug was safe to use as an OTC product for women who are 17 years of age and older. Still the FDA is unable to reach a decision on the acceptability of the application because it contends that it has never determined whether a drug may be simultaneously prescription and OTC based on the factor of age, it questions how the an age minimum could be enforced,

and it has not dealt with the issue of versions of the same active ingredient being marketed in a single package. These newly emergent issues do pose as a legitimate policy oriented challenge to the FDA, but it cavaliers this as a façade because it is overwhelmed by the extraneous pressure exerted on it from morally conservative groups that have political and economic clout in the United States. </3: 1.2>

<4: 3.8.1>In codifying its interpretation of section 503(b), the FDA will need to include direct and coherent policy statements that diminish the incomprehensive rhetoric that it currently ascribes to its decision making in section 503(b). The agency should present a multifaceted application that is capable of addressing the contemporary drug product needs of subpopulations such as young adults, that advises pharmaceutical companies of their responsibilities to the FDA in receiving its approval for the less mainstream drug products, that prescribes to the pharmacies and doctors exact procedures as to how and to whom they will distribute these products, and the FDA should refine and make available to anyone concerned their own internal procedures and time frames under which occur the approval processes for such drugs. </4: 3.8.1>

<5: 7.4.4>In the previous section one of the numerous recommendations touched upon the issue of distribution of medication. This is an issue of key importance that might very well merit more consideration and analysis than the issue of codification. Several questions that will now be addressed have arisen around this precept that pertain to dispensing the products to subpopulations as prescriptions only, enforcing this restriction, and the practicality of doing so.

The FDA has to distinguish between the prospective populations that will be purchasing the drug products by delineating them as minors from adults. Let the tobacco sales legislation be a framework for which the sale of drug products will follow suit. If the individuals are at least eighteen years of age, they should be allowed to purchase the same active ingredient as a prescription or as an OTC drug free of age restriction guidelines. If the individuals are minors, they should not be prohibited to purchase the active ingredient in its OTC form. They must be restricted to the active ingredient on a prescription only basis whereby they will be required to first have the consent of their legal guardian and if they cannot obtain this, then they may purchase the drug independently provided that the licensed professional has made a valid attempt to notify their guardian to make them aware of the situation.</5: 7.4.4>

<6: 7.3.2, 7.5.3>The second condition has limitations but it is a proposal that functions on a basis that can negotiate, head on and realistically, the challenges that confront the FDA and those that are charged with prescribing and selling prescription drugs. An inevitable reality is that subpopulations will need reproductive and other nontraditional drugs. Another issue is that there might be circumstances where it is impossible to directly contact the legal guardian for consent or to inform them of what is transpiring. Finally, if an individual needs a drug product, and this will hold true especially in cases of emergency for the individual, there is no amount of legislation or enforcement that can prevent the individual from obtaining what they want. This would suggest that the FDA limit its attempts at enforcement and allocate its financial resources to education which proves to be more effective than policing. Reference the "War on Drugs" for a more accurate presentation of how the combatant attitude is ineffective as we still have the largest drug epidemic in the world. To reiterate, the second principle that applies to minors requires a minimal awareness contact by the licensed professional to the legal guardian and the drug must be on a prescribed basis. This idea is essential because in effect it says: "As a morally responsible society, we recognize that we have an obligation to regulate the privilege of the subpopulation purchasing these drug products, absolute control is not a possibility and is counterproductive to our agenda, and we will not endanger their wellbeing nor deny them of their civil liberties by some authoritarian stranglehold." </6: 7.3.2, 7.5.3>

<7: 3.8.1>If the FDA were to formulate policies based on the general principles mentioned here in the codification of its interpretations and in the principles of regulatory distribution, if it were to align itself to

the needs of a more contemporary America, and if it could stand firm and make decisions in the face of its opposition, it would function as a far more effective federal agency. </7: 3.8.1>

COMMENT NUMBER - 2005N-0345-EC13851

2005N-0345-EC13851 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Nguyen, Marie

2005N-0345-EC13851 - TEXT

GENERAL

For the action of the advance notice or proposed rulemaking, a request to the public for comments on the issue confronting the FDA whether or not to initiate a rulemaking to codify its interpretation of section 503[b] of the Federal Food, Drug and Cosmetic Act, regarding when an active ingredient may be simultaneously marketed in both prescription drug product and an over-the-counter drug product. With that question, being proposed, other minor concerns arise from this proposal. <1: 3.1>Addressed in this comment are the reasons why I believe there should be an imitative in rulemaking and following are the comments on certain concerns. </1: 3.1>

<2: 3.8.1>The FDA should initiate a rulemaking to codify its interpretation of section 503[b] of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product. With the dichotomous description of the prescription drug and OTC, there have been problems with the interpretation of section 503[b]. In initiating this rulemaking, the benefits would include a simple interpretation of the prescription drug and the OTC drug's meaning, and a more absolute guideline for the FDA to use to regulate the drugs.</2: 3.8.1> <3: 4.1>There is significant confusion in regarding the FDA's interpretation of section 503[b].</3: 4.1> <4: 4.3.3>The act does not define OTC drug. This has caused the confusion over what can be marketed and hence the debate over which drug can be available in both fields.</4: 4.3.3>

<5: 5.1, 5.3.2>A rulemaking would be the key to help dissolve the confusing language in section 503[b] of the act. With an adjustment and a revision to the language brought on by the rulemaking, this would allow an easier interpretation of the meaning of what constitutes a prescription drug or an OTC drug. </5: 5.1, 5.3.2>

<6: 6.1>The FDA would be able to enforce the limitation as a matter of law to the sale of OTC product to a subpopulation.</6: 6.1> <7: 6.6.3>Anything can be enforced with the use of law. A clear example is the controversy concerning Plan B. There is a concern regarding the ability to regulate the purchase of Plan B if made OTC to the subpopulation, which would be women under the age of 16. The regulation still allows for Plan B to be available, but if you are of the subpopulation, the purchase would be through prescription rather than OTC. This enforcement would be similar to cigarette sales.</7: 6.6.3> <8: 7.1>The enforcement can be a practical matter.</8: 7.1> <9: 7.4.4>It would be as said above, similar to cigarette sales. There would be an enforcement such as age limits to a certain OTC drug. Purchases would be prohibited for OTC drug if that individual does not meet the limit. </9: 7.4.4><10: 7.4.5>Other enforcement would be setting heavy fines or penalties to deter purchasers to purchase OTC drugs if they

do not meet those limitations. </10: 7.4.5>

<11: 8.3.4>If the prescription and OTC drug were able to be marketed in the same label, I believe that there is no harm and that it can be legally be sold with the same package. Furthermore, the package would have to display accurate information of the drug, such as the dosage or strength of the drug. </11: 8.3.4>

COMMENT NUMBER - 2005N-0345-EC141

2005N-0345-EC141 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Connors, Meaghan

2005N-0345-EC141 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes. Doing so would move this prolonged, highly politicized process.</1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes, as answered above.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Confusion at best, disillusionment at worst.</2: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.1>Hopefully.</3: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.6.3>Absolutely, a prescription would not be necessary. No prescription is required for cigarettes or alcohol or lottery tickets, and those items are available only to specific populations.</4: 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 1.2.1>Individuals over the age of 16 should be able to freely purchase this safe, important product. This product will undoubtedly prevent countless abortions and medical complications.</5: 1.2.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.4.1>If they are in fact the same product with the same specifications, I don't see the relevance of this question.</6: 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.3>This seems to be an unnecessary question; perhaps any implications by having the product sold in a single package should be further explicated by the FDA, as this is the FDA's area of expertise.</7: 9.3>

GENERAL

GENERAL

<8: 1.2.1>I am grateful to Dr. Woods for taking a stand. Commissioner Crawford's latest 'action' on Plan B, which is actually a lack of action, is most disconcerting and sullies the FDA's reputation, in my opinion.</8: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC14261

2005N-0345-EC14261 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Owens, B

2005N-0345-EC14261 - TEXT

GENERAL

<1: 4.3.3>This submission is in response to FDA Advanced notice of proposed rulemaking of Docket number 2005N-0345. It is quite apparent that the issue that is in contention now has obviously been one of great controversy for quite some time now. Upon submission of the Federal Food, Drug, and Cosmetic Act, there was already confusion as to which drugs were acceptable for public use without the supervision of a licensed medical practitioner and which drugs were not. Section 503(b), which was enacted in 1951, was the attempt to remedy the aforementioned confusion. The apparent problem with section 503(b) is

that it attempts to regulate any product which we now term as an OTC drug, but in doing so fails to give a clear definition of the term. In fact, the term OTC is missing from the section altogether. In solving the problem and answering the questions put forth for submission, the most obvious remedy comes in the form of precedent. The key question is whether or not an active ingredient can be simultaneously marketed as both prescription drug and OTC. Several drugs that have been released over the years have done so, but only when a meaningful difference exists between the two products, (i.e. ibuprofen given at 400+mg for arthritis but given at 400mg and below for aches and pains). </1: 4.3.3><2: 6.5.2>The FDA has yet to approve a drug for both OTC sale for one population and prescription in another population, but the biggest question is why? Obviously there are legal issues associated with such a drastic shift in the policy of public administration of drugs, and it should be apparent for one simple fact: time. It is apparent because of the length of time that this issue has been debated. Section 503(b) was introduced in 1951, and has remained the standard for the last 50+ years not because the policy was written so well and works so effectively, but because it is simply not possible to accomplish the aforementioned task of dual marketing to OTC and prescription population on the basis of age alone.</2: 6.5.2>

<3: 6.5.2>The most prominent advocate of this theory is the Plan B drug. The drug was proposed for marketing to both OTC and prescription patrons based on age restrictions. The makers of Plan B want to make the drug available for OTC sale to women age 16 and older, but simultaneously make it available to women under the age of 16 by prescription only. The problem with this is that there is not significant evidence in the research presented by the drug maker to show that women under the age of 16 can safely use the drug without professional supervision of a practitioner licensed by law to administer the drug. Also, it is furthermore obvious that this burden of proof is too great for the drug maker to handle, due not only to the fact that new studies of the drug have not been released since the initial submission of the new drug application on April 16, 2003, but also to the significant fact that a follow up proposal was made more than 30 times over the course of about a year.

The burden of proof is too great to be tackled at this time. Precedent has made it more than obvious that dual marketing of a drug on the basis of a difference that cannot be shown as being a meaningful bar of separation is not possible. It could not legally be done due to the fact that any active ingredient administered to one population by prescription and to another population OTC without meaningful difference proven by research would be viewed as discrimination. Therefore sale of any drug to one individual over another without a proven valid basis is illegal. </3: 6.5.2>

<4: 8.1, 8.4.1>Furthermore, the question of whether or not the drug should be marketed in the same packaging OTC and by prescription is technically a waste of time. . If a prescription box of an active ingredient was given to a patient, then they acquired an OTC box of the same active ingredient, there would be no meaningful difference in the patient choosing to use one box over the other. Having two packages for the same item is not necessary.</4: 8.1, 8.4.1>

COMMENT NUMBER - 2005N-0345-EC14388

2005N-0345-EC14388 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Soriano, Lauren

2005N-0345-EC14388 - TEXT

GENERAL

"See Attachment"

2005N-0345-EC14388-Attach-37.TXT

ATTACHMENT:

Lauren Soriano
1257 Raleigh Way
Lawrenceville, GA 30043

In response to dual approval for prescription and over-the-counter pharmaceuticals, Docket No. 2005N-0345:

<1: 2.2>Since the Food and Drug Administration cannot decide whether or not to approve the selling of Plan B as both a prescription and over-the-counter drug, the action of taking an advanced notice of proposed rulemaking is a good idea. If any agency is having problems with deciding whether or not to initiate rulemaking, an ANPRM should be taken immediately. However, the Food and Drug Administration does have evidence and recommendation from the FDA staff regarding the approval of the drug, which makes the ANPRM seem pointless. But since the FDA commissioner, Lester M. Crawford, seems to take the politics behind the Plan B drug into account, an action should take place because neither the staff of the agency, such as Susan Wood, nor the public wants any more delay with rulemaking. Seeing that the Plan B, emergency contraceptive, is such a sensitive issue, the FDA should look and take every aspect into account due to the consequences one decision could have on a lot of people, especially women.</1: 2.2>

<2: 3.1, 3.8.3>The Food and Drug Administration should initiate rulemaking in order to see if an active ingredient can be simultaneously marketed in both a prescription and over-the-counter drug. However, there has to be stipulations on the over-the-counter drug because if the same active ingredient is in both the prescription product and the over-the-counter product, then what would be the purpose of a prescription drug. People would just flock to the OTC drug, since it is so accessible. </2: 3.1, 3.8.3> <3: 5.3.2>Also, Section 503(b), the active ingredient segment, should be more clear and cohesive so that there is no confusion regarding the interpretation of that section. The only way to ensure that section 503(b) would change is if rulemaking is put into affect. No drastic change in the section would be taken seriously without rulemaking approved by the FDA. </3: 5.3.2> <4: 3.9.1, 6.3.4>If the FDA did approve of the selling of Plan B as both a prescription and over the counter drug, they would have to make stipulations. Limiting the sale to a particular subpopulation should be one of the stipulations that the over-the-counter product should have. Just as other OTC products like flu medicine are sold, Plan B should be sold to women age eighteen years or older and remain as a prescription for others that are under the age of eighteen years old. Much of the controversy lies on whether or not to market the drug to women sixteen years or older, but seeing how women are not even close to being fully developed at age sixteen, the drug should not be available to them because they are more likely to use the drug improperly. </4: 3.9.1, 6.3.4>

<5: 7.3.1.1>Another way to regulate the distribution of Plan B is to put strict rules behind the buying and selling of the over-the-counter product, and then women would have to take the drug more seriously.</5: 7.3.1.1> <6: 6.6.3>The agency should use the same process of enforcement as tobacco products because there are strict rules and regulations that distributors have to enforce or they would be out of business. If the Food and Drug Administration uses the same plan of action with the over-the-counter product of Plan

B, then more people will understand the seriousness of the drug.</6: 6.6.3>

<7: 7.4.6, 8.6.4>Furthermore, one stipulation for the over-the-counter drug is not enough. If girls really needed the emergency contraceptive, they would find ways to get the OTC product even if their not eighteen years old. The over-the-counter product should be marketed in a single package and at a higher price than the regular distribution. Girls would find it harder to get an over-the-counter product if a single package costs were not within their price range. It would also be harder for women to take too many pills or overdoes, if the Plan B drug is sold in single packages. However, the prescription product should not be as expensive as the over-the-counter product and it does not have to be sold in single packages. If women are prescribed the emergency contraceptive from a licensed doctor or practitioner then they should not go through the hassle that those who buy the over-the-counter product have to go through.</7: 7.4.6, 8.6.4>

<8: 2.1>Lester M. Crawford, the FDA Commissioner, has to make a major decision of whether or not to initiate rulemaking for the emergency contraceptive. He may have to weigh the political aspects but that should not be his major focus, instead he should focus more on the scientific and clinical evidence. If the Plan B, emergency contraceptive, really does cause more harm than help, then of course the drug should stay as a prescription, but if the drug does not show any proven evidence of harming those who consume the pill, then he should initiate rulemaking. He may however, have to take precautionary steps in the process by limiting sale of the over-the-counter product to a certain age group and selling the drug in single packages. </8: 2.1>

COMMENT NUMBER - 2005N-0345-EC14491

2005N-0345-EC14491 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Corlette, Chauncey

2005N-0345-EC14491 - TEXT

GENERAL

See Attachment

2005N-0345-EC14491-Attach-39.DOC

ATTACHMENT:

<1: 2.2>The process of proposed rulemaking and allowing the public to provide their input on key factors of today's important regulatory and policy questions and is a great privilege to have here in America. The trends of the nation are constantly changing and with the constant growth in the fields of medicine, technology, agriculture and so many more. There is a new burden placed on governmental agencies to make rules that apply to this growing nation.</1: 2.2> There are several questions that have been raised during the subject of allowing the plan B pill to the over the counter market, those questions were;

1) Can age be used as a criterion on which we decide whether a drug should be prescription or over-the-

counter, as has been proposed in this case?

2) Can the prescription and over-the-counter version of the same drug be marketed in a single package?

3) In addition, if we do use age as the only criterion on which we decide whether a drug is sold as a prescription product, or an over-the-counter product, how, as a practical matter, would such a limitation be enforced?

4) In the Plan B application, we are grappling not with the same question but with a different question: whether we can have the same molecule exist as both a prescription and over-the-counter product for the SAME indication?

5) And if FDA were to attempt to limit sale of an over-the-counter product to a particular sub population, would FDA be able to enforce such a limitation as matter of law, and could it do so as practical matter and then how?

This paper will answer the listed questions, but not in the listed order.

The question was posed Question #2) Can the prescription and over-the-counter version of the same drug be marketed in a single package? <2: 8.1, 8.3.1>The prescription and the over-the-counter version of the same drug can be used and marketed in the same package only if the product is labeled properly. The FDA has very rigid rules for labeling for over-the counter drugs. The prescription and the over-the-counter version would need to adhere to the rigid rules of labeling; Drug Facts, Active ingredient, Purpose, Use(s), Warning, Do not use , Ask a doctor before use if you have, Ask a doctor or pharmacist before use if you are ,When using this product, Stop use and ask a doctor if ,Pregnancy/breast-feeding warning, Keep out of reach of children/Accidental overdose warnings, Direction , Other information, Inactive ingredients, and Question(Optional) and also have a statement on the package addressing the fact that the drug's intended use is safe for women 17 years of age and older without a prescription and for younger females they would require a licensed physician to write a prescription for the drug.</2: 8.1, 8.3.1>

The question of having the same packaging for a drug leads to Question # 4) whether we can have the same molecule exist as both a prescription and over-the-counter product for the SAME indication? <3: 3.9.1, 6.3.4>Currently the FDA allows the same molecule to be sold as a prescription product and an over-the-counter product, but there is a meaningful difference in the way the two products are used. Understanding that and the previous precedent was if a drug was unsafe for any public it would be classified as a prescription drug. The precedent would have to change, to serve the majority of the population it is purposed for, the majority of women would be able to benefit from this drug and be unsafe for a small sub-population. The drug will have a meaningful difference in being safe and appropriate for women 17 years of age and older. This Plan B drug is relatively safe for the majority of the public which is women 17 years of age and older the sub-population of minors until the age of 16 would be the only ones that the drug use would be inappropriate for without the consent of a doctor.</3: 3.9.1, 6.3.4>

Since age is a major issue with the use of the plan B drug it relates to Question # 1) <4: 6.3.4, 6.6.3>Can age be used as a criterion on which we decide whether a drug should be prescription or over-the-counter, as has been proposed in this case? Yes, there is already a precedent of the government regulating items based on age regarding alcohol and cigarettes. In today's markets there are controlled substances and items that have regulations based on age. The examples of which are alcohol and cigarettes both have had age limits set by the federal government. Alcohol and cigarettes, both are products that are sold publicly with only burden to prove, which is age. The reason of doing so is that some items take a certain maturity that hopefully comes with age to govern whether one should use the item and the amount of the item that

one should use. </4: 6.3.4, 6.6.3>

The following questions ask how the age limit would be enforced in practical ways. Question # 3) In addition, if we do use age as the only criterion on which we decide whether a drug is sold as a prescription product, or an over-the-counter product, how, as a practical matter, would such a limitation be enforced? And Question # 5) And if FDA were to attempt to limit sale of an over-the-counter product to a particular sub population, would FDA be able to enforce such a limitation as matter of law, and could it do so as practical matter and then how?<5: 3.8.2, 7.4.1> Ways to enforce the limitation of age would to sell the drug behind the counter. The creation of behind the counter option in the United States would alleviate safety concerns between the availability of over the counter drugs to the public without any kind of professional conciliator. Pharmacists would be able not only limit the amount of drugs and keep track of buyers but also to provide counseling prior to administering the drug. The matter of law is making it mandatory for the drug to be sold behind the counter, having the pharmacist describe the drug and its side effects, having the persons who purchase the drug to agree to sign for it and present identification with their age on it. This would enforce the regulations for being able to sell the drug. There is a growing need for behind the counter drugs. For example; There has already been a push to have drugs that contain pseudoephedrine (ex. Sudafed), as their active ingredient, behind the counter because they are used to make crystal methamphetamine, an illegal drug. Having behind the counter drugs would allow effective medications that are relatively safe to be used in proper ways and available to the public. </5: 3.8.2, 7.4.1>

<6: 1.1>In a changing and growing society with a new self- care movement becoming more and more popular, the FDA is faced with a challenge to set new precedents to serve the majority of people instead of small sub-populations also to incorporate measures of safety by introducing new safe guards like behind the counter drugs. The changes would not only effect the decision of allowing the plan B drug to be introduced to the over-the counter market but many other drugs to maintain the health of United States citizens and allow drugs that are safe and effective to serve their purpose.</6: 1.1>

COMMENT NUMBER - 2005N-0345-EC14598

2005N-0345-EC14598 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Garden, Nicole

2005N-0345-EC14598 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.1, 3.3.3>Part of the reason the birth control pill is marketed as a prescription and not an over-the-counter product is because of the many dosages, forms, and active ingredients it comes available in,

which require dosing by a medical professional such as a physician, and monitoring to ensure effectiveness.

Because the emergency contraceptive is a standardized one-time dose, these factors do not come into play.</1: 1.2.1, 3.3.3>

GENERAL

GENERAL

<2: 1.2.1>Many of the reasons surrounding blocking the much-lauded Emergency Contraceptive Pill are related to Right-To-Life movements and the anti-choice agenda. These individuals in groups attempt to restrict the personal freedoms of women using proven, safe, effective birth control methods such as the Pill and Plan B, in the hopes of producing an unwanted pregnancy. Morally, these groups claim to be 'pro-life', but a lack of availability of these products (and the incredible cost to the state and otherwise of surgical abortions that must then be performed, which many low-income women cannot afford, when they could have afforded Plan B over the counter,) results in a high birth rate among impoverished women, further increasing loads on the social safety net, further impoverishing these communities as a whole, and guaranteeing an all-around poor quality of life for these children and their mothers. Approving Plan B for use over the counter would help drive down the astonishing abortion rate. Even the anti-choice movement cannot argue with a dropping abortion rate.</2: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC146

2005N-0345-EC146 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Steele, Robert

2005N-0345-EC146 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.3.3>If 503(b) does not allow for the simultaneous marketing of a drug based on age or other factors, it should be amended. Precedences exist for such substances such as alcohol and tobacco products to be marketed based on age. The purchase of other non-ingestible items are certainly marketed by age, mental competency, criminal convictions, etc.. This is not a difficult and/or complexed procedure.</1: 3.1, 3.3.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 3.1>This too is not a difficult or complexed task. If an amendment is - based on changing circumstances warrants - obvious and needed, then the change(s) should be made based on procedural issues and not politics or ideological leanings.</2: 3.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

I do not have sufficient insight to warrant commenting on this issue.

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.1, 5.5>Certainly greater clarification and less ambiguity is always a plus. 503(b) does not have to be fit for all issues, amendments - with future consolidation - are appropriate.</3: 5.1, 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2, 6.5.1>"Enforcement" should not be the FDA's primary responsibility in these cases - rulemaking is.</4: 6.2, 6.5.1> <5: 7.3.1.4, 7.4.1>Rules governing the OTC and prescription sale of certain drugs are guidelines for the distributors and retailers, it is they who must determine how this will occur. If they fail, the FDA has grounds for action, possibly to cease distribution until remedial action is taken to resolve the problem. However, I doubt that this would be necessary since manufacturers benefit a lot more from sales than from a loss of their ability to sell. OTC and prescription drugs can be simultaneously sold from behind the counter to eligible customers.</5: 7.3.1.4, 7.4.1> <6: 6.2, 6.5.1>At issue is whether the eligible customer distributes the drug to his or her child - as long as the drug is deemed safe - this is outside of the realm of FDA jurisdiction.</6: 6.2, 6.5.1>

B. If it could, would it be able to do so as a practical matter and, if so, how?

<7: 7.1, 7.4.1>Very simply. By distribution of the drug from the pharmacist's store room, after he or she has determined that the buyer is eligible to make the purchase. This is already in effect for many products being sold in our pharmacies.</7: 7.1, 7.4.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 6.6.3, 8.1>Of course they can. The customer is buying an OTC product which has a buyer's stipulation. Think tobacco products and alcohol. If a doctor prescribes the use of the drug (which is commonly OTC for a certain age group and above) than handing the customer the same product in the same package (accompanied by the pharmacist's normal instructions and packing) is not a mind bending issue.</8: 6.6.3, 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be

inappropriate to do so?

<9: 9.1.1>It would be inappropriate if the sale was made to an ineligible customer or an ineligible (say with age restrictions) customer who does not have a valid doctor's prescription. If it were possible for a person of authority to "prescribe/authorize" the sale of cigarettes to a minor, simply the seller would hand them the Marlboro of their choice.</9: 9.1.1>

GENERAL

GENERAL

<10: 1.2.1, 2.1>I'm responding to these questions as a result of recent FDA decisions regarding Plan B. The issue here really isn't how do we make sales to authorized buyers only... there are simple and obvious answers to this procedural question... the issue really feels like personal ideologies and/or political-ideology. The scientific and health related facts seem to be in - the conclusions (at this point in time)are that Plan B post-intercourse anti-conceptual drugs are safe. The FDA's unbiased ruling(s) should track with the scientific evidence unless otherwise refuted by competent counter-conclusions. Birth control is a personal decision only. As much as certain fundamentalist groups would like to dictate their beliefs on to others, that is unacceptable, as sure as I am that rules made contrary to their beliefs would be unacceptable to them. The FDA needs to follow the guidances provided by their doctors and researchers and shy away from ideological pressures coming from any direction.</10: 1.2.1, 2.1>

COMMENT NUMBER - 2005N-0345-EC147

2005N-0345-EC147 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Loomis, Shirley

2005N-0345-EC147 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes, provided the drug is safe for distribution.</1: 3.1> <2: 1.2.1>Items such as Plan B have an impact on "quality of life," and if someone under 16 is seeking it, they are either already a child at risk for whom life is very challenging, or for some reason they are not in a position of being able to seek the assistance of their parents. As a parent, I want my children to always be able to come to me but more importantly I want them to be able to get what they need in a crisis through whatever means in available.</2: 1.2.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

See above.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1>There's significant confusion regarding all regulations. It's what keeps your lawyers working.</3: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.2>No. You will not dispel confusion. You may just simply be better able to serve the American public.</4: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.2, 6.7, 7.5.3>No you would not necessarily be able to enforce it but there are many unenforceable laws. You would however be putting forth a best efforts practice.</5: 6.2, 6.7, 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

See above.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2, 8.6.2>They should be packaged differently to help alleviate confusion for those responsible for handling them.</6: 8.2, 8.6.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

See above.

GENERAL

GENERAL

See above.

COMMENT NUMBER - 2005N-0345-EC148

2005N-0345-EC148 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Scott, Cindy

2005N-0345-EC148 - TEXT

Issue Areas/Comments

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

THIS SEEMS LIKE BS TO ME. <1: 3.9.1, 8.1, 8.8>I ALREADY RECEIVE CLARITIN (LORATADINE) 10 MG BOTH VIA PRESCRIPTION OR I CAN BUY IT OVER THE COUNTER. I DON'T THINK THERE IS A PROBLEM WITH SELLING THE PRODUCT IN THE SAME PACKAGE.</1: 3.9.1, 8.1, 8.8>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<2: 9.2.2>NONE</2: 9.2.2>

GENERAL

GENERAL

<3: 1.2.1, 2.1>I find it to be an extreme disservice to women and shame on the FDA that the Plan B pill is not available over the counter. Women - particularly adult women in the United States should have had access to this a long time ago. Please STOP ALL THIS BEAURACRATIC BS AND approve this reproductive health care option ASAP. </3: 1.2.1, 2.1>

sincerely,
Cindy Scott

COMMENT NUMBER - 2005N-0345-EC15

2005N-0345-EC15 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Marshall, Laura

2005N-0345-EC15 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.1>Codifying an interpretation can only help--make it clear exactly why and when a drug is being marketed OTC and Rx at the same time, and make it clear that the reasons are not political but medical.</1: 3.1, 3.8.1> <2: 3.9.1>Ibuprofen, ranitidine and other histamine receptor agonists, many drugs are currently sold OTC and prescription, but the issue there is about dosage, not a moral determination.</2: 3.9.1>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1>I would say so; confusion and rumor, not to mention bad PR for the FDA.</3: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.1, 5.3.2>Yes. Make it clear what the determiners are of such decisions; that will make it easier on the FDA and clearly more of an issue of fact than politics.</4: 5.1, 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 7.2, 7.5.3>As a matter of law, perhaps, but fake IDs and passing on of a prescription legally purchased would make the reality different.</5: 7.2, 7.5.3> <6: 6.5.4>And the likelihood is that making it harder to get for a specific subpopulation would engender lawsuits, more court cases, and further confusion as non-medical agencies and entities enter into the process.</6: 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

See Above.

GENERAL

GENERAL

<7: 1.2, 2.1>Please try to keep politics out of the drug-approval decision-making process. I don't know the FDA charter, or the regulations binding its decision, but my guess is that nowhere in those documents is there any requirement that so-called moral factors be taken into account. There are moral arguments on both sides of this issue, and the best middle ground is factual and scientific when the matter is, itself, a factual and scientific matter. Is the drug safe for the population it will be sold to? Is it effective? Is it, perhaps, already available off-label? Those are the questions the FDA should answer, not whether it's

either moral to sell or politically expedient.</7: 1.2, 2.1>

COMMENT NUMBER - 2005N-0345-EC155

2005N-0345-EC155 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Lamotte, Diane

2005N-0345-EC155 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes, I believe a rulemaking is in order.</1: 3.1> <2: 3.9.1>It doesn't seem too different from a medication being OTC in one case and not being OTC when combined with something else - especially when that something else is also OTC. Note Guaifenesin - long acting vs short, with or without a decongestant. Patients ask us why these items are prescription but can be bought separately OTC when combined.</2: 3.9.1>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.3.2, 7.1>I believe that health professionals and consumers expect the FDA to make a decision. Also they expect that the FDA can make any decision - and we will of course comply, whatever it is - even if it is novel.</3: 4.3.2, 7.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.1>Yes, just give us the rulemaking.</4: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.1>I believe that the FDA can enforce whatever it wants or needs to.</5: 6.1> <6: 6.6.1>Pharmacies currently comply with a multitude of regulations and policies. I manage a small pharmacy at a student health clinic and have no space for OTC self selection (or payment). Therefore, as a matter of policy, we pharmacists put OTC's into our Rx computer system and house them inside our pharmacy - so that the

patient has to request the OTC item. We have personalized records on everyone regarding Rx and OTC medications. This is great for medication review and counseling. Additionally, I have practiced pharmacy in 3 different states. The pharmacists comply with both federal and state regs. The state regs change from state to state and we keep the records as required - logs for needles and syringes - C-V cough medicines can be signed out in some states - whatever the ruling, we'll comply.</6: 6.6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 3.8.2, 7.4.1>I visited Ontario, Canada and saw that they had a form to fill out and keep regarding EC. Of course, Canada already has that third class of "OTC, but limited and behind the counter", where patients must request the medication. We have a similar system in California, where pharmacists can prescribe and dispense EC. This works very well - if you have enough counseling space in your pharmacy.</7: 3.8.2, 7.4.1> <8: 7.1>Whatever you decide will be what is complied with.</8: 7.1> <9: 7.4.4>How about checking ID like for alcohol purchasing</9: 7.4.4>, <10: 7.4.6>or accepting implied truth of asking for the patient's birthday and believing them.</10: 7.4.6> <11: 7.5.3>Obviously, if patients over 16 years of age can get it OTC, then it will be easy to acquire and anyone old enough can get it and give it to whomever they choose.</11: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<12: 8.1>I think it is perfectly fine to use the same packaging. The patient will benefit from the best packaging whether they are 15 or 35.</12: 8.1> <13: 8.8>Also, the packaging is the same for C-V cough medicines that are prescription in some states but behind the counter in other states, where patients sign a special book.</13: 8.8>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<14: 9.2.2>Don't know of any</14: 9.2.2>...

GENERAL

GENERAL

<15: 1.2.1>It seems to me like the United States is behind the eight ball on this one. Many other developed countries have EC OTC - there is precedence elsewhere - we are not re-inventing the wheel here. I know that women have sex (what a surprise!) and either have a problem with their contraception or, the couple didn't plan ahead. The woman should not be the only responsible party here - it takes two to tango. I help women every day avoid abortion, by providing contraception and EC. I would think that every health care provider would want to join me! I am sure you are aware of the JAMA article about access to EC that points out that promiscuity is not increased by the availability of EC. And abortion rates have been reduced since EC has been available. Our pregnancy numbers have reduced here at UC Santa Cruz when we began providing EC through the pharmacy. You can't argue with success! </15: 1.2.1>Thank you for the opportunity to comment.

COMMENT NUMBER - 2005N-0345-EC1565

2005N-0345-EC1565 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Yao, Yvonne

2005N-0345-EC1565 - TEXT

Issue Areas/Comments

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 1.2.1>Although I believe that OTC access to all age groups would benefit the individual as well as society</1: 1.2.1>, <2: 6.1, 6.6.3>I also see that age limited access is used in the sale of other products e.g. tobacco and alcohol. Therefore it seems that regulation by law would be possible as it has for these other products.</2: 6.1, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.1, 7.4.1, 7.4.4>It could be handled like alcohol and tobacco, but perhaps by the pharmacist instead of the general retail clerk. For patients 18 or older, a picture id would allow purchase; for patients under 18, a prescription would be required. (Those without photo id might prefer to get a prescription from their doctors.)</3: 7.1, 7.4.1, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.1, 8.4.1>As long as the product is the same, it seems more "truthful" to package it in the same manner. It avoids the impression that one product is better or stronger.</4: 8.1, 8.4.1>

GENERAL

GENERAL

<5: 1.2.1>Although it is possible to sell this product differentially to different types of patients, given that the product is safe and effective in younger as well older women, it would be preferable to sell it to all women over the counter to reduce barriers to access. Younger woman are perhaps more likely to require confidentiality and also are more likely to be intimidated by the need to speak to a person of authority.</5: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC15687

2005N-0345-EC15687 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Academy of Managed Care Pharmacy

2005N-0345-EC15687 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

The FDA has interpreted the language in section 503(b) of the Durham-Humphrey Amendments to allow marketing of the same active ingredient in products that are both prescription and OTC, assuming some meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner. The key distinction in all current examples of products sold both OTC and by prescription is that there is some meaningful difference between the two products (e.g., indication, strength, route of administration, dosage forms). To date, the FDA has not allowed marketing of the same active ingredient in a prescription product for one population and in an OTC product for a subpopulation. However, the FDA has acknowledged that its interpretation of section 503(b) of the act has not been explicitly set forth in any of the regulations that discuss the process by which FDA classifies drugs as OTC or prescription.

AMCP does not believe that the FDA has the authority to allow marketing of the same product as both a prescription drug and OTC product. For a medication to be granted OTC status, it must have a wide safety margin, be effective, and bear labeling understandable to ensure proper use. The FDA must determine that the labeling provides enough information for safe use by the general public. If the FDA determines that a drug meets the above conditions to be granted OTC status, then the drug is considered safe enough to be sold without a prescription.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

One question posed by the FDA in the Federal Register is whether, assuming that it is legal to market the same active ingredient in both a prescription and OTC product, the different products may be legally sold using the same packaging. The Academy believes that the two products must be sold in different packaging. On May 16, 2002, OTC drug manufacturers were required to begin using the new standardized label for OTC medicines. The following information must appear on the OTC label:

? The product's active ingredients, including the amount in each dosage unit.

? The purpose of the medication.

? The uses (indications) for the drug.

? Specific warnings, including when the product should not be used under any circumstances, and when it is appropriate to consult with a doctor or pharmacist. The warnings section also describes side effects that

could occur and substances or activities to avoid.

? Dosage instructions addressing when, how, and how often to take the medication.

? The product's inactive ingredients, which is important information for those with specific allergies.

The FDA requires that this information be in a certain format with standardized headings and subheadings and requires that the information be presented with certain graphical features.

The FDA also has specific labeling requirements for prescription medications. A prescription drug product is deemed to be misbranded if, at any time prior to dispensing, its label fails to bear the statement ?Rx only? or ?Caution: Federal law prohibits dispensing without prescription.?

AMCP also recommends that the Rx and OTC products need to have two distinct National Drug Code (NDC) numbers. The NDC number is the commonly accepted code for identifying packages of drugs. It is a unique number that identifies the drug, strength and packaging and is the HIPAA-required identifier for drug product claims. To allow managed care organizations, other third-party payors and drug information database providers to properly differentiate the prescription and OTC products for claims adjudication, the product must have a distinct NDC number.

2005N-0345-EC15687-Attach-48.DOC

2005N-0345-EC15687-Attach-48.DOC

ATTACHMENT:

October 31, 2005

Documents Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket 2005N-0345

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Food and Drug Administration (FDA) on circumstances under which an active ingredient may be simultaneously marketed in both a prescription drug product and an over-the-counter (OTC) drug product.

The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 4,800 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

<1: 3.3.2, 3.9.1>The FDA has interpreted the language in section 503(b) of the Durham-Humphrey Amendments to allow marketing of the same active ingredient in products that are both prescription and OTC, assuming some meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner. The key distinction in all current examples of products sold both OTC and by prescription is that there is some meaningful difference between the two products (e.g., indication, strength, route of administration, dosage forms). To date, the FDA has not allowed marketing of the same active ingredient in a prescription product for one population and in an OTC product for a subpopulation. However, the FDA has acknowledged that its interpretation of section 503(b) of the act has not been explicitly set forth in any of the regulations that discuss the process by

which FDA classifies drugs as OTC or prescription.</1: 3.3.2, 3.9.1>

<2: 3.3.2, 6.2>AMCP does not believe that the FDA has the authority to allow marketing of the same product as both a prescription drug and OTC product. </2: 3.3.2, 6.2> <3: 3.3.2, 6.5.1>For a medication to be granted OTC status, it must have a wide safety margin, be effective, and bear labeling understandable to ensure proper use. The FDA must determine that the labeling provides enough information for safe use by the general public. If the FDA determines that a drug meets the above conditions to be granted OTC status, then the drug is considered safe enough to be sold without a prescription.</3: 3.3.2, 6.5.1>

One question posed by the FDA in the Federal Register is whether, assuming that it is legal to market the same active ingredient in both a prescription and OTC product, the different products may be legally sold using the same packaging. <4: 8.2>The Academy believes that the two products must be sold in different packaging. </4: 8.2> <5: 8.5.1>On May 16, 2002, OTC drug manufacturers were required to begin using the new standardized label for OTC medicines. The following information must appear on the OTC label:

The product's active ingredients, including the amount in each dosage unit.

The purpose of the medication.

The uses (indications) for the drug.

Specific warnings, including when the product should not be used under any circumstances, and when it is appropriate to consult with a doctor or pharmacist. The warnings section also describes side effects that could occur and substances or activities to avoid.

Dosage instructions addressing when, how, and how often to take the medication.

The product's inactive ingredients, which is important information for those with specific allergies.

The FDA requires that this information be in a certain format with standardized headings and subheadings and requires that the information be presented with certain graphical features.

The FDA also has specific labeling requirements for prescription medications. A prescription drug product is deemed to be misbranded if, at any time prior to dispensing, its label fails to bear the statement "Rx only" or "Caution: Federal law prohibits dispensing without prescription."</5: 8.5.1>

<6: 8.5.3>AMCP also recommends that the Rx and OTC products need to have two distinct National Drug Code (NDC) numbers. The NDC number is the commonly accepted code for identifying packages of drugs. It is a unique number that identifies the drug, strength and packaging and is the HIPAA-required identifier for drug product claims. To allow managed care organizations, other third-party payors and drug information database providers to properly differentiate the prescription and OTC products for claims adjudication, the product must have a distinct NDC number.</6: 8.5.3>

Therefore, although the Academy believes that an identical medication should not be approved in both a prescription and OTC form, if such a decision is made, the Academy believes the prescription and an OTC medication must be sold in different packaging in order to be in compliance with existing regulations and to allow proper claims adjudication.

AMCP appreciates the opportunity to comment on this extremely important issue. If you have any questions, please contact Judith A. Cahill, AMCP Executive Director, at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,

Judith A. Cahill

Executive Director

COMMENT NUMBER - 2005N-0345-EC15690

2005N-0345-EC15690 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Association of American Physicians & Surgeons

2005N-0345-EC15690 - TEXT

GENERAL

See Attachment

2005N-0345-EC15690-Attach-49.TXT

ATTACHMENT:

Comments re: Docket No. 2005N-0345, RIN 0910-AF72
Drug Approvals: Circumstances Under Which an Active Ingredient May be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product.

The Association of American Physicians & Surgeons (AAPS) is a nonprofit national group of thousands of physicians. Founded in 1943, we are entirely member-supported and do not accept funding from industry. Courts and medical boards frequently welcome our amicus curiae briefs and letters. Justices of the United States Supreme Court have cited materials we submitted, see *Stenberg v. Carhart*, 530 U.S. 914 (2000); the Privacy Rule also cited us, see 65 F.R. 82462, 82468 (Dec. 28, 2000). We have successfully sued the Food and Drug Administration (FDA) for exceeding its authority in the past. See *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002).

<1: 3.1, 3.4>The FDA should not render a decision affecting millions of Americans without allowing full notice and comment by physicians and patients, pursuant to a formal rulemaking proceeding. The Administrative Procedures Act (APA) requires notice and comment prior to promulgation of a new rule, and there is no valid reason to deny public input on the important issue of marketing an active ingredient as both a prescription drug and over-the-counter (OTC) drug. AAPS objects to any attempt by the FDA to bypass notice and comment procedures in connection with Section 503(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), as modified by the Durham-Humphrey Amendments, which governs the classification of drugs.</1: 3.1, 3.4>

<2: 6.5.1>AAPS further observes that the FDA lacks statutory authority to approve a drug for OTC purposes for one age group while retaining prescription requirements for the same drug for another age group. If the FDA feels it has such authority, then it needs to promulgate its position in a formal rulemaking procedure, including notice and comment by physicians. For the following reasons, AAPS submits that the FDA lacks such authority to classify the same drug as OTC for one age group but prescription use for another.</2: 6.5.1>

<3: 6.5.1, 6.6.1, 6.6.2>Once the FDA has determined that a drug requires a prescription, then by definition that drug has a potential for harmful effect. That potential for harm does not change based on whether the recipient is 15 years old, 16 years old, 17 years old or 18 years old. Congress and state legislatures have the sole power to draw distinctions between those ages for the consumption of food or drugs. The FDA does not. </3: 6.5.1, 6.6.1, 6.6.2>

<4: 6.5.2, 6.6.1>An age-based classification for prescriptions would constitute an intrusion by the FDA into an area of traditional state regulation: parental notification or consent for the medical treatment of minors. If the FDA were to decide that a drug requires a prescription for a 15-year-old but not for a 17-year-old, then such decision would transfer power over issues of consent by minors to the FDA from the states. Nothing in Section 503(b) or elsewhere gives the FDA such authority to decide at what age a minor is mature enough to buy OTC drugs that have life-changing effects.</4: 6.5.2, 6.6.1>

<5: 6.6.1, 7.5.2>The possibility that a state could regulate the age at which a minor could purchase an OTC drug does not satisfy our objection. States have regulatory schemes that are not designed for, or equipped to, deal with the illegal distribution of OTC drugs to minors. In the case of reproductive activity, adult men are often responsible for victimizing and impregnating much younger girls. The adult men could and often would circumvent any age requirement on the purchase of the OTC drugs by underage girls. The FDA should not propose an age requirement for OTC drugs unless it has adequate means and resources to enforce it. It does not.</5: 6.6.1, 7.5.2>

<6: 1.2.3, 7.5.3>Our concerns are heightened in the context of teenagers confronting sexual reproduction. They often lack the maturity and financial independence of adults to make informed decisions about their health and well-being. Teenagers are highly susceptible to peer pressure and misinformation denying possible long-term adverse effects of interference with a pregnancy. It is wholly unrealistic to suggest, as some have, that a "morning after pill" made available on an OTC basis to 16 or 18 year-olds will not be widely distributed to younger girls. As an organization of physicians who must deal with subsequent medical harm, AAPS objects to an age-based classification allowing OTC sales of a morning after pill.</6: 1.2.3, 7.5.3>

<7: 6.6.1>AAPS reminds the FDA that the states require parental consent for most medical decisions made by minors. California, for example, just reenacted its requirement of parental consent for body-piercing of a minor. See 2005 CA A.B. 646 (signed by the governor of California on Sept. 22, 2005). The vast majority of states require parental notification or even consent prior to performing an abortion on a minor. Making a drug available on an OTC basis renders parental consent impossible. When a prescription is required for the drug, a trained physician can assess the benefits and harms, and advise a minor and her parent appropriately. When the drug is sold over the counter, there is no professional evaluation or meaningful way for a minor to learn and evaluate the medical harm. </7: 6.6.1>

<8: 10>AAPS emphasizes that childbirth confers undeniable health benefits on the mother, and interruption of a pregnancy is indisputably harmful compared to childbirth. The FDA should not render any decision concerning increased availability of a drug to interfere with pregnancy without hearing from all sides of the medical community about the harm of preventing childbirth. The medical literature contains many peer-reviewed studies demonstrating how harmful pregnancy termination is to one's health. See generally J.M. Thorp, Jr., K.E. Hartmann, and E.M. Shadigian, "Long-Term Physical & Psychological Health Consequences of Induced Abortion: Review of the Evidence," 58 OB/GYN Survey 1, at 67-79 (2003); D.C. Reardon, P.G. Ney, F.J. Scheuren, J.R. Cougle, P.K. Coleman, T. Strahan, "Deaths associated with pregnancy outcome: a record linkage study of low income women," 95 Southern Medical Journal 8, at 834-41 (August 2002) ("Higher death rates associated with abortion persist over time and across socioeconomic boundaries."); Karen Malec, "The Abortion-Breast Cancer Link: How Politics Trumped Science and Informed Consent," 8 J. Am. Physicians & Surgeons 41 (Summer 2003)

(the vast majority of studies have found that abortion increases the risk of breast cancer), <http://www.jpands.org/vol8no2/malec.pdf> (viewed Aug. 3, 2005). A morning after pill can be expected to cause harm and the FDA should not facilitate bypass of informed consent in consultation with a physician. Mixing OTC and prescription classifications for the same drug would thwart informed consent and lead to unanticipated harm to patients.</8: 10>

<9: 3.1, 3.4>In sum, AAPS objects to any assertion in authority by the FDA to make age-based classifications for prescription and OTC sales of drugs. If the FDA is seeking such authority, then at a minimum it needs to comply with formal rulemaking and address the objections raised by physicians and patients alike.</9: 3.1, 3.4>

COMMENT NUMBER - 2005N-0345-EC157

2005N-0345-EC157 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Smith, Jennifer

2005N-0345-EC157 - TEXT

GENERAL

<1: 1.2.3, 3.8.8>If this product contains one of the same active ingredients used in ordinary prescription birth control pills -- only in the case of Plan B ? each pill contains a much higher dose and is taken in a different way. Then, why is it being considered for OTC when other birth control pills require a perscription? Whouldn't some women use this OTC as birth control rather than visit their physician for a perscription and checkup? </1: 1.2.3, 3.8.8>

COMMENT NUMBER - 2005N-0345-EC15931

2005N-0345-EC15931 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Walsh, Melissa

2005N-0345-EC15931 - TEXT

Issue Areas/Comments

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.8.4>A. The FDA's current interpretation of section 503 (b) is a common sense definition of the law. Although it is unnecessary, the FDA could codify its current policy and reasoning for how it decides whether a product with the same active ingredient is distinguished from OTC and prescription (i.e. A product with the same active ingredient is available OTC in low concentrations because it is safe at weak concentrations, while the same product is made prescription based on the greater concentration or more potent method of dispersal). Since the FDA's policy on the law has served our country well for about 20 years, there should be no doubt to the validity of its interpretation.</1: 3.8.4>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 3.1, 3.3.2, 4.2, 4.4.1>B. The FDA's interpretation is an accurate interpretation of the law. It is also scientific, because this policy is in keeping with the known fact of chemistry that to decrease the toxicity of a product its concentration must be in some way decreased. Thus it must follow in medicine, if a drug is to be safe it must be marketed at non-injurious levels. If it is sold at higher concentrations it should be under the supervision of a physician. Consequently there should be no confusion to the FDA's policy as it is both scientific and in keeping with the intent of the law. In order to avoid future challenges by drug companies and pharmacies to the FDA's interpretation of 503(b) of the act, the FDA's unwritten interpretation should be codified as law.</2: 3.1, 3.3.2, 4.2, 4.4.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.2, 6.5.4>A. If the FDA limited the sale of an OTC product by making it remain prescription for a subpopulation what would be its reasoning? If a product is made over the counter, and yet is unsafe for certain individuals, the FDA's integrity could be held in question. The FDA could be accused of discrimination against that subpopulation or approving a dangerous drug to please drug companies. Either way the general public would receive mixed messages which may cause them to doubt the trust they put in the FDA.</3: 6.2, 6.5.4> <4: 7.5.3>Also, if the FDA did put such questionable policies into practice, would be unable to ensure that the drug did not fall into the hands of the subpopulation they are trying to protect. Illegal activities could take place, for example the problem with underage intake of alcoholic beverages; it is illegal yet the drug falls into the hands of minors. The only way the FDA could insure a dangerous drug does not fall in the wrong hands is through a prescription basis.</4: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2, 7.5.2>B. If the FDA made an OTC product illegal for an underage population. It would not be practical because a possible dangerous drug would be used with less caution by the public because it is readily accessible. A product, with possible dangerous side affects, under a physician's guidance are more quickly detected and treated. If such a drug is readily available the FDA would need to educate and protect the public in the same way as a physician. This would be an unnecessary role for the FDA to take on.</5: 7.2, 7.5.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 9.1.1, 9.2.2>A. In the FDA's current policy it has established the precedent that if the same product is sold as prescription and OTC the difference would need to be the concentration or method of dispersal. If the FDA were to sell different products legally under the same package it would have to ensure that the following conditions were met: I. The product has no harmful or damaging effects on the patient. II. Prescription only for the sub-population that may be harmed by the drug, for example if drug is only dangerous to the person who is a minor or has allergies or diabetes. III. The FDA would need to ensure that the OTC product did not fall into the hands of minors which must gain access to the drug by prescription basis. They must be able to prove the agency's effectiveness to overcome the common problem of illegal drugs such as steroids falling into the wrong hands. The FDA would need the necessary strength to overcome this negative precedent which it has not been able to do in the past. IV. The regulation is not made to discriminate based on age, race, or ethnic background. Since the product should be safe for the general population, if the same product is marketed as OTC and prescription in the same package.</6: 9.1.1, 9.2.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.1>B. It would be inappropriate to lawfully sell under the same package an OTC product that could permanently change normal bodily functions. For example steroids and other drugs which alter the hormones to treat a disease or remove unwanted symptoms of growth or illness. If the FDA made these products readily available without distinguishing, as it has in the past, the danger of a product under different concentrations, the public would be done great damage and disservice by the FDA's change of policy.</7: 9.1.1>

COMMENT NUMBER - 2005N-0345-EC16

2005N-0345-EC16 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Smart, Stephanie

2005N-0345-EC16 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.3.3>A drug is not only its active ingredient. It is a combination and has different uses based on the combination or the dosage. So yes, I think that a drug should be available by prescription and OTC containing the same active ingredient.</1: 3.1, 3.3.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC

drug product?

Same answer as above

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No, but I do not agree with the interpretation.</2: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.5.4>I think this is a poor policy consideration. By limiting drug availability you open the door for discrimination based on race, age, gender, and socioeconomic status. The drug should be available to anyone who would have a usage for it based upon the labeling.</3: 6.5.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.9>How could they be in the same package if they have different uses? Why would you have exactly the same product available by prescription and OTC? If an active ingredient is available OTC and by prescription then wouldn't they automatically have different packaging because they would have different uses?</4: 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<5: 8.9>What two products? This is not clear. If you are referring to the above question it doesn't make sense. They wouldn't be in the same package if one is by prescription and one is OTC.</5: 8.9>

GENERAL

GENERAL

Please approve Plan B for OTC with no limitations on purchase. This is not Birth control. This is for emergencies and allows women a recourse when accidents occur such as a condom breaking. By allowing the sale of this product as an OTC item then you allow access to all socioeconomic classes of women.

COMMENT NUMBER - 2005N-0345-EC160

2005N-0345-EC160 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Bachelor, Emiliann

2005N-0345-EC160 - TEXT

Issue Areas/Comments

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 6.1>Yes.</1: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<2: 7.1>Yes.</2: 7.1> <3: 6.6.3>Akin to alcohol and tobacco, Plan B can be regulated.</3: 6.6.3> <4: 6.6.3, 7.4.6>This does not suggest a comparison of products, but a comparison of distribution methods. Pharmacies and drug stores can place notices, as with tobacco and alcohol, that no one under the age of 17 will be allowed to purchase Plan B over-the-counter.</4: 6.6.3, 7.4.6> <5: 7.4.4>Pharmacists and store cashiers should be allowed to require photo identification in order to purchase Plan B over-the-counter</5: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2>No.</6: 8.2> <7: 8.6.4, 9.1.2>That would cause undue confusion at the store level. Prescription drugs and their over-the-counter equivalents should always be packaged differently. </7: 8.6.4, 9.1.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.1.1>If the two products were actually different products, then it would be very inappropriate to sell them in the same packaging. However, this is not the case here.</8: 9.1.1> <9: 8.2, 8.7>This is a difference of classification. The product itself is the same. Other medications utilize different packaging for over-the-counter and prescription equivalents. These different classifications of Plan B should be packaged differently. </9: 8.2, 8.7>

GENERAL

GENERAL

<10: 1.2, 2.1>I implore your panel to not allow politics to interfere with science. Uninsured women need access to medications like these. If women cannot afford health insurance to provide prescription drugs to protect their reproductive rights, then is it very likely that the children raised in such environments will face the consequences of being poor in the United States. Women and children are the poorest demographics in the world, including the United States. Help them. </10: 1.2, 2.1>

COMMENT NUMBER - 2005N-0345-EC162

2005N-0345-EC162 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Hutson, Paul

2005N-0345-EC162 - TEXT

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.1, 3.8.2>The FDA should allow for the dispensing of selected drugs without a prescription by a licensed pharmacist, physician's assistant, or nurse practitioner.</1: 3.1, 3.8.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.1, 7.3.1.1>Yes, if the non-prescription sale was made through a licensed pharmacy and by a licensed pharmacist, PA, or NP.</2: 6.1, 7.3.1.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.1, 7.4.1>It would be quite simple, as indicated in section A above, to limit the non-prescription sales via a state-licensed pharmacist. Other drugs that would also be appropriate for this third level of dispensing would be NSAIDS, HMG-CoA reductase inhibitors ("statins"),oral contraceptives, pseudoephedrine, St John's wort, kava, and seasonal allergy medications.</3: 7.1, 7.4.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.1>Yes</4: 8.1>

COMMENT NUMBER - 2005N-0345-EC16427

2005N-0345-EC16427 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Marcelli, Christian

2005N-0345-EC16427 - TEXT

GENERAL

<1: 3.9.1>There are already products sold both OTC and via Rx. Ibuprofen is one of them. This has been relatively safe considering the vast benefit to society.</1: 3.9.1> <2: 1.2.2>Plan B has a further reaching benefit to society given the long term effects of pregnancy or abortion. A product should be sold over the counter when it is safe to do so. Restrictions should not be made for religious or political reasons, otherwise we will have vastly different drug regulations when new administrations take office.</2: 1.2.2>

COMMENT NUMBER - 2005N-0345-EC165

2005N-0345-EC165 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Reusch, Elizabeth

2005N-0345-EC165 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.1>Yes, this would help to determine the product packaging and restriction labeling requirements needed between a drug sold as a prescription and one sold over the counter. In many instances, the information received with prescriptions is more complete and informative.</1: 3.8.1>

1.

C. If so, would a rulemaking on this issue help dispet that confusion?

Unknown.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.1, 6.6.3>Yes, limitation of products by age are common in the United States for the sale of lottery tickets, alcohol, cigarettes, even movie tickets by requiring the presentation of a legal identification. A movie rated R is restricted from teenagers buying the product; A lottery ticket is restricted to those over

the age of 21 (Arizona law); cigarettes are restricted to those over 18; alcohol is restricted to those over 21. Age restrictions are used throughout this nation to limit exposure to products.</2: 6.1, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.1, 7.4.4>By requiring an identification card be presented at the time of purchase.</3: 7.1, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.6.2>In my personal opinion, a product sold over the counter and then as a prescription should NOT be legally sold in the same package. This can create confusion and anxiety about where and how a product was obtained. Many prescriptions are filled in standard prescription bottles.</4: 8.6.2>

GENERAL

GENERAL

<5: 6.7>Yet, the age restriction would create a problem with obtaining the product via healthcare prescription plans that do not normally cover over the counter drugs.</5: 6.7>

COMMENT NUMBER - 2005N-0345-EC16543

2005N-0345-EC16543 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Jones, Kim

2005N-0345-EC16543 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No</1: 3.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No (this is the same question)

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2, 4.4.2>No. The American consumer understands that some medications are reasonably safe for self-medication in lower doses, but require physician monitoring for higher doses and certain uses.</2: 4.2, 4.4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 4.2>There is no confusion.</3: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2, 6.5.4>No. It would implicate equal protection rights, among other problems.</4: 6.2, 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2, 7.5.4>No. Looking, for example, at minors, if minors can obtain cigarettes and alcohol, they will be able to obtain OTC medications as well.</5: 7.2, 7.5.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1>Yes</6: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

I have no comment

GENERAL

GENERAL

<7: 1.2.1, 2.1>The present rulemaking procedure should not delay the approval of Plan B for OTC sales. There is no credible reason to apply different rules regarding this contraceptive medication to different subpopulations. There is no evidence that its effects are different on different subpopulations, nor that it is any less safe for one subpopulation. The decision to consider different rules for different subpopulations is a purely political decision, which is inappropriate when it comes to the FDA's charter to ensure the safety and health of the American consumer. The FDA should follow nearly unanimous guidance and immediately approve Plan B for OTC sales for all individuals. The present rulemaking process can continue, but need not delay the immediate approval of Plan B for OTC sales, because there is no need to explore the simultaneous marketing approach for this safe and effective product.</7: 1.2.1, 2.1>

COMMENT NUMBER - 2005N-0345-EC16546

2005N-0345-EC16546 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Saling, Elle

2005N-0345-EC16546 - TEXT

GENERAL

<1: 6.5.1>If a drug is safe and helps people and if it is not habit forming it should be made available. It is not up to the FDA to make moral or ethical judgements on drugs, if it was Viagra should never have received approval. It is up to the FDA to determine the safety of the drug. This particular drug is not a narcotic, it is as safe as aspirin and yet since it relates to women and this current administration has rallied around denying women rights to their own health and safety, this is the reason it is being held up. It is up to each and every individual citizen to determine what medications they will or will not use. This once free country becomes more and more like Russia and China everyday.</1: 6.5.1> <2: 3.9.1>Pepcid AC is sold as both prescription and over the counter as is Motrin.</2: 3.9.1> <3: 1.2.1>This drug, regardless of it's intended use falls under the same right to privacy as the two noted above. Americans are not children. Under the current HMO and health system crisis we are forced to make decisions about our personal health every single day. To use or not use this drug should be up to the people. Holding it back is unethical and immoral and just plain wrong.</3: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC16675

2005N-0345-EC16675 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: American Pharmacists Association

2005N-0345-EC16675 - TEXT

GENERAL

See Attachment

2005N-0345-EC16675-Attach-59.DOC
2005N-0345-EC16675-Attach-60.PDF

ATTACHMENT:

American Pharmacists Association

Improving medication use. Advancing patient care.
APhA

October 31, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2005N-0345

Dear Sir/Madam:

Thank you for the opportunity to comment on the September 1, 2005 Federal Register notice addressing circumstances under which an active ingredient may be simultaneously marketed in both a prescription drug product and an over-the-counter drug product. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The Food and Drug Administration (FDA) is soliciting public comments on several regulatory and policy issues related to the Agency's process to classify drug products as "prescription" or "over-the-counter" (OTC). Specifically, the Agency is interested in examining its authority under the Federal Food, Drug, and Cosmetic Act (the Act) to simultaneously approve an active ingredient as both a prescription and OTC. The Agency is also looking at related issues including its ability to enforce sales limitations of OTC products and the marketing of "dual status" products in a single package. APhA appreciates the Agency's decision to conduct an open evaluation of these regulatory and policy questions and we welcome the opportunity to add our comments to the discussion. <1: 3.2, 3.8.5>Please note that APhA is not responding to these questions in the context of a single drug product; rather, we are providing our comments on the overall "dual status" issue which could apply to any number of drug products. As such, pending issues need not necessarily be resolved by rulemaking before the Agency acts on a specific pending application.</1: 3.2, 3.8.5>

APhA offers the following comments on the questions for public comment included in the Federal Register notice.

1A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 3.1>Yes, APhA would support efforts by the FDA to codify the Agency's interpretation of Section 503(b), the Federal standard used to classify drug products as prescription or OTC. </2: 3.1>

<3: 3.8.2>In simplest terms, if a drug does not meet the definition of prescription drug product from Section 503(b), it must be an OTC. However, there may be drug products in which the standard two class system is not sufficient. For example, certain drug products may not distinctly fall into the "prescription" or "OTC" class - the active ingredient could be considered both a prescription and an OTC if some meaningful difference exists between the products. In other circumstances, certain drug products may not require the assistance of a learned intermediary (the deciding factor in classifying a drug as a

prescription), yet patients would still benefit from access to a health care professional's services when selecting and using the product. Such access may not always be available with "full" OTC status.</3: 3.8.2>

<4: 3.8.1>While the Agency's proposal to codify its interpretation of Section 503(b) would only directly address the situation in which an active ingredient can be marketed as both a prescription and as an OTC because of a meaningful difference between the products, it is important for the FDA to formalize its interpretation of the statute on this point. And activities to formalize the Agency's interpretation may also provide the opportunity to engage in a discussion about expanding the current classification system of medications beyond only prescription and OTC.</4: 3.8.1>

<5: 3.8.1>The realities of our current health care environment underscore the need for the FDA to clarify its interpretation of Section 503(b) and participate in an open discussion of the drug classification system. Over the past decade, a number of prescription products have made the switch to OTC status. A non-sedating antihistamine, a full strength H2 receptor antagonist, and a proton-pump inhibitor have all made the transition to OTC. And with the support of consumers, manufacturers, and regulators, all indications point to even more products making the move - including products for asymptomatic conditions such as osteoporosis or dyslipidemia. As the number of "switch" applications increase, so will the potential for active ingredients that may best be simultaneously classified as both a prescription and an OTC, or placed in some type of in-between or transition category. An examination of the current two class system and codification of the FDA's interpretation of Section 503(b) will aid the Agency and product sponsors with future switch requests, and will facilitate the transition of appropriate products to OTC status, ultimately providing consumers with greater access to safe and effective medications.</5: 3.8.1>

1B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<6: 4.1>There is some confusion regarding the Agency's interpretation of the statute.</6: 4.1>

<7: 4.3.4>As the FDA has acknowledged, the Agency's interpretation of Section 503(b) has not been explicitly set forth in any regulation that addresses the drug classification process. [Footnote 1: 70 FR at 52,051.] Without an official interpretation in the Act or implementing regulations, manufacturers, health care professionals, state regulatory bodies, and even FDA officials, may not have a concrete understanding of the Agency's process to classify, or in some cases, reclassify, drugs as prescription or OTC.</7: 4.3.4>

<8: 4.3.2>The confusion has also been evidenced recently in the reaction to the Agency's decision to seek public comment on these regulatory issues. After the Agency's announcement, members of the private sector began making public, and conflicting, pronouncements on whether the FDA currently has the authority to approve a product as both a prescription and as an OTC, how the Agency has handled similar approvals in the past, and what restrictions, if any, the Agency can place on such approvals. The differing opinions on these issues illustrate the need for clarification of Section 503(b). </8: 4.3.2>

1C. If so, would a rulemaking on this issue help dispel that confusion?

<9: 5.1>Yes, a well developed regulation that codifies the Agency's interpretation of Section 503(b) should reduce confusion. </9: 5.1>

2A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<10: 6.1>Yes, as a matter of law, the FDA can enforce a subpopulation limitation on the sale of an OTC product. </10: 6.1>

<11: 6.4.1, 7.3.1.1, 7.3.1.2>The Agency currently enforces a sales limitation on the over-the-counter smoking cessation product Nicorette (nicotine polacrilex). As part of the drug's conditions of approval, the FDA, in conjunction with the product sponsor, restricted the product to individuals 18 years of age or older. According to the approval letter, "The product cartons must bear the legend: Not for sale to those under 18 years of age. Proof of age required. Not for sale in vending machines or from any source where proof of age cannot be verified." [Footnote 2: Food and Drug Administration. Letter to Hoechst Marion Roussel, Inc. February 9, 1996.] To help ensure that the product is not distributed to underage individuals, the product sponsor also implemented a marketing plan that restricts product distribution to pharmacies, mass merchandisers, and supermarkets where other OTC drugs are sold. The product is not distributed through convenience stores or vending machines. Retailers were also trained on the product's age restriction. According to the product sponsor, retailers are responsible for enforcing the age restriction, and each retailer has flexibility in developing its own system to verify a purchaser's age. [Footnote 3: Plan B Debate May Spotlight Smoking Cessation Age Limit Precedent. The Tan Sheet. September 5, 2005.]</11: 6.4.1, 7.3.1.1, 7.3.1.2>

<12: 6.4.1>Through its approval of Nicorette(TM), the Agency established a precedent for approving a drug product as an OTC and restricting its availability to a limited population. While the situation under consideration by the FDA - approving a drug as an OTC for one subpopulation and making it a prescription for another subpopulation - is different, the underlying premise remains that same; the Agency could enforce a sales limitation on products available as an OTC. To do so, the Agency could include the sales restriction as a condition of approval and work with the product sponsor to craft labeling that reflects the restriction. Including the conditions for sale in the product labeling and approving the product labeling enables the FDA to enforce a sales restriction for an OTC. It is important to note that if the Agency includes a sales restriction as part of the conditions of approval for a drug product, any generic products subsequently approved for marketing would also have to be approved under those same terms and abide by the same requirements. [Footnote 4: Comments of Dr. Edwin Hemwall and Dr. Jonca Bull. Transcript of the Food and Drug Administration's Endocrinologic and Metabolic Drugs Advisory Committee and Non-Prescription Drugs Advisory Committee Hearing on Over-the-Counter Use of Mevacor (lovastatin). January 14, 2005. Pgs. 82 - 84.]</12: 6.4.1>

2B. If it could, would it be able to do so as a practical matter and, if so, how?

<13: 7.1>Yes, there are practical means available for the FDA to enforce a sales limitation on OTC products. APhA offers the following recommendations for the Agency's consideration.</13: 7.1>

<14: 7.3.1.1, 7.3.1.2>As discussed above, the Agency can enforce a sales limitation through regulation of the product sponsor. If the Agency, in conjunction with the product sponsor, determines that a sales limitation is appropriate, the FDA can require the sales restriction through the approved labeling as part of the conditions of approval. This process would mirror the conditions of approval for Nicorette although the particular sales restriction (i.e., age, sex, etc.) could vary. The product sponsor could also be required to educate retailers about the sales restriction. Ultimately the product sponsor and retailer, not the FDA, would be responsible for ensuring that the product is supplied according to its approved labeling. As with any other OTC product, the FDA would not be responsible for policing any off-label use of the product.</14: 7.3.1.1, 7.3.1.2>

<15: 7.4.1>Following the Nicorette example, a product with an OTC sales restriction should only be distributed in retailers where other OTC drugs are sold and in settings where the retailer can verify that the purchaser meets the conditions for sale, such as verifying the purchaser's age. However, in situations

where the product would also be available as a prescription and presented in the same package, the product should be further limited to settings licensed to provide prescription drug products; by definition, "dual status" products should be limited to entities with a pharmacy or other dispensing environment. By limiting the product to an entity with a pharmacy, the entity can verify that individuals seeking the OTC product meet the sales restriction criteria and a pharmacist can dispense the product to individuals who do not meet the sales restriction pursuant to a valid prescription. This approach navigates the challenge of enforcing the federal prescription requirement.</15: 7.4.1>

<16: 7.4.1>Restricting a dual status product to entities with a pharmacy will also allow consumers seeking input from a health care professional to have ready access to that advice. Dual status products would work well within the Pharmacy Care OTC concept (See Attachment A). Pharmacy Care OTCs are a sub-category of non-prescription medicines available only in outlets with pharmacies to facilitate interaction between consumers and pharmacists. Like other OTCs, Pharmacy Care OTCs would be available in pharmacies on the open shelf with other over-the-counter medications. What is different with Pharmacy Care OTCs is the availability of the pharmacist and the marketing, product placement, and pharmacist preparation to support consumer/pharmacist interaction. Pharmacist intervention is not required but strongly supported for Pharmacy Care OTCs - such as products being used for chronic, asymptomatic conditions or other conditions where consumers would benefit from additional interaction with their pharmacist. The FDA could place OTC products in the Pharmacy Care OTC category through an interpretation of current law; the Pharmacy Care OTC category would not require a statutory change.</16: 7.4.1>

<17: 7.4.1>If the FDA would prefer to amend the Act, the Agency should consider creating additional classes of drugs. APhA has long called for the establishment of an option that would call on pharmacists to play a greater role in expanding access to designated medications. Under an expanded drug classification system, designated products could be dispensed without a prescription order; however, the product would only be dispensed by pharmacists. Such availability would expand access beyond the traditional system, while maintaining health professional interaction. Requiring consumers to consult with pharmacists to obtain the product can be valuable in ensuring appropriate medication use, reducing adverse events, and ensuring consumer persistence and compliance with therapy. A so-called "pharmacist only" class has been used successfully in a number of countries including the United Kingdom, Canada, Australia, New Zealand, and Singapore. [Footnote 5: Robert Field, JD, MPH, PhD. Support Grows for a Third Class of "Behind-the-Counter" Drugs. *Pharmacy & Therapeutics*. May 2005. Pg. 261.] For example, the United Kingdom recently moved the cholesterol drug Zocor™ (simvastatin) over-the-counter; however, consumers must obtain the product from a pharmacist. Pharmacists in Great Britain can supply the drug to consumers following simple health checks such as asking about their health and offering various health tests to ensure that it is safe to dispense the medication. A cholesterol test may be offered but it is not mandatory. This example illustrates the benefits of an expanded drug classification system - consumers experience increased access to a relatively safe drug, but some level of professional involvement remains.</17: 7.4.1>

<18: 3.3.3, 6.3.1, 7.3.1.3>If the FDA approves a product for inclusion in the Pharmacy Care OTC category or for placement within a statutorily-established expansion of the drug classification system, either option could be supplemented, when necessary, with some form of postmarketing risk management program. Subpart H of the Act gives the Agency the authority to approve a product with restrictions to assure safe use "if the FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted." [Footnote 6: 21 CFR 314.520] The restrictions can include distribution restricted to certain facilities or physicians with special training or experience; distribution conditioned on the performance of specified medical procedures; or limitations imposed that are commensurate with the specific safety concerns presented. [Footnote 7: *Ibid.*] The Agency can place these postmarketing restrictions on both prescription and OTC products. The Agency could use its authority under Subpart H

to require a risk management program - such as distribution restricted to a pharmacy or entities with a pharmacy or requiring additional education on product use - for products that have been approved with a dual status because the Agency has concluded that the drug may only be safely used in a particular subpopulation as a prescription product.</18: 3.3.3, 6.3.1, 7.3.1.3>

3A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<19: 7.4, 8.4.1>Yes, an active ingredient that is marketed as both a prescription and OTC product may legally be sold in the same package if the following conditions are met:

1. The product sponsor develops a product label and packaging that is appropriate for both the prescription and the OTC environment; and the FDA approves the product labeling.
2. The product is only sold in settings licensed to provide prescription drug products. Because the characteristics of the potential user of the product determines whether or not a dual-status product is prescription or OTC, dual status products should be presumed to be a prescription and limited to outlets with appropriate licensing to dispense medications. Such outlets, then, must develop policies and procedures to comply with prescription requirements to avoid selling medications to individuals who would require the prescription product.</19: 7.4, 8.4.1>

3B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<20: 8.7, 9.1.1>It would be inappropriate to market a dual status product in the same package in the following circumstances:

1. The products have truly different indications such as the Meclizine (prescription for vertigo/OTC for nausea with motion sickness) example provided in the Federal Register notice.
2. The products have different strengths, dosage forms, routes of administration, or directions for use.</20: 8.7, 9.1.1>

<21: 4.3.2>In closing, we would like to reiterate our appreciation for the opportunity to contribute to the public dialogue on these important regulatory and policy issues. There is a great deal of confusion regarding the FDA's process for classifying drugs as prescription or OTC, and the level of confusion has increased dramatically in recent months as the Agency has discussed the concept of simultaneously approving drug products as both prescription and OTC.</21: 4.3.2> <22: 5.1>Codifying the Agency's interpretation of Section 503(b) would be a step towards dispelling that confusion. </22: 5.1> <23: 7.4>As the Agency reviews comments and evaluates the need for additional rulemaking, APhA urges the Agency to consider limiting "dual status" products to entities with a pharmacy. We also recommend that the FDA consider the need for an alternative to the current "prescription" and "OTC" classification system such as the Pharmacy Care OTC concept or expanding the drug classification system by amending the Act. Either of these systems would significantly increase access to designated medications, while ensuring some level of access to or oversight by pharmacists - the medication experts on the health care team. </23: 7.4>

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan K. Bishop, Associate Director, Regulatory Affairs, at 202-429-7538 or SBishop@APhAnet.org, or Susan C. Winckler, Vice President, Policy & Communications and Staff Counsel, at 202-429-7533 or SWinckler@APhAnet.org, with any questions.

Sincerely,

John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
Susan K. Bishop, MA, Associate Director, Regulatory Affairs

<24: 10>APhA Pharmacy Care OTC Task Force
Report of Opening Meeting</24: 10>

The movement of products from prescription to over-the-counter (OTC) status is a reality of our health care environment, a reality intended to increase consumer access to safe and effective medications. In the past few years, a non-sedating antihistamine, a full strength H2 receptor antagonist, and a proton-pump inhibitor have made this transition from prescription to OTC status. With the support of consumers, manufacturers, and regulators, all indications point to even more products making the move ? including products for asymptomatic conditions like osteoporosis or high cholesterol. As a component of these discussions, the American Pharmacists Association (APhA) is exploring the concept of enhancing the role of pharmacy through increased encouragement of consumer-pharmacist interaction and distributing some OTCs exclusively in outlets with a pharmacy, creating a new category of these products: Pharmacy Care OTCs. The combination of expanding consumer access to these products in the OTC area of the pharmacy and providing access to the pharmacist for assistance is powerful and helpful. Consumers seeking access to the product in the pharmacy would have ready access to the product, and those seeking input from the medication expert on the health care team-their pharmacist-would have ready access to that advice.

In August 2004, the American Pharmacists Association convened a Task Force to discuss these issues and develop recommendations for incorporating additional OTC products into pharmacy practice and implementing the Pharmacy Care OTC category. Task Force members (identified in Attachment A) include representatives from independent and chain community pharmacy practice, managed care, academia, and pharmacy management. Pharmacy Care OTCs are a sub-category of non-prescription medicines available only in outlets with pharmacies¹ to facilitate interaction between consumers and pharmacists. [Footnote1: A 'pharmacy' is facility, licensed and designated by appropriate state regulators as a pharmacy, where drugs or devices are dispensed and/or pharmacist services are provided.] These medications may be used for chronic, asymptomatic conditions or other conditions where consumers would benefit from additional interaction with their pharmacist. Pharmacy Care OTCs can provide significant benefit to consumers, who may also benefit from the expertise of pharmacists to help them effectively utilize these products. This category presents an opportunity for consumers to have greater access to important medications that can benefit their health while using the medication expertise of pharmacists to help consumers use those medications appropriately.

Task Force Mission Defining a "Pharmacy Care OTC" Category

Moving products from prescription to OTC status affects pharmacy practice in many ways, including pharmacists' efforts to coordinate and monitor medication use, the need to prepare pharmacy personnel for the product shift, and the financial impact of the shift. OTC products designated as Pharmacy Care OTCs will require additional thought and planning on the part of the manufacturer, pharmacists and facility staff. The Task Force mission included providing advice to the profession of pharmacy and other stakeholders on helping consumers make the best use of Pharmacy Care OTC medications.

Objective

The task force discussed this new category and developed guiding principles for implementation of the category. The task force made recommendations (provided below) on issues such as:

Necessary training and education of pharmacy personnel and facility staff to support pharmacist/consumer interaction, including providing consumer education materials.

Considerations in selling such products, including access to pharmacy personnel, product placement, and support services such as in-pharmacy point-of-care testing.

Recommendations

The APhA Task Force on Pharmacy Care OTCs recommends manufacturers, pharmacists and pharmacies consider the following when choosing to provide Pharmacy Care OTCs. Task Force recommendations are meant to be flexible, allowing for individualization within a specific pharmacy practice setting.

Management of the Pharmacy Care OTC Category

Products in this category should demonstrate a proven health benefit.

Availability as a Pharmacy Care OTC is recommended only for certain appropriate products where consumers will benefit from increased access to a pharmacist. The Task Force urges the development of criteria to identify those types of products that would benefit from this category.

Guidelines for patient identification and risk assessment should be available.

Information about appropriate populations and necessary risk assessment procedures should be provided in product labeling, as well as in educational material for pharmacists.

Supporting Consumer/Pharmacist Interaction

Product placement and promotion should support direct interaction with the pharmacist.

Pharmacy Care OTCs present an opportunity for consumers to easily access important medicines and ask questions of their pharmacist. To facilitate that interaction, consumers must have direct access to pharmacists, access that is supported by product placement, promotion, workflow, and staffing patterns. Business models should support providing these services. Marketing approaches (e.g., print ads, shelf-talkers, etc.) should direct consumers with questions to their pharmacist; some facilities may choose to position a pharmacist in the OTC area to offer assistance. As a contingency in those outlets that remain open when a pharmacist is not on duty, such as a grocery store or mass merchandiser, methods to provide access to counseling and education should be developed, including alternatives to face to face approaches, such as use of the telephone and the internet. (Pharmacist availability will be consistent with state requirements for pharmacy licensure.) Appointment systems should be considered if the consumer requests lengthy consultations or if the pharmacy environment is not always conducive to consumer/pharmacist interaction.

Facility staff should be educated about Pharmacy Care OTCs.

When the pharmacy is one component of the facility (e.g., a grocery store or mass merchandiser), appropriate non-pharmacy staff should be educated generally about Pharmacy Care OTCs so that they may direct consumers to the pharmacy area and advise them of the pharmacist's availability for consultation..

Education about Pharmacy Care OTCs and specific products included in the category should be provided through the media, marketing, pharmacists, and pharmacies.

Scope of Consumer/Pharmacist Interaction

Pharmacy staff should be educated and trained about the product and the appropriate population for product use.

Pharmacists are responsible for responding to consumer inquiries. Pharmacists, student pharmacists, technicians and others working in the pharmacy should be educated about the product and condition being treated, risks, appropriate monitoring, and follow-up; as well as procedures for responding to consumer inquiries and referring consumers to other health care professionals, as appropriate. Such education and training is important to adequately prepare pharmacists to deliver these services.

Pharmacist/consumer interaction includes:
identifying consumers who should use the medication,
identifying consumers who should be referred to another health care professional, and
providing appropriate support.

Consumer/pharmacist discussion may encompass screening activities as well as consultation at the point of purchase. Recommendations for consumer use should be consistent with product labeling and clinical guidelines, where available. For consumers using Pharmacy Care OTCs for chronic conditions, the consumer/pharmacist interaction may include ongoing support, such as compliance monitoring and monitoring for therapeutic endpoints.

Other Services

Support services should be available or referral information provided.
Some Pharmacy Care OTCs may require point-of-care testing to identify appropriate consumers and monitor consumer progress. Where such services are not available in the pharmacy facility, referral information should be provided.

Documentation of Pharmacy Care OTCs in the patient profile is encouraged.
Pharmacy Care OTCs facilitate documentation of product use, supporting drug/drug interaction screening, protection against drug/disease contraindications, and outcome monitoring. Consumers should report use of Pharmacy Care OTCs to their pharmacist and their doctor or other prescriber. Pharmacists who sell Pharmacy Care OTCs should recommend and request consumer approval to add these products to their medication profile. Consumers and pharmacists share in the decision-making for communicating information about their use of Pharmacy Care OTCs with the primary physician providing their healthcare.

APhA Pharmacy Care OTC Task Force* [*Task Force participants served as individuals. This report does not necessarily represent the opinions of their organizations.]

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COMMENT NUMBER - 2005N-0345-EC167

2005N-0345-EC167 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Blume, John

2005N-0345-EC167 - TEXT

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 3.7.2>It depends on the subpopulation. It would probably be difficult to do it based on race for example, but not based on age. Although certain drugs seem to be more effective on certain races I don't see how somebody selling a drug is supposed to determine the buyers race. However, age limitations are common.</1: 3.7.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<2: 7.4.4>Yes, depending upon the subpopulation, With age, identifications could be checked or in my comments below I also have a possible alternative solution.</2: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<3: 8.1>Yes, but see my comments below.</3: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<4: 9.2.2>I don't see any.</4: 9.2.2>

GENERAL

GENERAL

Instead of answering the questions I omitted above,I am going to answer the questions in your letter.

<5: 1.2.1, 6.5.1>1. Can age be used as a criterion on which we decide whether a drug should be prescription or over-the-countger, as has been proposed in this case (Plan B)?

Yes. However, I suspect that political pressure may be at play here. If that is the case, it is inappropriate. The FDA should be considering whether an age limit would be justified based on the safety of the product for the given age group, not based on their or anyone else's moral beliefs. I can easily believe that certain

drugs are safer for certain age population than for others. I am not in the field of medicine and therefore do not feel qualified to say whether or not this drug is safe for those under 16. If it is, make it over-the-counter for all age groups and let parents do their job of raising their own kids. </5: 1.2.1, 6.5.1>

<6: 8.4.1, 8.6.2, 9.1.1>Can the prescription and over the counter version of the same drug be marketed in a single package? I don't see why not. I don't see how that could do any harm if they are to be used in the same way and contain the same dosage of the same medicine. In fact, it might be more dangerous to market them in different packages, which could lead some people to believe that the over-the-counter version is different in that it is safer. However, if you see a reason that it would actually be more dangerous to market them in the same package, I don't think it would be much of a burden on the drug company to make two different packages.</6: 8.4.1, 8.6.2, 9.1.1>

<7: 7.4.4, 7.4.6>If we do use age as the only criterion on which we decide whether a drug is sold as a prescription product, or over the counter product, how as a practical matter would such a limitation be enforced?

The cashier could ask for identification just like is done when somebody buys alcohol or tobacco products. Also, I don't know exactly what information pharmacies already have in their computer systems about patients, but if age is one they could check their computers or if it is not, it could be something that doctors could supply. This, of course, would mean that the drug would have to be sold only where prescriptions drugs were sold, but that it could be bought without the prescription. </7: 7.4.4, 7.4.6>

COMMENT NUMBER - 2005N-0345-EC16770

2005N-0345-EC16770 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy

2005N-0345-EC16770 - TEXT

GENERAL

See Attachment

2005N-0345-EC16770-Attach-62.DOC

Docket Number and Title: 2005N-0345 - Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed In Both a Prescription Drug Product and an Over-the-Counter Drug Product

RIN Number: 0910-AF72

FR Type: Advanced Notice of Proposed Rulemaking

Action: Other

Comment Period End Date: November 1, 2005

Comments Submitted by: The House Subcommittee on Criminal Justice, Drug Policy and Human Resources,
Committee on Government Reform
B-377 Rayburn House Office Building
Washington, DC
202-225-2577

Barr Pharmaceuticals has proposed that Plan B be marketed both prescription and over-the-counter (OTC) in a single package. This presents several new significant legal and regulatory questions for FDA.

The statute under question is §503(b)(1) of the Federal Food, Drug and Cosmetic Act. To date, FDA has interpreted that statute to allow marketing of the same active ingredient in products that are both prescription and OTC only if there is "a meaningful difference between the two that makes the prescription product safe only under the supervision of a licensed practitioner." By "meaningful difference," FDA means a difference regarding indication, strength, route of administration, dosage form, etc...that makes the prescription product safe only under the supervision of a licensed physician.

I. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<1: 3.1>Yes</1: 3.1>. <2: 3.8.1>It is crucial that FDA continue and codify its current interpretation of this law. FDA has set a consistent standard, the "meaningful difference" standard, which the American public and pharmaceutical companies have relied upon. If FDA codifies its current interpretation, this provides a further service to the public and to pharmaceutical companies, as this would give FDA's future decisions clarity and meaning. </2: 3.8.1>

A. It is potentially unlawful and against public policy for FDA to market the same drug both prescription and OTC in the same package.

<3: 6.5.4>In light of FDA's longstanding and well-established interpretation of this statute, there are no bases, legal or otherwise, for allowing marketing of the same active ingredient in a drug both OTC and prescription. Barr has proposed that FDA interpret 503(b) in a completely different way than it ever has before. Neither Barr nor FDA has given any substantial justifications for why FDA would suddenly change its interpretation for such a controversial, and in many ways, untested, drug. In fact, FDA's reconsideration of its established interpretation in this situation is confusing at best, both in terms of how FDA uses information and data to make policy decisions, and what standards FDA uses to create interpretations of law that are completely contrary to its prior interpretations.</3: 6.5.4>

<4: 3.4>Furthermore, FDA is constrained to act in accordance with the APA's mandate to refrain from any agency activity that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." [Footnote 1: See APA §706(2)(A).] In determining what constitutes "arbitrary" agency action, administrative case law has consistently held that a court will intervene if it "becomes aware, especially through a combination of danger signals, that the agency has not really taken a 'hard look' at the salient problems, and has not genuinely engaged in reasoned decision making." [Footnote 2: See *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 850-852 (D.C.Cir.1970).]</4: 3.4>

<5: 3.4>It appears clear that FDA has not taken a hard look at the salient problems which surround changing its interpretation of the statute. Plan B, the drug which FDA has decided to use towards

considering changing its interpretation, is one of the most controversial drugs on the market. Barr Pharmaceuticals has also experienced a long history of falling far short of FDA's testing and safety standards regarding this drug. [Footnote 3: See, e.g., http://www.fda.gov/cder/drug/infopage/planB/planB_NALetter.pdf (accessed Oct. 27, 2005).] To date, Barr has not rectified this situation; there is still a troubling shortage of clinical data on Plan B as to safety and effectiveness, particularly involving young adolescent women. [Footnote 4: See <http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm> (accessed Oct. 27, 2005).] This disturbing state of facts surrounding FDA's actions is the very definition of a "combination of danger signals" surrounding agency action. In a more general sense, if FDA allows simultaneous marketing of any active ingredient in a drug both prescription and OTC, thus interpreting its rule in a way directly contradictory to its past interpretation, without any apparent justification whatsoever, that easily constitutes arbitrary and capricious agency action.</5: 3.4>

<6: 3.8.4>Additionally, to allow FDA to change its interpretation of this statute or to allow an exception to its current interpretation for Plan B is against public policy. It not only opens the door to instability in the way agencies interpret their own statutes, but also leads to significant public doubt as to how FDA interprets its own rules. How does FDA serve the American public by arbitrarily changing its statutory interpretation merely at the behest of a pharmaceutical company, which furthermore provides insufficient data to support its request? As an executive agency that ultimately serves the American people, FDA must pay careful attention towards maintaining consistency in its interpretations of law, especially in situations like this where there is little evidence-medical or legal-which would support a change in FDA's existing interpretation. </6: 3.8.4>

II. Using age as the criterion for determining whether a drug is marketed as prescription or OTC is arbitrary and dangerous.

<7: 1.2.3, 6.5.4, 7.5.3>One of FDA's prime concerns is that there appears to be no way to ensure that women under 16 years of age will not have access to Plan B OTC. This unanswerable problem highlights the overarching flaws inherent in allowing age as the criterion to determine whether a drug is prescription or OTC. </7: 1.2.3, 6.5.4, 7.5.3>

<8: 1.2.3, 6.5.4>The age requirement is arbitrary. FDA has not explained this requirement and appears to have no basis for it. And to date, Barr Pharmaceuticals has submitted no credible, scientific evidence as to why it wants this arbitrary age distinction to determine how Plan B will be marketed. Barr has only stated that allowing Plan B OTC will make Plan B more available. As a stated reason, this is empty and ineffective. There are countless drugs which would be more accessible if patients could obtain them OTC. That hardly provides a justification for completely changing a long-established agency interpretation.

Moreover, Barr has performed no studies to determine the safety and effectiveness of Plan B in patients younger than 14, and has based its request for girls age 14-16 on a sample of only 29 girls. [Footnote 5: See <http://www.go2planb.com/PDF/PlanBPI.pdf>. (emphasis added) Accessed October 18, 2005.] Barr states on Plan B's website that "safety and efficacy of progestin-only pills have been established for women of reproductive age for long-term contraception. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older." [Footnote 6: Id.] So, in effect, Barr is hazarding a guess that Plan B will be safe for minors. Nor has Barr performed any research either on overdosage or on dependence on Plan B. Effectively, Barr has provided wholly inadequate research or no research at all to support its request to make Plan B available OTC.</8: 1.2.3, 6.5.4>

<9: 7.5.3>FDA is correct in its concern that there appears to be no way to ensure that women under 16 will not have access to Plan B OTC. Providing Plan B OTC appears to negate the need for using

traditional channels to obtain a prescription. Furthermore, there are no existing incentives for women younger than 16 to obtain Plan B prescription only. It will be cheaper and easier for minors to obtain Plan B OTC. It is also more expedient to obtain Plan B OTC, which is a key factor in the case of emergency contraception. In effect, a ruling allowing Plan B OTC would mean that women under the age of 16 will be able to obtain Plan B without a prescription in a number of ways. They may have their older friends buy it for them, or even their parents. If FDA has imposed the arbitrary line of age 16 as to when Plan B OTC is safe, who is to say that parents will not just decide for themselves that it is perfectly safe for their minor daughters to take Plan B OTC?<9: 7.5.3> <10: 6.3.4>Furthermore, it would be nearly impossible for concerned family members to detect the use of Plan B underage. As to the enforcement concern, Barr has not presented FDA with even a semblance of enforcement mechanisms for ensuring compliance with its age requirement.</10: 6.3.4>

<11: 1.2.3>Two, Plan B may act as an abortifacient, which initiates its own subset of legal questions. Barr states on the Plan B website that "Plan B is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization. In addition, it may inhibit implantation (by altering the endometrium)." [Footnote 7: Id.] Needless to say, there is some confusion as to the actual mechanism Plan B employs. If it truly acts as an abortifacient, this presents even more compelling safety and public policy reasons to restrict its use to prescription. </11: 1.2.3>

<12: 3.1>For the foregoing reasons, we strongly suggest that FDA codify its current interpretation of §503(b)(1) of the Federal Food, Drug and Cosmetic Act.</12: 3.1>

ATTACHMENT FROM COMMENT EMC0462:

Ms. Butler,

Attached is a letter clarifying that the Subcommittee's comment on Plan B. <13: 8.2>Our comment said it is against public policy and potentially unlawful to market the same drug as both prescription and OTC in the same package. As the attached letter explains, this is the view of the Majority side of the Subcommittee only.</13: 8.2> Thank you for your assistance in allowing us to clarify the attribution. Best,

Michelle Gress
Counsel
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Government Reform Committee
U.S. House of Representatives
202.225.2577
202.225.1154 (fax)
<http://reform.house.gov/CJDPHR/>
<<11.16 letter to FDA Dockets Management Branch.pdf>>

Jennie Butler
Director
Dockets Management Branch
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Via email to jbutler1@oc.fda.gov

Re: Comment Number EC16770

Dear Ms. Butler:

This letter is to clarify that the comment submitted to the FDA on November 1 (Docket Number 2005N-0345) is attributable to the Majority side of the Subcommittee on Criminal Justice, Drug Policy and Human Resources only.

Comment Number EC16770 addressing "Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product," cannot be attributed to the minority members of the subcommittee.

Please amend the comment by attaching this letter, and/or the following addendum:

<14: 6.5.4>The comment expresses the view that allowing the marketing of the same drug in the same packaging as both prescription and over-the-counter is bad public policy and potentially illegal; using age as the sole criterion for determining whether a drug may be purchased over-the-counter or by prescription only is arbitrary and dangerous. The views of the majority side of the Subcommittee are reflected in this comment. This comment may not reflect the view of the minority.</14: 6.5.4>

Thank you for your attention to this matter, and for allowing the Subcommittee to clarify attribution of the comment. Should you have any questions, please contact Michelle Gress of the Subcommittee Staff at 202-225-2577.

Sincerely,
Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Policy and Human Resources
Government Reform Committee

COMMENT NUMBER - 2005N-0345-EC168

2005N-0345-EC168 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Hein, Rachel

2005N-0345-EC168 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.5>no...drugs cleared for OTC usage should not have additional restraints of prescription requirements based on age. But instead should have clearly labeled information for dosage and dangers, especially when applied to minors.</1: 3.2, 3.8.5>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

no...drugs cleared for OTC usage should not have additional restraints of prescription requirements based on age. But instead should have clearly labeled information for dosage and dangers, especially when applied to minors.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>yes...why are you holding up the release of a scientifically approved drug for prescription requirements that would lend the drug ineffective?</2: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.2>no...please follow previous rulemaking precedents and release the drug for use.</3: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2>The FDA should not limit the sale of an OTC product to a particular subpopulation.</4: 6.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2, 7.3.1.2>It should NOT. Clear instructions and warnings should instead be required of the drug distributor.</5: 7.2, 7.3.1.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 3.7.1>It is illegal to withhold OTC suitable active ingredients based on discrimination by age, gender or race. All packaging should contain full information.</6: 3.7.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.1>Only if there is a proven danger of bodily harm to the actual user.</7: 9.1.1>

GENERAL

GENERAL

<8: 1.2.3>If the FDA has found this drug (Plan B) to be scientifically safe for OTC use, then it should be

released as such. No additional delay or politically motivated restrictions should be applied. </8: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC170

2005N-0345-EC170 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Babb, Beverly

2005N-0345-EC170 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

Please read answer 2B

2

B. If it could, would it be able to do so as practical matter and, if so, how?

<1: 1.2.1, 7.4.4, 7.4.6>On the front of the package the label could read, "Prescribed for women over the age of 16". On the bar code put a line that "bings" when going thru the cash register line and alerts cashier to ask for ID. You need to acknowledge that kids get "adults" to buy them beer and young women under 16 will get older friends to do the same thing for Plan B.

Face reality and put it on OTC. Stop the obstruction and put it out there for use. This is from a Grandmother with daughters and granddaughters. Use common sense.</1: 1.2.1, 7.4.4, 7.4.6> Thanks for the opportunity to have a say. Beverly Babb

COMMENT NUMBER - 2005N-0345-EC171

2005N-0345-EC171 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Pinkerton, Mike

2005N-0345-EC171 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.5>No. I believe that the interpretation is overly restrictive and ignores situations such as this (appropriate for a sub-population) and should not be codified. Case by case determination is more appropriate.</1: 3.2, 3.8.5>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 3.2, 3.8.8>No. The interpretation is too restrictive.</2: 3.2, 3.8.8>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1, 4.4.2>Affirmative, you seem quite confused between your role in approving drugs on scientific merit and benefit (vs social engineering and backdoor legislated morality).</3: 4.1, 4.4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.2, 6.5.1>No. A reminder to the FDA that its role is to approve or disapprove drugs for use based on potential harm and validity of claims is needed.</4: 5.2, 6.5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.6.1, 6.6.3>Not relevant. Other such enforcement is already performed: alcohol, tobacco, pseudophedrine, spray paints and other inhalable solvents, ...</5: 6.6.1, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

See answer to A above. Follow the existing models.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.5>Differentiation should only be required if it can facilitate enforcement.</6: 8.5>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 8.5>When the package differentiation is necessary as part of enforcement procedure.</7: 8.5>

GENERAL

GENERAL

<8: 1.2.1>I do not believe that this should be restricted for any age group. I believe that this is a necessary part of giving underage pregnant females a chance to prevent unintended pregnancy. With the explosion of unwanted pregnancy in females under 16 anything that allows them to address the mistake is a positive step. Young females will not tell parents or doctors, but will try this if its available. Requiring a doctor or parent will simply make this inaccessible. The staggering statistics regarding the impacts of inintended teen pregnancy on society as a whole include the continuation of the cycle of poverty/lack of education/low income/crime that many unintended births feed. How moral is that?</8: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC172

2005N-0345-EC172 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Ross, Angela

2005N-0345-EC172 - TEXT

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 6.1, 6.6.3, 7.4.4>Absolutely. In the same way that alcohol and tobacco are perfectly legal to one population (those over the age of 21 and 18, respectively) and enforceably illegal to a subpopulation (those underage), it would be enforceable to limit sales of an FDA-approved product. It would absolutely not be enforceable to limit sales to a subpopulation based on almost anything other than age, however, as age is easily determined by simple identification.</1: 6.1, 6.6.3, 7.4.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<2: 7.4.4, 7.4.6>It seems to me that this would be entirely practical. Again, in the same way that a person selling tobacco or alcohol is required to check identification of the purchaser, a pharmacist would have this same requirement. Additionally, birth date is a matter of medical record and would either be in a pharmacist's file already or can be requested as an identification tool. Over-the-counter has come to mean different things in this day and age. At present, we do not have to interact with a pharmacist for all of our medical needs. As Commissioner Crawford stated, most cough syrups, pain killers, flu remedies, etc., are just on shelves outside of the pharmacist's counter. However, there are also certain OTC medications that are kept in locked cabinets or behind the counter. While they do not require a prescription, a person has to request them from pharmacy personnel. It would be easy to keep an OTC product behind the counter and to request identification from anyone asking for the product -- not as a matter of record but for the purposes of determining age.</2: 7.4.4, 7.4.6>

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<3: 9.2.1, 9.2.2>Assuming that the package has the same instructions for use both OTC and by prescription, I see no problem with selling the same product in the same package. However, if there are different usage instructions depending on whether the product is OTC or by prescription, a separate packaging would be important.</3: 9.2.1, 9.2.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<4: 9.2.2>As I stated above, if the product requires different usage instructions based only on whether it is sold OTC or by prescription, it may be inappropriate to use the same package.</4: 9.2.2>

GENERAL

GENERAL

<5: 1.2.1>The real question in all of this seems to be "What is the danger in the subpopulation getting ahold of this particular OTC product?" In the case of emergency contraception, marketed as Plan B, most if not all of the scientific research has indicated little to no risk to any population. Also, in this case there are so few pills sold at once (i.e. it is a one-dose package, in my understanding) that an overdose is highly unlikely. Additionally, the risks for abuse, overuse, or addiction are slim to none. So what is the real purpose of limiting the sale? One possibility is lack of scientific research on the effects of emergency contraception on women below a certain age. Another possibility is the belief of our society that people under a certain age are unable to make sound and reasonable choices about their own lives, including their own health care (e.g. age of consent laws, drinking/smoking age laws, driving age laws). These are both sound explanations for limiting activities. In addition, the examples I provided are examples wherein performing these activities (driving, drinking, smoking, etc.) before a certain maturity level is reached could cause a danger to oneself or another. So, is there a serious danger to selling emergency contraception to a 15-year-old or even a 13-year-old woman that is not present when selling emergency contraception to a 17-year-old woman? Regardless of the answer, no one is asking for the drug to be available to women under the age of 16. While I understand the need for consistency in approving medications and also what it means to set a precedent, this type of drug is unprecedented and the FDA needs to create a healthy policy accordingly. If this society is serious about women's health care, about reducing the number of unwanted children, and about decreasing the number of abortions, emergency contraception needs to be easily available to all women of reproductive age. </5: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC176

2005N-0345-EC176 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Murphy, Cynthia

2005N-0345-EC176 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

This is a completely insignificant question.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.2>No. </1: 3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No. </2: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 3.2>n/a The last thing we need in this country is MORE rules!</3: 3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1>Yes, but why would it want to.</4: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 6.1, 6.3.5, 6.6.3>Yes, this should be obvious as there are several products sold at market that the sales of which are restricted only by age. (alcohol, cigarettes, alieve-neproxin) </5: 6.1, 6.3.5, 6.6.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1>of course.</6: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.2.2>none.</7: 9.2.2>

GENERAL

GENERAL

<8: 1.2.1>Birth control is a personal issue and women should be free - AT ANY AGE - to deal with it however they choose to. </8: 1.2.1><9: 2.1>Quit fiddle-farting around and approve it already.</9: 2.1>
<10: 1.2.1>Allow women the same sexual freedom - AT ALL AGES - as men have!!! It is long overdue!
</10: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC181

2005N-0345-EC181 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Steward, Linda

2005N-0345-EC181 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>no. It should be one or the other,not both.</1: 3.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 3.2>no.</2: 3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>no.</3: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 5.2>no.</4: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.1, 6.3.5>yes. Laws would be made to make sure of that.</5: 6.1, 6.3.5>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 6.6.1, 7.1>yes. The states would regulate it.</6: 6.6.1, 7.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1>yes.</7: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.2.2>None.</8: 9.2.2>

GENERAL

GENERAL

<9: 6.6.1, 7.4.4>A drug is either safe for over the counter sale or it isn't. I now have to buy my otc sinus pills at the pharmacy and sign for them. The same thing could be done in this case. ID could be required also. </9: 6.6.1, 7.4.4>

COMMENT NUMBER - 2005N-0345-EC186

2005N-0345-EC186 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Wilson, Rhianna

2005N-0345-EC186 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.9.1>Yes. There are already other laws and rules involved in the process of purchasing OTC medications. Such as only being allowed to purchase so many packages of sudafed etc. So inflicting

another law on societies consumers will not come as a shock. Especcially dealing with a medication that carries so much of an importance to release because of its immeditate window of effectivness.</1: 3.1, 3.9.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.2, 6.5.4>No, the gaurdians and parents of that subpopulation should be able to purchase the medication for the subpopulation.</2: 6.2, 6.5.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<3: 1.2, 8.1>Yes. There should be more information about Plan B on the FDA website and should be readily available to all consumers.</3: 1.2, 8.1>

GENERAL

GENERAL

<4: 1.2.1>I believe that it is very important that Plan B is available OTC. Specifically becuae it needs to be taken within such an immediate window period in order to be effective. The packaging of Plan B should have more information about the product Plan B, including all known side effects and precautions. Help lines and websites with further information should be included. Teenagers under 16 should still be able to recieve the medication through prescription.</4: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC1927

2005N-0345-EC1927 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Moon, Kristin

2005N-0345-EC1927 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.3>Yes--often patients will abuse the OTC product--that is--to take it incorrectly and do themselves harm--even when the package is labeled for safe use. Other times, patients need doctor contact to rule out severe illnesses or needs, but having the medication available OTC keeps them out of the doctor's office</1: 3.1, 3.8.3>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes</2: 4.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 7.5.3>If the drug is available AT ALL in OTC, the subpopulation will have a much easier time of getting the drug--and if they want it, they WILL find a method to get the drug. The FDA would have a very difficult time enforcing such a law. Better to leave the item in RX status.</3: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.6.4>It should not be legal to sell the items in the same packaging--the average consumer would have too easy a time of calculating what was necessary for a prescription dosing of the drug.</4: 8.6.4>

GENERAL

GENERAL

<5: 1.2.3>I would strongly urge the FDA to not permit the OTC sale of the 'PLAN-B' type oral contraceptive--the so called morning after tablet. Women should be checked by their physician (i.e. need to get a prescription for this drug) so that:

- 1) Sexually transmitted disease can be detected and
- 2) Statutory rape or sexual abuse can be guarded against</5: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC193

2005N-0345-EC193 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Witherwax, Carol

2005N-0345-EC193 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.3>When the product would help to benefit the majority of the people (in this case women) and assist in alleviating the unnecessary medical, social, and psychological impact on society if the drug was not dispensed.</1: 3.8.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 7.4.4, 7.5.3>Probably not 100%. Pharmacies can be mandated by law to request that customers show photo ID, but as we all know IDs are very easy to forge. A person age 16 could or could not look their age. It would be difficult.</2: 7.4.4, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<3: 8.2>I think that the packaging should be different (maybe just in color) so that the prescription drug is more distinguishable from the OTC product.</3: 8.2>

COMMENT NUMBER - 2005N-0345-EC194

2005N-0345-EC194 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Morrisroe, Julia

2005N-0345-EC194 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.9.1>There are many otc drugs available that are not suitable for children...but here were talking about girls....under 16. Clairitn for adults vs. clairitin for children. We rely on individuals to make the right decision. The FDA is supposed to check on the safety of the drug, not police individual usage, because if individual usage were the issue the FDA has failed miserably....valium for example.</1: 3.9.1>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.3.4>The confusion relates to the FDA unwillingness to move forward on this particular drug, had the FDA's action been consistently obstructionist about Viagra and access to Viagra, you'd be in a better position to defend this case.</2: 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.5>If you rule that access is a right for all women.</3: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 7.4.1>We're able to sell cigarettes behind the counter, many drug stores sell condoms behind the counter, or pornography for that matter. Why this is a problem for the FDA I do not know.</4: 7.4.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2>No, keep you hands off. Your talking about individual rights here, the agency is stepping out of bounds.</5: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1>Yes, again this seems like your making problems in order to avoid making a decision on this drug.</6: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.2.2>None</7: 9.2.2>, see above

GENERAL

GENERAL

<8: 2.1>I am so deeply offended that the FDA has become a politicized agency. Your rulings are no longer trustworthy, your decision making ignores science in favor of political position, because of the agencies inability to fulfill it's mission you should disband the agency. You've become a waster and

abuser of taxpayer money, and I thought your job was to investigate the effectiveness and safety of drugs.
</8: 2.1>

COMMENT NUMBER - 2005N-0345-EC195

2005N-0345-EC195 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Dowell, Duane

2005N-0345-EC195 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>there is no compelling reason to initiate the process at this time</1: 3.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

Same as "A" above

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>There seems to be confusion at the FDA.</2: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.1>That is not likely</3: 5.1>.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 7.5.4>It seems that it would be overly cumbersome for the pharmacist.</4: 7.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 6.6.4>There is some precedent in control of firearms and of narcotics.</5: 6.6.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

Yes

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 3.4, 9.2.2>None</6: 3.4, 9.2.2>

GENERAL

GENERAL

<7: 1.2.1>In the case of the drug, Plan B, the science is clear that it is safe and effective. It is also clear that prompt and easy access is important for ALL women of childbearing age.</7: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC196

2005N-0345-EC196 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Hibberd, Rachel

2005N-0345-EC196 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.11>This is a non-issue, as you are well aware, Mr. Crawford. First of all, there is no reasonable objection to marketing a product as simultaneously OTC and prescription. The only problem this type of marketing is likely to cause is confusion in the public as to why a woman of 16 and a woman of 17 must go through different processes in order to have access to adequate contraceptive care. The confusion will be justified, because the Not Approvable letter issued to Barr regarding the drug's not being safe for women under 17 was just one of a series of politically motivated and completely irresponsible moves taken by you, against the wishes of the FDA's scientific advisory panel.</1: 3.11>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

See above.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1, 4.3.4>Yes, it makes no sense from a public health standpoint. Women are not served by this kind of maneuvering; if this agency were really interested in protecting women's health, they would allow women access to this needed drug.</2: 4.1, 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.2>No.</3: 5.2> <4: 5.4.2.2>The majority of the public is not familiar enough with the facets of the FDA's bureaucracy to understand even the questions on this "public" comment form.</4: 5.4.2.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 7.1, 7.4.4>YES, this again is a ridiculous question. The ruling would be enforced in the same way all other age-controlled substances are enforced: the vendor will simply ask the consumer for ID proof of age.</5: 7.1, 7.4.4>

B. If it could, would it be able to do so as a practical matter and, if so, how?

<6: 6.6.3>Asking this question makes the FDA look ridiculous from a public perspective. Everyone is familiar with the processes in place to keep minors from purchasing, for example, tobacco products and alcohol. While these enforcement efforts may not be perfect, it must be admitted that allowing a 15 year old to prevent an unwanted pregnancy poses less of a public health risk than allowing an underage person to consume tobacco products.</6: 6.6.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1>Why not? Again, a question that is absurd and reinforces women's belief that the FDA is not being honest with the public regarding its reasons for blocking Plan B.</7: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

Can you think of any?

GENERAL

GENERAL

<8: 1.2.1, 2.1>Mr. Crawford, I cannot express the level of frustration and bitterness that I and every woman I know is experiencing over your latest decision. We feel that we are being grossly misrepresented, as you pander to a small minority opinion based on erroneous medical data (the anti-choice groups who insist that Plan B is an "abortion pill.") Please take a moment to consider the profound impact your decision is having on women in vulnerable situations, ESPECIALLY the nation's most disenfranchised women: young women, poor women, women without an adequate support network. Imagine a teenaged girl who comes from an abusive, unsafe environment. She is more likely to experience unplanned pregnancy, because she is less educated and suffers from behavioral problems related to her family instability. She is financially unable to go see a doctor, she has no car to get to a doctor's appointment, she is unclear on what her options are regarding confidentiality, and she cannot turn to her family for help. She does not want to have a child. Under the current system, her options are to give birth or have an abortion. By allowing Plan B to be sold over the counter, we can give countless women in similar situations a "second chance." </8: 1.2.1, 2.1>

COMMENT NUMBER - 2005N-0345-EC1970

2005N-0345-EC1970 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Crousey, Joshua

2005N-0345-EC1970 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No.</1: 3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.2, 6.5.4>No, as a law student I can say that there would be significant limitations. This would be regarded as creating a 'class' of people. This always has problems associated with it.</2: 6.2, 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.5.3>Here's my biggest problem. If it's available easily, what's going to stop an older person from buying it when he finds out that he got an underage girl pregnant? Right now, we have the prescription

process in place and serious consequences for trying to avoid using a prescription. This is a drug that we just might want people to have to get a prescription.

How would you be able to tell who should or shouldn't receive it? Are you going to check ids at the store? How can we be sure that older people won't give it to younger people?</3: 7.5.3>

COMMENT NUMBER - 2005N-0345-EC199

2005N-0345-EC199 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Gay, Sarah

2005N-0345-EC199 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

Maybe- see below.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

This is the same question as above, except with a typo.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<1: 1.2.1>There is significant confusion as to why FDA is making such a huge deal of its interpretation in this single case, which has such important ramifications for women, and whose drug has been demanded as OTC-available in the U.S. for years, by both doctors and the public. There is also confusion as to why the application for the combined status (Rx and OTC) was framed in terms of age in the first place, instead of requesting simply to make it OTC across the board. Did the applying agency craft its request in terms of age, based on FDA agency findings (such as those quoted below)?</1: 1.2.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<2: 5.5>Yes and No. If FDA Rules are based on scientific recommendations, rather than political pressure, the current application to make 'Plan B' available OTC to women 17 and over is consistent with the FDA Commissioner's own statement that 'The FDA's drug center, the Center for Drug Evaluation and Research or CDER, completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an over the counter product, but

only for women who are 17 years of age and older,' and the drug application should be approved. A rulemaking on the issue of general interpretation of section 503(b) is irrelevant in this case.</2: 5.5>

<3: 6.3.4>IF it's a medical concern, based on research, that age affects how the drug is received by the body, and that the drug will affect younger women differently **BIOLOGICALLY AND MEDICALLY**, the supporting science is there, and the drug should be allowed to go to market as proposed, based on earlier precedents establishing different medical indications and effects for such an allowance. If it is NOT a medically-based distinction, and sound scientific research (free from political framing) shows it is safe for any woman regardless of age, the drug's availability OTC for anyone should be approved as has been consistently recommended by FDA scientists, doctors worldwide, and by the public who wishes to exert control over their reproductive health.</3: 6.3.4>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.3.5>As a matter of law, it's a moot point; if the FDA passes such a regulation, it is already law, no? Isn't the FDA granted law enforcement powers related to its regulations?</4: 6.3.5>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 6.6.3, 7.3.2>I don't know, that is a question for YOU to deal with! What does FDA enforce now? Why should it be any more difficult for the FDA to enforce this than any other prescription-only regulations?</5: 6.6.3, 7.3.2>

<6: 7.4.4>OK, you've got a supply available to the larger population OTC. Why couldn't, for example, age-i.d. requirements such as those governing sales of cigarettes and alcohol be enforced at the sales counter, and become the responsibility of general law-enforcement, while regulation of the prescription sales remains purvue of the FDA?</6: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1>I frankly don't see why this is an issue. Yes.</7: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.2.2>None.</8: 9.2.2>

GENERAL

GENERAL

<9: 1.2.1, 2.1>The reversal of the FDA's promise to make a decision on this application by September, is disappointing in the least and quite frankly, a bit sickening. It appears quite political and is a sad state of affairs. Your statement of August 26, 2005 reads as a transparent stalling tactic, devoid of solid scientific

foundation and based on thinly devised 'concerns for long-term policy implications.' I fear for the integrity of the agency. While genetic engineering has been introduced and encouraged by the FDA for major industry growth over the past ten years, with no assurance I know of that long-term implications are non-existent, I recall no such waffling on considerations about or calls for further research on it. We now have fish genes in our corn with no real knowledge of how this will affect our immune systems and gene pools over generations; yet you are so 'concerned' about the implications of a proven, safe way for women to take their own health and reproductive decisions into their own hands, you would limit that ability for another span of years. This behavior is inconsistent with an interest in the public health and is deplorable on the part of the FDA. I urge you to change your direction and allow the resolution that has been recommended by responsible scientists and experts for two years: get the drug to market and available over the counter, whether to those only over 17 or to all. You don't need the public's input on how to do that. That is your area of expertise. You already have the public's mandate that it be done.</9: 1.2.1, 2.1>

COMMENT NUMBER - 2005N-0345-EC2009

2005N-0345-EC2009 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Gibbons, Bridget

2005N-0345-EC2009 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes.</1: 3.1> <2: 3.8.1, 3.9.1>The FDA already does this for nicotine replacement drugs, and in the interest of legislative clarity, a clear rule should be established for drugs available in both prescription and OTC. This will finally allow the FDA to make a decision regarding Plan B, a decision consumers have waited on for years.</2: 3.8.1, 3.9.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<3: 3.1>Yes.</3: 3.1> <4: 3.8.1>Such a rule will clarify this rule for future drugs so that consumers will have easier access to drugs. As the pharmaceutical industry becomes more and more involved in the everyday lives of Americans, increasing ease and access will aid both industry and consumers in making the right drug choices free from the need for prescriptions for drugs determined to be safe for OTC by the FDA.</4: 3.8.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<5: 4.2>I disagree that there is confusion over this issue. </5: 4.2><6: 5.3.2>I believe that the confusion surrounding Plan B stems from religious and political disagreement with the drug itself. However, if a clarification of the rule will allow the FDA to finally make a decision regarding Plan B, I would approve of a rulemaking in order to facilitate decisionmaking.</6: 5.3.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<7: 5.3.2>As stated above, I think the "confusion" is merely a political smokescreen. However, future drugs may cause legitimate confusion, so perhaps it is in the best interest of the consumer population to have a bright-line rule regarding these drugs.</7: 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<8: 6.1>Absolutely.</8: 6.1> <9: 6.4.1>Although I personally disagree that there should be an age limit on access to Plan B, there are already age limitations on other drugs like Nicoderm and Nicorette.</9: 6.4.1> <10: 6.6.2>As a matter of public policy, it is up to the legislature to determine age limits, as the FDA commission has tried to do, despite interference from outside sources.</10: 6.6.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<11: 6.4.1, 7.4.4>The FDA already only allows nicotine drugs to be dispensed to those over 18. Adults present an ID to get their product. Any other drug could be enforced in the same manner.</11: 6.4.1, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<12: 8.4.1, 9.1.1>Yes. There is no reason to make arbitrary distinctions in packaging as long as the content of the drug is the same. As long as the products are substantially the same product, with no difference in content or dosage, there is no reason to require different packaging.</12: 8.4.1, 9.1.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<13: 9.1.1>If the products differed in dosage or content, it would be inappropriate to sell them in a single package.</13: 9.1.1>

GENERAL

GENERAL

<14: 1.2, 2>The delay in approving Plan B is a political smokescreen. The deception on the part of certain staff members at the FDA goes against the agreement reached with Senators Clinton and Murray this past

summer. Either approve or deny this product. Follow your own policy. Remain independent and act in the best interest of the population. Please. </14: 1.2, 2>

COMMENT NUMBER - 2005N-0345-EC201

2005N-0345-EC201 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Tuchinsky, Marla

2005N-0345-EC201 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.3>To the extent that your interpretation is preventing women from getting access to a perfectly safe and effective drug, yes.</1: 3.1, 3.8.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.6.3>1. You already do limit the use of certain drugs by age -- alcohol and tobacco are both age-regulated drugs. </2: 6.6.3>

<3: 6.6.1, 7.4.1>2. Drugstores routinely keep OTC products behind the counter (albeit usually to prevent theft).

3. Several states have imposed limits on purchasing Sudafed, for example. Clearly, this should not pose a stumbling block to releasing Plan B.</3: 6.6.1, 7.4.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

See my reply above.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.4.1>Why not, if the reason that one is prescription and the other not is based on the age of the patient and not the drug itself? As I understand it, the product isn't different.</4: 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be

inappropriate to do so?

<5: 9.1.1>If the dosage were different. If they were manufactured by different companies.</5: 9.1.1>

GENERAL

GENERAL

<6: 1.2.1>It seems against your core mission to keep a safe and effective pharmaceutical off the market. Denying women access to Plan B several years after it passed your scientific screens is inexplicable.</6: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC2022

2005N-0345-EC2022 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Munro, Margaret

2005N-0345-EC2022 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No - the FDA should not initiate rulemaking.</1: 3.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 3.2>No - the FDA should not initiate a rulemaking to codify its interpretation.</2: 3.2>

GENERAL

GENERAL

<3: 6.5.1, 6.6.2>It is not the FDA's job to create public policy, merely to judge on the safety and efficacy of pharmaceuticals, and to keep the food supply safe. Rulemaking may be effective in cases where dosages need to be monitored in order to keep a pharmaceutical safe and effective - beyond that question, the FDA should not be creating rules; if action is needed to keep a pharmaceutical from a certain group of people, let Congress create and pass that legislation, and let them bear the responsibility of their actions.
</3: 6.5.1, 6.6.2>

COMMENT NUMBER - 2005N-0345-EC206

2005N-0345-EC206 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Levy, Gayle

2005N-0345-EC206 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.9.1>This same situation has worked for Claritin. It is now available OTC and by prescription. No other law making is necessary.</1: 3.2, 3.9.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

Same answer as above.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>It would seem so.</2: 4.1> <3: 4.3.4>Apparently when allergy medication is involved and not a political controversy, the FDA has no problem letting the medication go OTC. However, despite medical and health officials deeming Plan B safe, the FDA has a problem with interpretation for political gains.</3: 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.2>No. No amount of rulemaking (barring the overturn of Roe v. Wade) will change the politics involved.</4: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.1>Yes.</5: 6.1> <6: 6.6.3>The government does it for both cigarettes and alcohol. Are you planning to make both illegal to everyone because the age limitations cannot be 100% enforced?</6: 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 7.1, 7.4.4>The same as they do for tobacco and alcohol. When someone comes to the register to buy that product they will be asked for proof of age. </7: 7.1, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 8.8>I'm not sure how Claritin does it. You could look to that as a model.</8: 8.8>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<9: 9.2.2>I can't think of any.</9: 9.2.2>

GENERAL

GENERAL

<10: 1.2.1>This product has been safely used all over the world. The medical and professional staff at the FDA have overwhelmingly approved it safe for OTC use in the US. There should be no reason why this should be stopped. </10: 1.2.1><11: 6.6.3, 7.4.4>The age concern can be alleviated the same way the government does it for buying tobacco and alcohol. The person buying the medication can be asked for age identification. </11: 6.6.3, 7.4.4><12: 2.1>Once Barr Labs proves it safe for those under 16 this should not be an issue at all.

One of the reasons that the US is a great country is that we have political and religious freedoms, however, these should not be intertwined. The thoughts of conservative Christians should not be ruling how the FDA approves it MEDICAL products. The MEDICAL experts have deemed this product safe and that is the advice you should follow. Although the administration and the country seems to be following a conservative bent right now, the FDA does not need to bend to religious pressures. I am a scientist and am very dishartened that the FDA will not respect the views and opinions of their own medical and scientific staff.</12: 2.1>

COMMENT NUMBER - 2005N-0345-EC21

2005N-0345-EC21 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Richman, Bobbi

2005N-0345-EC21 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>DEFINATELY NOT.</1: 3.2> <2: 1.2.3, 3.3>IF IT WERE SAFE ENOUGH FOR OTC SALES IT WOULDN'T NEED TO BE PRESCRIPTION. THE PUBLIC IS NOT KNOWLEDGEABLE ENOUGH TO KNOW WHEN DR. SUPERVISION IS NECESSARY OR NOT. </2: 1.2.3, 3.3><3: 1.2.3, 7.5.3>THERE COULD BE NO MORE CONTROL OVER WHO BUYS IT OTC THAN THERE IS FOR CIGARETTES OR LIQUOR. IF THERE IS AN AGE LIMIT, IT IS EASY TO HAVE SOMEONE ELSE PURCHASE IT FOR THE PERSON. NOT ALL STORES INFORCE THE AGE CRITERIA, NOR CAN THEY ADVISE CUSTOMERS WHETHER THEY SHOULD CONSULT A PHYSICIAN.</3: 1.2.3, 7.5.3>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<4: 4.3.4>IT IS THE MOST POORLY WRITTEN LETTER I HAVE READ. REDUNDANT, POORLY EXPLAINED WITH NO INFORMATION ABOUT PLAN B FOR THE READER. TOTALLY CONFUSING TO UNDERSTAND THE POINT BEING MADE</4: 4.3.4>

C. If so, would a rulemaking on this issue help dispet that confusion?

FIRST OF ALL WHOEVER WROTE THIS QUESTION "C" SHOULD HAVE PROOF READ IT. WHAT DOES DISPET MEAN? <5: 1.3, 5.4.2.2>IF YOU ARE ASKING THE PUBLICS OPINION, AND WE FEEL THERE IS CONFUSION, WHY DO YOU THINK IT WOULD BE ANY CLEARER IF YOU MAKE A DECISION YOURSELVES. WE ALL KNOW THE CORRUPTION IN THE FDA IN FAVOR OF MONEY MAKING DRUG COMPANIES SO WHY ASK OUR OPINION. YOU WILL DO WHAT YOU WANT ANYWAY. LOOK AT VIOX. NO MORE TO BE SAID AFTER THAT. </5: 1.3, 5.4.2.2>

COMMENT NUMBER - 2005N-0345-EC210

2005N-0345-EC210 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Felty, Amy

2005N-0345-EC210 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

They could make it a law but I do not think they would be able to enforce it. <1: 7.5.3>At your local drug store, who would have the responsibility of enforcing such limitations? The pharmacists are occupied with their duties of providing the correct prescription medication and should not be required to additionally 'police' who is buying what OTC drug and how old they are. The workers at the registers should not be given the responsibility of controlling who buys what unless an entire system is set up as we do for the purchasing of alcohol.</1: 7.5.3> <2: 7.2>Therefore, no I do not think it could be enforced in a practical manner.</2: 7.2>

GENERAL

GENERAL

<3: 7.5.2, 7.5.3>As a quality assurance professional I would be concerned that it would not be practically feasible to have the appropriate controls in place to prevent abuse of some drugs if they were sold as both prescriptions and OTC. Unless clinical studies covered things like misuse and over use of the drugs I would be concerned for the safety of the public. We have to remember that the majority of the public are not highly educated in the areas of science and would potentially not understand the negative affects of the active ingredients if not used exactly per the label indications. </3: 7.5.2, 7.5.3>

<4: 1.2.3>As a woman and a human being I am particularly concerned with the effects of these prescription vs. OTC discussions as it pertains to the Plan B drug. When the word got out of this drug being sold OTC (provided that is what happened) I can foresee nothing but misuse of this drug by the majority of the population. Either it would be taken too frequently as a substitute for the birth control pill or it would be taken at incorrect times and could harm the development of a fetus.

Therefore, at this time I would disagree with making an active ingredient, used for the same indication, available for use by both prescription and OTC. </4: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC2107

2005N-0345-EC2107 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Oyen, Duane

2005N-0345-EC2107 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes.</1: 3.1> <2: 3.9.1>Please explain the effective difference between, for example, OTC ibuprofen and Motrin 600 with regard to prescription enforcement. This is neither new nor "molecular biochemistry" (a subject specific "rocket science" metaphor) </2: 3.9.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<3: 2.1, 3.1>Yes- and in a realistic way, not as outlawing disguised as regulation. </3: 2.1, 3.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1, 6.6.3>Society does it all the time with substances that are legal but limited to adults- cigarettes and alcohol, for example; prescription items are easier to track than those products.</4: 6.1, 6.6.3> <5: 6.7, 7.4.5>The enforcement in a free society is imperfect, as is enforcement of any law in a free society, but there are balancing tests that can be applied- risk versus cost, probability of misuse, penalties for fraudulent acquisition and use, etc. that will mitigate the problem. </5: 6.7, 7.4.5>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.4.6, 7.6>The cutoff age should be 18, or 15 with parental approval- not 16. That means the parent buys and signs for it, not a minor under any circumstances. </6: 7.4.6, 7.6><7: 7.4.1, 7.4.5, 7.4.6>Over age 18, the person must ask at the pharmacy counter and sign a specific certification acknowledging that it is illegal to pass the compounds on to anyone else, and the signature is an oath not to do so, under significant penalty of legal sanctions, including possible jail time. </7: 7.4.1, 7.4.5, 7.4.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 8.2>The different products should not be sold in the same packaging. </8: 8.2><9: 8.6.4>There should be significant alert notices on the OTC package and the rules regarding consumer eligibility should be broadly disseminated to enhance enforcement success. </9: 8.6.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

N/A

GENERAL

GENERAL

<10: 6.5.1>As with all liberty versus regulation issues, in a free country there should be a presumption that the public is not moronic, nor criminal, nor incapable of being responsible for his or her own life. There are a lot of places where things should be culturally discouraged but not outlawed- and morality is absolutely the first area to which that applies. We need the same campaigns against underage promiscuity that we have against smoking, but that is not a reason to play Big Brother to adults.

If the only criterion for illegality is the possibility that a drug might be improperly dispensed second-hand, we need to outlaw ALL pain medications, period. </10: 6.5.1>

<11: 6.5.4>But the parental rights to deal with minor children should not be curtailed under any circumstances. There is a point where the family has to trump the culture, and the law should enable that. </11: 6.5.4>

COMMENT NUMBER - 2005N-0345-EC211

2005N-0345-EC211 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Young, Stan

2005N-0345-EC211 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

No.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.2>No.</1: 3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No.</2: 4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.2>No.</3: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2, 6.5.3>No, this question has already been addressed in the case of parental notification laws, for example. They linger for a little while, then are tossed out at appeals court level.</4: 6.2, 6.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2>No. </5: 7.2><6: 7.5.3>A teenage girl who feels the need for this medication will borrow an older sister's ID, or use her fake ID, or get an older friend to get it, or heaven forbid, shop lift it. Of course, a friendly pharmacist must might not ask the age question. And as an over the counter med for some, I'm sure some enterprising soul will set up a website and offer it over the internet.</6: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

Moot point.

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

Moot point.

GENERAL

GENERAL

<7: 2.1, 3.8.7>As a conservative Republican, I'd note that the commissioners should not waste my money trying to go down this twisty path of logic. You'll trip yourselves up, and cost the government and the consumer money.</7: 2.1, 3.8.7> <8: 1.2.1>The women who feel the need for this product need it quickly, without jumping through regulatory hoops. It's not your job to protect their virginity - by definition, that's gone anyhow. Contraception is legal, abortion is legal. If this drug is reasonably safe and effective, approve it and get your noses out of these women's personal lives.

We're talking someone old enough to have sex, old enough to have a baby. I'd rather have a 12 year old

buying and using this than having a 13 year old mother. Sticking your heads in the ground and saying "don't have sex" is too late by the time we're talking this drug.

Let's make this the least traumatic we can on all concerned. </8: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC212

2005N-0345-EC212 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Kisly, Anne

2005N-0345-EC212 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.4>I think the text and examples provide clear examples of when a drug product may be marketed as both prescription and OTC. Examples should not be interpreted to mean that they cover all situations. They are after all, examples.</1: 3.8.4>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 3.8.5>The interpretation of it may be confusing because, as in the case in question, the safety data for levonorgestrel is different from the safety data in the examples and the past regulatory decisions. I would expect decisions regarding prescription(RX) and OTC access to be made on a case-by-case basis. Not all drugs will fit the examples provided. The regulatory interpretation of section 503(b) will never explicitly address all the different possible situations.</2: 3.8.5>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 3.8.5>I think a sentence could be added to clarify that decisions are made on a case-by-case basis. I doubt that any rule is hard and fast and will cover all submissions.</3: 3.8.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 7.4.4>Someone would have to act in the role of the enforcer. In the case of the OTC availability of levonorgestrel, the pharmacist would have to check the consumer's age by asking for personal

identification. The pharmacist would have to assume the person, if of legal age, is buying it for herself or for someone who is of legal age. The assumption is the problem.</4: 7.4.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.5.3>No. I do not think it is practical. We know that minors have friends who are of legal age who buy restricted items for them. The situation with levonorgestrel is no different. Consider the motivation level of a young woman who does not want to handle an unwanted pregnancy. The motivation to acquire and take emergency contraception (EC) would be high. While a licensed medical practitioner could still prescribe and counsel the younger patient on the safe use of EC, I'm not convinced this is an absolute necessity. If there are data, from a randomized controlled study, that show a younger woman is at risk if her access to EC is not limited by prescription and she does not receive counseling, I would challenge the extrapolation of the findings from the sample of study participants in the study to the population at large. I expect a highly-motivated young woman would read and follow the instructions on an OTC product.</5: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.3.4, 8.9>Do you mean the same products (not different in terms of strength, route of administration, indication, etc) or the same package? Is less information required on an RX package because someone assumes the licensed practitioner provides counseling, than an OTC package? The patient or consumer information, regarding dosing instructions and safety risks provided in the package, should be the same for a product available OTC or RX. An OTC package should list the following in large font size: (1) specific situations in which levonorgestrel should NOT be used; (2) the side effects to be expected; (3) information for special groups, possibly diabetics? The choice of words should be carefully selected, eg, side effects not adverse events, specific situations in which levonorgestrel should NOT be used, not contraindications.</6: 8.3.4, 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.1>This must be determined on a case-by-case basis. All possible scenarios can't be foreseen. As soon as we agree, this circumstance or that circumstance requires different packages, another circumstance will arise to be an exception.</7: 9.1.1>

GENERAL

GENERAL

The following information can be read easier in the attachment, where my response in italics follows the FDA question or comment. The italic font doesn't show up below (at least not on this screen). I would appreciate acknowledgement that this was received.

<8: 8.9>The question we have been asked to address is whether Plan B should be available without a prescription on a pharmacy shelf, similar to the way other OTC medicines like some cough syrups and allergy pills are sold, for women age 16 and older, and remain prescription-only for those under the age of 16.

How severe are the side effects (nausea and vomiting) if taken incorrectly, enough to meet the criteria for a serious adverse event, or are they mild, transient events that occur in isolation (without other events)? Are the proposed dosing instructions in the package provided by the drug company clearly written, such that counseling by a licensed practitioner is not necessary?</8: 8.9>

<9: 1.2.1>Can age be used as a criterion on which we decide whether a drug should be prescription or OTC, as has been proposed in this case?

I would question if factors other than age comprise the real underlying basis for restricting access to a medication. In the case of EC, age, in and of itself, is not a valid criterion for ethical reasons. I don't think the majority of women should have restricted access to EC, because a few women are at greater risk from of a lack of understanding dosing requirements, dosing limitations, lack of understanding the potential safety issues, etc.

In the case of levonorgestrel, the decision to restrict access by younger women sends a message to young women that they can't read and understand instructions on a package that describes dosing instructions, safety warnings, etc. Limiting access to EC to younger women is not ethical and is discriminatory, because it assumes low intellectual abilities and poor judgment on the part of the younger women.

My 12-year-old son, with his 7th grade education, can walk into a store, buy, and take aspirin or Tylenol following the dosage chart on the bottle. </9: 1.2.1>

Am I supposed to be convinced that young women are less intelligent than he is in understanding how to take an OTC drug?

<10: 1.2.1>The FDA's drug center, the Center for Drug Evaluation and Research or CDER, completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an over the counter product, but only for women who are 17 years of age and older.

The decision to restrict access by younger women sends a message to young women that they can't read and understand instructions on a package that describes dosing instructions, safety warnings, etc.

I have a question for you. Is this really about concern for the safety of younger women, or is it about preventing legal problems if young women acquire the drug OTC, take the drug incorrectly, develop safety issues then sue the pharmaceutical company and accuse the FDA representatives of not doing their jobs? A prescription is no guarantee that the patient received the necessary counseling from the licensed practitioner on the specifics of how to use the medicine correctly, regardless of age. A prescription is no guarantee that the patient will be compliant, regardless of age.

I commend you on your extensive safety review. Please continue. Since when was Congress staffed by anyone who knows anything about evaluating the safety of drugs?</10: 1.2.1>

2005N-0345-EC212-Attach-1.PDF 2005N-0345-EC212-Attach-1.PDF 2005N-0345-EC212-Attach-1.PDF 2005N-0345-EC212-Attach-1.PDF 2005N-0345-EC212-Attach-1.PDF 2005N-0345-EC212-Attach-1.PDF 2005N-0345-EC212-Attach-1.PDF 2005N-0345-EC212-Attach-1.PDF 2005N-0345-EC212-Attach-1.PDF 2005N-0345-EC212-Attach-1.PDF

COMMENT NUMBER - 2005N-0345-EC213

2005N-0345-EC213 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Goggin, Terresa

2005N-0345-EC213 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.3.2, 3.8.4>No, I believe your previous guidelines are adequate. If it is safe without a practitioner's prescription then it should be available OTC.</1: 3.2, 3.3.2, 3.8.4>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

See statement above.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2, 4.4.2>I think the current guidelines are adequate and straightforward. Personal politics are what is clouding the availability of this drug, and probably others in the future if this precedent is allowed.</2: 4.2, 4.4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

See statement B.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 1.2.1, 6.5.4>OTC should not be limited; no more than we limit the sale of say aspirin, acetominaphin, ibuprofen, cough syrups, decongestants, etc. Risk warnings...absolutely! Limited access...absolutely not!</3: 1.2.1, 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 6.6.3, 7.1, 7.4.4>Certainly by prescriptions for minors and "carding" everyone else, just like alcohol

or cigarettes</4: 6.6.3, 7.1, 7.4.4>...<5: 1.2.1>but the age limitation should not exist...if sex occurs (consensual or non-consensual), even for a minor, quick access to the drug is essential to efficacy.</5: 1.2.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1>Yes, but this is just administrative wrangling...complicating things by trying to "please" a certain political constituency.</6: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.2.2>Under no circumstances would it be inappropriate; the drug is what it is...what is the point of making the package a different color to show that someone is underage...other than discriminating against them and singling them out for possible ridicule.</7: 9.2.2>

GENERAL

GENERAL

<8: 2.1>Let's get away from trying to satisfy a political base...the FDA was established to protect the health of all Americans, not just one particular constituency.</8: 2.1>

COMMENT NUMBER - 2005N-0345-EC216

2005N-0345-EC216 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Ellis, Pamela

2005N-0345-EC216 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

yes

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.1>yes</1: 3.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.1>Yes</2: 6.1>. <3: 8.8>Similarly to the current requirement of the statement 'Federal law requires prescription for this medication' be printed on the Rx version and not on the OTC version. Although, psuedoephedrine has recently been restricted to 18 and over and behind-the-counter status and it underwent no package change whatsoever. Who is enforcing this limitation? This stall tactic is ridiculous in light of the fact that these situations already exist in todays market.</3: 8.8>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.1>Yes.</4: 7.1> <5: 6.6.1, 7.4.3>State Departments of Health will inspect the process as it does all other processes.</5: 6.6.1, 7.4.3> <6: 6.6.3, 7.4.4>ID's will be checked for OTC product as with nicotine patches, alcohol, cigarettes, etc</6: 6.6.3, 7.4.4>...<7: 1.2.1>However, let me be clear and say that Plan B should be available OTC with NO age restriction. A bottle of Tylenol, which can be purchased by anyone, poses a far greater health threat if used incorrectly than Plan B ever would.</7: 1.2.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 3.9.1>It is legal. For example, I currently have OTC Prilosec in my pharmacy AND a prescription-only omeprazole.</8: 3.9.1> <9: 8.6.4>Therefore, Plan B would require different packaging on the outside stating its Rx requirement for Rx version and not for the behind-the-counter version. The inside packaging would remain the same as 15 year-olds will take it the same way as 30 year-olds will. </9: 8.6.4><10: 2.1, 6.6.1>This is no reason for a delay to market. Incidentally, pseudoephedrine products were just put behind-the-counter, at least in my state, with NO change in packaging. Perhaps if pregnancy affected everyone as does nasal congestion, years of delay and request for public comment would not be necessary.</10: 2.1, 6.6.1>

GENERAL

GENERAL

<11: 1.2.1, 3.3.3>Plan B is safe for use by women of ALL ages. It has been available OTC in over 38 other countries for years. The data is available on use in teenagers and adults and should have been consulted at the time of application. Withholding this incredibly effective and safe drug, the 2 requirements for OTC status, the FDA is doing a disservice to women and women's healthcare and destroying its reputation as a sound, scientific entity on which the American public can depend.</11: 1.2.1, 3.3.3> <12: 1.2.1, 2.1>It should be clear to all, regardless of beliefs or values, that the effects of taking Plan B is infinitely less damaging to the body than a pregnancy is. Especially when a 13 year-old

is carrying to full term. When will women stopped being punished for their biology? Women must have all the options possible to control their reproduction. This product is one of the best to come along in some time. Stop bowing to right-wing political pressure and do the job the FDA was commissioned to do! Be scientists and let individuals decide their morality.</12: 1.2.1, 2.1>

COMMENT NUMBER - 2005N-0345-EC217

2005N-0345-EC217 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Dietz, Ken

2005N-0345-EC217 - TEXT

GENERAL

<1: 1.2.1, 2.1>Your position on Plan B is clearly an attempt to delay approval of non-prescription sales for some unstated reason. Your stated reason is full of holes, and is clearly unsupportable. </1: 1.2.1, 2.1><2: 6.1, 6.6.3, 6.6.4>The government currently has regulations in place requiring age-limited availability for cigarettes, alcohol, firearms, pornography, and lotto tickets. But you can't establish a similar regulation for Plan B? </2: 6.1, 6.6.3, 6.6.4>

I smell a rat here.

COMMENT NUMBER - 2005N-0345-EC22

2005N-0345-EC22 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Rankis, A

2005N-0345-EC22 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

No, Current situation is fine

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.2>No, Current situation is fine</1: 3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No,</2: 4.2> Current situation is fine

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.2>No</3: 5.2>, Current situation is fine

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2>No</4: 6.2>, the use of the product would be abused

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2, 7.5.3>No, the use of the product would be abused</5: 7.2, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2>no</6: 8.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.2.2>none</7: 9.2.2>

GENERAL

GENERAL

<8: 7.5.3>If a drug is indeed for "emergency contraception", there appears no way to control or enforce it's use in emergencies only</8: 7.5.3>

COMMENT NUMBER - 2005N-0345-EC224

2005N-0345-EC224 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Roettcher, Phil

2005N-0345-EC224 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.1, 6.3.2>I see no reason why a single molecule cannot be sold in two different formats though I would prefer you follow the advice given by your medical staff that Plan B medications are safe for all women of child bearing age. </1: 1.2.1, 6.3.2><2: 6.6.3, 7.3.1.1>Over the counter is fine, but if you must compromise, treating it like tobacco, where there is a minimum age restriction would be fine. For those under the age, a prescription should be obtained and dispensed by a licensed Pharmacy.</2: 6.6.3, 7.3.1.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<3: 3.8.5>Decisions can be made on a case by case level.</3: 3.8.5><4: 1.2.1> In the case of Plan B medication, since the medication causes no harm by itself, it should be made widely available. Adult women should be allowed to make decisions for themselves.</4: 1.2.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<5: 4.2>only by the FDA who are more politically bound!</5: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<6: 5.5>Advance with the technology and society. Change the rules to allow for multiple applications of the same molecule and let the market sort it out.</6: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<7: 6.6.3>I don't really see enforcement as a legitimate issue for the FDA. The same folks who enforce marihuana and vitamin supplement laws can enforce any unusual rules here. Personally, I don't think there should be prescription restrictions here but if you must, enable the ATF to take on this task. Maybe they can rename themselves DAFT.</7: 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<8: 7.6>Does it really require law enforcement to make sure a young girl doesn't have an unwanted pregnancy? Time is important with this drug. Restrictions only hurt society over time.</8: 7.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<9: 8.1, 8.9>Yes, unquestionably. The only people that would complain would be the pharmacy who can mark up their product more than OTC.</9: 8.1, 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<10: 9.2.2>None</10: 9.2.2>!

GENERAL

GENERAL

<11: 1.2.1, 2.1>As VP Dick Cheney said last year, "Freedom means Freedom." This product has proven to be safe by all research and is not mind altering. Let women decide for themselves if they can stop an unwanted pregnancy. Government should step as far away from this as they do nutritional supplements. Make sure it is safe and effective for the public and let the public decide for themselves. If it is stupid, the knowing user bears the consequences herself. Don't let fear and ignorance trump freedom for people to make good and informed decisions for themselves. </11: 1.2.1, 2.1>

COMMENT NUMBER - 2005N-0345-EC226

2005N-0345-EC226 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Cepeda, Baudi

2005N-0345-EC226 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding

when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

NO;

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.2>NO</1: 3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>NO</2: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.2>NO</3: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1>YES</4: 6.1>.

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.4.4, 7.4.6>Last resort would be to ask those who look young to provide ID and to limit the sale to just one package.</5: 7.4.4, 7.4.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1>YES</6: 8.1>.

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

N/A

GENERAL

GENERAL

<7: 2.1>Very disgusted that this decision is being based on political reason and not scientific. The FDAs

mission is not being fulfilled when we have enough scientific data that ensures consumers that Plan B is safe & effective and yet no decision is made. FDA needs only to act on data, not politics. </7: 2.1>

COMMENT NUMBER - 2005N-0345-EC23

2005N-0345-EC23 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Parks, C

2005N-0345-EC23 - TEXT

GENERAL

<1: 1.2.1>This drug should be sold over the counter, period.</1: 1.2.1> <2: 3.7.2>If there are health risks to those younger than 16 or 17 years of age, they should be made very clear on the packaging of the drug. There are many OTC drugs sold in dosages that are not supposed to be given to children under a certain age, but the FDA has not initiated any special sales practices in order to regulate who buys those drugs. The same practices that are applied to other OTC drugs should be applied to this one.</2: 3.7.2>

COMMENT NUMBER - 2005N-0345-EC2314

2005N-0345-EC2314 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: National Research Center for Women

2005N-0345-EC2314 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No, a rulemaking on Section 503(b) is unnecessary.</1: 3.2> <2: 3.3.2, 6.3.4>The FDA notes in the ANPR that it has in numerous instances approved the dual marketing of an active ingredient for both prescription and OTC use in just this manner. The differences noted by the FDA between these products and Plan B (the age at which the user takes the medication and under what degree of medical supervision) are all simply various conditions of use of the product, and are along the same lines as these other differences in condition of use noted by the FDA. </2: 3.3.2, 6.3.4>

<3: 3.2, 3.3.2, 3.9.1>The supplemental application submitted at the request of the FDA presupposes a meaningful difference in the conditions of use ? in this case, the comprehension levels ?between the two populations. The FDA has concluded that users under 17 require a physician?s assistance, while users 17 and over can take the medication without that condition.

The dual marketing of Plan B to these respective populations defined by the FDA is permissible under Section 503(b). Because the FDA has found that the product is safe for OTC users aged 17 and over, OTC and prescription marketing of the same active ingredient is as appropriate with this drug as with any of the others approved for both OTC and prescription use. The FDA has customarily approved drugs for different conditions of use without requiring any statute, regulation, codification, formal or informal guidance. While these administrative tools are often used by the FDA, they have not been deemed necessary for the simultaneous marketing of an OTC and prescription product with identical active ingredients and dosages.</3: 3.2, 3.3.2, 3.9.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No, a rulemaking on Section 503(b) is unnecessary. The FDA notes in the ANPR that it has in numerous instances approved the dual marketing of an active ingredient for both prescription and OTC use in just this manner. The differences noted by the FDA between these products and Plan B (the age at which the user takes the medication and under what degree of medical supervision) are all simply various conditions of use of the product, and are along the same lines as these other differences in condition of use noted by the FDA.

The supplemental application submitted at the request of the FDA presupposes a meaningful difference in the conditions of use ? in this case, the comprehension levels ?between the two populations. The FDA has concluded that users under 17 require a physician?s assistance, while users 17 and over can take the medication without that condition.

The dual marketing of Plan B to these respective populations defined by the FDA is permissible under Section 503(b). Because the FDA has found that the product is safe for OTC users aged 17 and over, OTC and prescription marketing of the same active ingredient is as appropriate with this drug as with any of the others approved for both OTC and prescription use. The FDA has customarily approved drugs for different conditions of use without requiring any statute, regulation, codification, formal or informal guidance. While these administrative tools are often used by the FDA, they have not been deemed necessary to effectuate the simultaneous marketing of an OTC and prescription product with identical active ingredients and dosages.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<4: 4.2>No, there should be no confusion regarding the FDA?s interpretation of Section 503(b)(1).</4: 4.2>

<5: 4.4.1>Barr established, as required by the relevant regulations, that Plan B is safe and effective to treat a condition that can be diagnosed by the patient. Furthermore, Barr established to the FDA?s satisfaction that women could follow the directions for the medication that would render its self-administration safe and effective.</5: 4.4.1>

<6: 1.2.2>The FDA's own advisory panel also overwhelmingly found that Plan B is safe and effective for use by women of all ages. The FDA's finding that there is insufficient evidence on the use of Plan B for those under 17 presents no additional legal or practical concerns for its OTC use by women 17 and over. </6: 1.2.2><7: 6.1>The FDA has the legal authority to restrict an OTC product in this manner</7: 6.1>.

C. If so, would a rulemaking on this issue help dispel that confusion?

<8: 5.4.3>No, because there is no confusion.</8: 5.4.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<9: 6.1, 6.3.1, 6.4.1>The Office of Chief Counsel has previously determined that age restrictions for an OTC product are legal, as in the case of Nicorette nicotine replacement therapy. Furthermore, there is no indication that counsel was concerned that such a restriction would be unenforceable. A document regarding the approval of Nicorette for OTC status states:

Furthermore, the OGC has provided us with a legal opinion that it is possible under the FC&C act to impose restriction on the sale of the product to minors, if such restrictions are needed to ensure their safety.

The FDA's decision that it has the authority to restrict the sale of OTC products to minors in the case of Nicorette applies with equal and full force to Plan B. While we disagree with the FDA's view that Plan B has not been proven safe for the restricted age cohort, FDA has, on advice of its own counsel, made exactly the same kind of age distinction for Nicorette as it can make for Plan B in approving the drug for OTC use.</9: 6.1, 6.3.1, 6.4.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<10: 7.4.2, 7.4.3>It is the professional responsibility and ethical duty of pharmacies and pharmacists to abide by legally imposed restrictions on sales, such as age limitations. In the event that they do not do so, state boards of pharmacies and others with authority to deal with issues of professional responsibility can always step in, either directly or by notifying FDA.</10: 7.4.2, 7.4.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<11: 8.1, 8.3.4>The products should be sold in the same packaging. Not only would it be legal to do so, but it might be in violation of Section 502(a) to have different packaging if the drug works in the exact same way for every user. Having different packaging for OTC and prescription users would convey to the 16-year-old user that she is in some way taking a different drug than her 22-year-old counterpart, which would constitute misbranding under Section 502(a)</11: 8.1, 8.3.4>.

B. If the two products may be lawfully sold in a single package, under what circumstances would it be

inappropriate to do so?

<12: 9.2.1>No circumstance can be hypothesized where it would be inappropriate to sell the two products in identical packaging so long as: (1) it is the identical drug; (2) it is identically labeled for each user of the product; and (3) it has an identical method of action for each user of the product. </12: 9.2.1>

<13: 8.3.1, 8.4.1>OTC packaging is intended to be far more "consumer friendly" than prescription products. According to the FDA, "the intended uses, directions and warnings [for OTC drugs] have to be written so that consumers, including individuals with low reading comprehension, can understand them." While important information for a prescription product may be buried in a lengthy insert, OTC products are required to have such information on the label. The current packaging for Plan B is appropriate for both OTC and prescription users.</13: 8.3.1, 8.4.1>

GENERAL

GENERAL

<14: 1.2.1, 3.2, 7.6>We strongly urge the FDA to abandon the proposed rulemaking, and to approve over-the-counter availability of Plan B for women of all reproductive ages based on its impressive safety record.

Greater access to this medication is likely to reduce the incidence of unintended pregnancy and abortion. The pharmaceutical and retail industries are well-equipped to handle the approval of Plan B as an OTC drug for those 17 and over, and as a prescription drug for those under 17. </14: 1.2.1, 3.2, 7.6>Thank you for your careful consideration of these comments. If you have any questions please do not hesitate to contact Diana Zuckerman, PhD at 202- 223-4000.

COMMENT NUMBER - 2005N-0345-EC24

2005N-0345-EC24 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Salvo, Aaron

2005N-0345-EC24 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.9.1>Currently there are several products that are available over the counter that are typically categorized as controlled substances, but there are also similar prescription productions. For example certain dosages of Ibuprofen are available by prescription only, but lower dosages can be purchased under brand names such as Advil, and there is nothing stopping a consumer from taking a single dose of the non-prescription strength product that would equal or even exceed the prescription dose. Also cigarettes

are known to contain Nicotine, which is a narcotic, but Nicotine is now available as an OTC product in forms such as Nicorette Gum. Neither of these products have caused the FDA any consternation.</1: 3.9.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Again, there are currently products that are available in an OTC and perscription form. So yes that FDA should allow an active ingredient to be simultaneously marketed in both an OTC and prescription form.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.1, 6.6.3>The FDA has enforced the sale of certains drugs without the assistance of a perscription. Once again alcholic beverages and cigarettes come to mind. A perscription is not needed for either product, yet the FDA limited access to these products by people below a specific age. Even though drinking ages are regulated by the states, there is at least precedence in law to keep a product out of the hands of a certain sub-population.</2: 6.1, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.1>The practicality of enforcement would be difficult, but no more than existing products available in both forms. </3: 7.1>As mentioned in previous questions a consumer may purchase an OTC Ibuprofin and take a single dose that would equal the perscription strength. <4: 6.6.1, 6.6.3, 7.4.1>Recently, however, certain states have take action to put certain OTC cold medications behind the pharmacy counter and only releasing them in certain quantities to people 18 or older. Putting both forms behind that counter would allow an individual to get the required medication and put the oneous of enforcement on the store to verify that it is legal to dispense the product. Again much in the same way that people are "carded" for alcohol and tobacco products.</4: 6.6.1, 6.6.3, 7.4.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.1, 8.4.1>In short I see no reason why separate packages would be needed. A person who could not legally purchase the product without a perscription would be stopped before leaving the store, unless they had a perscription.</5: 8.1, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 9.2.2>I see no time that it would be inappropriate to sell the two products in a single package.</6: 9.2.2>

COMMENT NUMBER - 2005N-0345-EC240

2005N-0345-EC240 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Cunningham, Wayne

2005N-0345-EC240 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.9.1>Yes, this is an issue that needs to be decided, and has certainly been resolved in areas concerning controlled substances. It's not all that new or novel.</1: 3.1, 3.9.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Apparently there is, since this question came up.</2: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.1>Yes</3: 5.1>.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1>Yes. Other items have been regulated in a similar fashion.</4: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 6.6.3, 7.1>It would be possible, just follow the examples set forth in how cigarettes and alcohol are

regulated.</5: 6.6.3, 7.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1, 8.4.1>They are the same product, so it would be unnecessary to have different packaging.</6: 8.1, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.2.2>None</7: 9.2.2>.

COMMENT NUMBER - 2005N-0345-EC27

2005N-0345-EC27 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Pechacek, Deborah

2005N-0345-EC27 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.1>Yes I think the FDA needs to clarify this rule to eliminate any future issues.</1: 3.8.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 3.8.1>This definitely needs to be done to help Healthcare Professionals know when a product can be sold as an OTC product and when it can not</2: 3.8.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.3.2>Obviously there is since the Drug company is asking you to do something that I thought was not legal.</3: 4.3.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.1>YES!</4: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 7.5.3>I do not see how. In the case of "Plan B"; if you limit sales to 17 and older without a prescription, what is to stop 13, 14, 15 and 16 year olds with "OLDER FRIENDS" from getting the medication. The 17 year old "FRIEND" purchases it and gives it to the younger girls. Also you are opening up a great BLACKMARKET industry for the product.</5: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.5.3>Again - I am at a loss as to how you will control and monitor where the product goes, once it is sold.</6: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.2>NO - they need to be in 2 separate packages.</7: 8.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.1.2>ANY TIME</8: 9.1.2>

GENERAL

GENERAL

<9: 1.1>I think you are opening a major "can of worms" with this regulation. By allowing this to happen with one drug, you are opening the door for ANY product to use this logic. All the manufacturer has to do is show a reasonably safe side effect profile and then state that any adult is able to decide for themselves whether they want the medication or not. I think we have already put too many unsafe products out in the OTC category and do not need to add any more. </9: 1.1>

<10: 7.5.4>My other comment is about monitoring. How do you think you will prevent consumers in the NON-EXEMPT category from purchasing and either giving or selling the medication to people in the EXEMPT category? I see this as just a way for the drug manufacturers to shove their products out where anyone can buy them. This will lead to irresponsible use of medications. If we are not concerned about patient safety, the FDA might as well close down and let us buy everything in a local "DRUG STORE"... Viva la Mexico</10: 7.5.4>

COMMENT NUMBER - 2005N-0345-EC278

2005N-0345-EC278 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Endris, Kelle

2005N-0345-EC278 - TEXT

Issue Areas/Comments

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<1: 4.1>YES</1: 4.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.1>Possibly.</2: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.4.2>Through Public Health Clinics.</3: 7.4.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.2>NO!</4: 8.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<5: 9.1.2>Over the Counter</5: 9.1.2>

GENERAL

GENERAL

<6: 1.2.3>The Plan B emergency pill has the strong potential to end a conceived life. It should not be accessible to any under aged person for a variety of reasons. A minor does not have the maturity or understanding to know the long term impact of using such a drug. </6: 1.2.3><7: 1.1>Also, no person,

should be forced to sell a drug, chemical or substance if it goes against that individual's religious or ethical beliefs. As a nurse, I would not assist with an abortion. A pharmacist should not be required to sell the Plan B pill if it is against his personal belief system. Generating a law to require an individual to do so negatively impacts that individual's constitutional rights. What are we becoming? </7: 1.1>

COMMENT NUMBER - 2005N-0345-EC281

2005N-0345-EC281 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: TomHon, Catherine

2005N-0345-EC281 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.1>This is purely dependent on whether this case represents an anomaly, which is not covered by section 503b. If this is so, then the restriction of OTC status is arbitrary and not based on a scientific basis. The question is whether one desires to leave future FDA drug approvals open to arbitrary arguments or whether the scientific integrity and strength of those decisions should be preserved.</1: 3.8.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 1.2.2, 3.3.2, 7.3.1>I do not see that Plan B represents a unique case that in future should be used to influence FDA activity and decisions. It may be difficult to argue that the population <16 years of age is subject to greater harmful effect. But section 503b B, states that it (a prescription drug) is limited by approved application under section 505.... One could argue that the "Prescription Drug" status is defined by the limitations that must be spelled out in the approval of a drug application. It does not state that the FDA is limited in its approval and must define an approved drug as only OTC or prescription. Therefore it could allow the FDA via its official approval to designate the same drug as OTC and Prescription dependent on different circumstances, in Plan B's case age.</2: 1.2.2, 3.3.2, 7.3.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1>In the particular case of emergency contraception - Plan B, yes. It is not clear why the FDA believes this section falls short.</3: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.2>No, the FDA can simply make transparent and concrete the basis for its decision.</4: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.1, 6.3.5>Yes, it should be able to legally enforce the limitation. The FDA should also be able to act against off-label drug use. But whether the FDA does undertake enforcement is another question. To make this the deciding factor for approval means that the FDA should hold its legal ability to enforce, as a standard to be met by all drugs up for approval. Given the rise in the number of prescriptions dispensed for conditions for which the drug was never approved, this would swamp the FDA with enforcement issues.</5: 6.1, 6.3.5>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.3.2>In general, the FDA should be able to pursue punishments for all drug misuse by those professionals who are in charge of controlling drug access. These multiple levels of control to drug access include: Pharmaceutical industry, FDA approval, FDA approval only for specific conditions, MD prescription, pharmacy dispensal.</6: 7.3.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1, 8.3.1, 8.4.1>Yes for the following reasons:

- the product is the same, no confusion as to content.
- simplification of inventory for the dispensing pharmacy
- Instructions for usage should include those for all ages and include any age-specific issues.
- within power of pharmacist to control or deny sale, at point of sale

With the control of OTC products which can be turned into Crystal Meth, we have a similar issue. The access to the same active ingredient is controlled differently. One may be able to select it off the shelf in one pharmacy chain but need to request it from the pharmacist in another. These drugs may also be in the same package.</7: 8.1, 8.3.1, 8.4.1>

GENERAL

GENERAL

<8: 1.2>With the realization that this is a politically charged issue, I appreciate your wanting to cover all the loopholes. In the end the FDA should strive for the solution, which supports its mission. The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.</8: 1.2>

COMMENT NUMBER - 2005N-0345-EC297

2005N-0345-EC297 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Levinson, R. Saul

2005N-0345-EC297 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.2, 3.1, 3.8.3>Yes, there are instances where a professional may prescribe a product when he has contact with a patient, and instances where a drug product may be needed without prescribing professional interaction. This is certainly the case with "Plan-B"... as it is an emergency contraceptive, the user could be in a situation where there is no time for contact with a prescribing professional (weekends, holidays, afterhours, etc.)... and needs immediate access to the drug.</1: 1.2.2, 3.1, 3.8.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

see above

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No confusion.... just old fashioned politics are entering into FDA's interpretation of section 503(b) of the act.</2: 4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.3.2>Yes....especially since FDA's own advisory group, and the majority of the medical/scientific community support the availability of Plan B as an OTC product and a prescription product.</3: 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.6.1, 7.3.1.1>The product could be sold only by licensed pharmacists who could determine if the requirements, if any, for OTC sale were met. Why is this so strange...FDA allows this with Category 4 and 5 controlled drugs, where allowed by individual State law.</4: 6.6.1, 7.3.1.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

Simple, see response above.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.1>YES</5: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 7.4.1>OTC product should not be sold to minors under the age of 16. Prescription product could be sold to any bearer of a legitimate prescription.</6: 7.4.1>

COMMENT NUMBER - 2005N-0345-EC307

2005N-0345-EC307 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Wu, Jackie

2005N-0345-EC307 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes. </1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.1>Yes. </2: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.1, 7.4.1, 7.4.6>In the case of Plan B, the subject needs to take the drug ASAP. The subject can buy the drug without prescription but still through the pharmacist window. She should take the first pill under the supervision of the pharmacist. An electronic pharmacy record will be helpful to track the number of drugs a subject takes. </3: 7.1, 7.4.1, 7.4.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.6.4>Not critical. For practical manner, different package is easy to handle. </4: 8.6.4>

GENERAL

GENERAL

<5: 1.2.1>Plan B should be made accessible to those who have made the decision. If people decide that they can not afford the risk of being pregnant, they should have a choice to prevent it happening. </5: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC311

2005N-0345-EC311 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Waychoff, W. Aaron

2005N-0345-EC311 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.5>Yes - the FDA should understand that, just like many other substances in our society, factors beyond simply the direct effectiveness and safety of the product on the human body must be taken into account. Many medications currently available OTC effect persons of different ages differently and carry labeling indicating such. In this labeling, use outside what is indicated by young persons is deferred to a physician's recommendation. Similarly, drugs such a Plan B could be made available OTC and carry labeling indicating that its use for women under 16 (or 17) is restricted to a physician's recommendation - in the form of a prescription. Remember, a prescription is little more than an official recommendation by a physician to use a particular medication at a particular dose.</1: 3.1, 3.8.5>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes - the FDA should understand that, just like many other substances in our society, factors beyond simply the direct effectiveness and safety of the product on the human body must be taken into account. Many medications currently available OTC effect persons of different ages differently and carry labeling indicating such. In this labeling, use outside what is indicated by young persons is deferred to a physician's recommendation. Similarly, drugs such a Plan B could be made available OTC and carry labeling indicating that its use for women under 16 (or 17) is restricted to a physician's recommendation - in the form of a prescription. Remember, a prescription is little more than an official recommendation by a physician to use a particular medication at a particular dose.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>The confusion is imagined on the part of the FDA. I believe that it is a trumped up excuse by Lester Crawford to stall the approval of Plan B because it does not meet with his personal religious beliefs and political aspirations.</2: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.3.2>It would help as long as the rulemaking is not used simply to further delay needed medications reaching the hands of those in need. The rulemaking *must not be religiously or politically motivated*</3: 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.3.5>As long as the subpopulation was not being discriminated against, and the limitation was in place for demonstrable safety reasons, it should be able to enforce the limitation by law.</4: 6.3.5>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 6.6.3, 7.4.5>Just like with cigarette and alcohol sales, there will certainly be those in a restricted subpopulation who will gain access to the drug. I do not believe that it will be necessary to enforce by law such a limitation. However it would be important not to punish the member of a subpopulation who obtains the product, but rather of the person(s) who enabled thier unlawful acquisition of the product just as

today the vendor or proxy is punished in underage cigarette and alcohol acquisition.</5: 6.6.3, 7.4.5>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2, 8.6.2>I believe it should be packaged differently. A prescription form of the product should look traditionally like a prescription medication due to the psychological impact it would make - particularly to a subpopulation defined by young age. Since the reason for the restriction is to prevent misuse by young women (in the case of Plan B) it should look like a "serious" drug to this group who obtains it via prescription.</6: 8.2, 8.6.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 8.2, 9.1.1>When there would be significant confusion as to the intended recipient of the product - for instance, if the same packaging was used for the non-prescription and prescription version (an idea I do not support) then the prescription version, at a minimum, must be marked with the standard information contained in a prescription label - name, directions, doctor, etc.</7: 8.2, 9.1.1>

GENERAL

GENERAL

<8: 2.1>I firmly and completely believe that this issue is being brought up as nothing more than a stalling tactic on the part of Lester Crawford. It is a shameful action and should result in the immediate expulsion of the man from his position at the FDA. It has shaken the confidence in the organization at the worst possible time. Lester Crawford is using his position to advance his own religious and personal beliefs and political aspirations. Though I feel that a clarification in 503(b) would be beneficial, it should not be used as a method for Lester Crawford to unilaterally impose his will on this country in direct opposition of all the scientific evidence presented. He can no longer be trusted to remain in such a position.</8: 2.1>

COMMENT NUMBER - 2005N-0345-EC319

2005N-0345-EC319 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Myers, Micah

2005N-0345-EC319 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.8>There is no scientific or legal reason to have two packages containing the same drug at the same dosage with one only available by prescription. That being said, there are moral and political reasons to do so. Please do not engage in morality or politics.</1: 3.2, 3.8.8>

2

B. If it could, would it be able to do so as practical matter and, if so, how?

<2: 1.2.1, 7.2, 7.5.3>Practically speaking, this is ludicrous. Girls or women who need the drug will get by having a second source get it for them. And this is all right. Currently on the market is a potent hallucinogenic called dextromethorphan. it can be bought by most anyone, but only adults should be using the stuff really, because it has the capacity to seriously mess a kid up if too much is taken. Plan B does not have this same capacity. It should be available OTC with no restriction the same as DXM. Please ignore the politics of the issue and strictly make your ruling on the science.</2: 1.2.1, 7.2, 7.5.3>

GENERAL

GENERAL

<3: 1.2.1>Make the ruling on Plan B emergency contraception. While it may be true that you are receiving pressure from the religious right on this issue, the science is clearly in favor of OTC status. Comparatively we can easily look to other countries which have already labeled Plan B OTC, such as Canada. Have they had some kind of societal meltdown? Are there disproportionate health consequences for 15 year olds (that is opposed to the 15 year olds actually getting pregnant and carrying the fetus to birth)? Forget the morals and politics and look at the science. It has already been too long in the coming, and americans are actually starting to grasp the incompetence of any scientific agency beholden to elective branches of government.</3: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC32

2005N-0345-EC32 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Hagan, Jane

2005N-0345-EC32 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.3.3>I believe the importance of making this drug available to the public is substantial enough that

the FDA should do whatever is necessary to accomplish that.</1: 3.3.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

I believe the importance of making this drug available to the public is substantial enough that the FDA should do whatever is necessary to accomplish that.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2, 4.4.2>Since there is a desire to impose an age restriction on whether this drug is available with or without a prescription, there should not be significant confusion regarding whether the consumer is of a certain age or not.</2: 4.2, 4.4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.5.1>The answer to that question should be determined by safety issues only. If the product is safe for all subpopulations, it should be available to all subpopulations under the same conditions and without a doctor's prescription. There would be no limitation needed and therefore no law required.</3: 6.5.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.4.4>If the product is not safe for all subpopulations based on age, then it should be limited by physician prescription and by law, and should be practical to enforce since age is provable and easily documented, particularly the age restrictions that are proposed. Both drivers' licenses and government ID cards are available for the subpopulations involved.</4: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 6.6.3, 8.4.1>Yes, just as other products such as tobacco and alcohol are limited to certain age subpopulations, this drug can be limited as well. Assuming enforcement will be at the point of sale, packaging should not be an issue.</5: 6.6.3, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 9.2.1>I cannot think of any, assuming that enforcement of restrictions is done at the point of sale.</6: 9.2.1>

GENERAL

GENERAL

See attachment

2005N-0345-EC32-Attach-1.DOC 2005N-0345-EC32-Attach-1.DOC 2005N-0345-EC32-Attach-1.DOC 2005N-0345-EC32-Attach-1.DOC 2005N-0345-EC32-Attach-1.DOC 2005N-0345-EC32-Attach-1.DOC 2005N-0345-EC32-Attach-1.DOC 2005N-0345-EC32-Attach-1.DOC

ATTACHMENT:

Additional comments as solicited by FDA on Plan B drug approval:

<7: 1.2.1>I have been following the course of approval of this drug for many years. I believe it is currently the only fair, practical and sane way to handle a very difficult and very personal physical and mental health issue. I believe this drug also takes the debate out of the realm of disagreement and confusion about whether a woman's choice to become pregnant or not is tantamount to homicide and whether the fetus feels pain or not upon early termination of pregnancy.

In my opinion it has already taken far too long, with far too much pain, sorrow and suffering, for this drug to get to this populations who need it. The FDA appears to be dragging their feet as they continue to focus on some details that seem spurious at best. Please get these details taken care of in a timely manner and get this drug out to the people who need it, who are all sexually active women over the age of puberty.</7: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC323

2005N-0345-EC323 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Rupp, Charles

2005N-0345-EC323 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.7.2>The FDA needlessly creating controversy and confusion by suggesting that one drug in one dosage could be two difference products. This is at best a semantic difference (not substantive). This rulemaking by FDA is generating confusion and not resolving it. No one would suggest that a pint of whiskey is a different product when held by a minor than when held by an adult. Nor would anyone believe that a minor attempting to buy a pack of cigarettes makes the pack of cigarettes different from the pack purchased by an adult. The FDA is asking should rules be issued that would attempt to make such artificial distinctions. The FDA is suggesting that Plan B purchased for an adult is different from Plan B prescribed for a minor. The FDA is attempting to say the age of the consumer of a product changes the

nature of the product. This is patently foolish. </1: 3.7.2>

<2: 3.9.1, 6.5.1>The example of ibuprofen cited by FDA in different dosages is in fact two different products. One, the 200 mg product is safe for the general public to self-medicate; however the 800 mg product requires significantly more knowledge to be used safely. Treating the 200 mg and 800 mg dosages of the same ingredient differently is reasonable and proper because of toxicity questions. This is the type of difference that should be controlled and indeed is at the heart of 'safe and effective' because the two items are not the same. Would the FDA consider regulating an 800 mg tablet dyed pink differently than an 800 mg tablet dyed yellow? I think not. The question is about the safety of the drug not cosmetic differences. The FDA should keep its focus on safety and effectiveness issues not on cosmetic differences (or non-existent differences).</2: 3.9.1, 6.5.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

The FDA needlessly creating controversy and confusion by suggesting that one drug in one dosage could be two difference products. This is at best a semantic difference (not substantive). This rulemaking by FDA is generating confusion and not resolving it. No one would suggest that a pint of whiskey is a different product when held by a minor than when held by an adult. Nor would anyone believe that a minor attempting to buy a pack of cigarettes makes the pack of cigarettes different from the pack purchased by an adult. The FDA is asking should rules be issued that would attempt to make such artificial distinctions. The FDA is suggesting that Plan B purchased for an adult is different from Plan B prescribed for a minor. The FDA is attempting to say the age of the consumer of a product changes the nature of the product. This is patently foolish.

The example of ibuprofen cited by FDA in different dosages is in fact two different products. One, the 200 mg product is safe for the general public to self-medicate; however the 800 mg product requires significantly more knowledge to be used safely. Treating the 200 mg and 800 mg dosages of the same ingredient differently is reasonable and proper because of toxicity questions. This is the type of difference that should be controlled and indeed is at the heart of 'safe and effective' because the two items are not the same. Would the FDA consider regulating an 800 mg tablet dyed pink differently than an 800 mg tablet dyed yellow? I think not. The question is about the safety of the drug not cosmetic differences. The FDA should keep its focus on safety and effectiveness issues not on cosmetic differences (or non-existent differences).

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 3.8.4, 4.2>This question can be answer in one word: NO! The FDA is doing the equivalent discussion of 'how many angels can dance on the head of a pin'? The FDA interpretation of section 503(b) is straightforward and simple. This notice suggests that FDA will needlessly add complexity to what is otherwise clear and simple.</3: 3.8.4, 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 1.2.2, 5.4.3>As stated above, there is no need for additional rulemaking. If the FDA decides that additional rulemaking is necessary, the FDA should issue emergency rules and not delay yet again availability of a safe and effective drug. The FDA has already needlessly delayed availability of safe and effective contraceptive products to American citizens. This delay clearly has been to please a religious

constituency and not in conformance with the purposes of the act. The FDA should cease its stalling immediately.</4: 1.2.2, 5.4.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 2.1, 6.6.3>This question is easily and simply answered by looking at the American marketplace today. It is ordinary practice today to restrict sales of products at the point of sale by the age of purchaser. Even the smallest "mom and pop" convenience store routinely enforces such restrictions in sales of liquor and cigarettes. Waiters and waitresses routinely check the age of customers before serving drinks. Sporting goods stores have no problem with age restrictions on the sale of firearms. Movie theaters restrict attendance at movies by age routinely. All of these examples demonstrate the capability of the marketplace to enforce age related restrictions on product. They also demonstrate that no extraordinary mechanisms are needed to "train, inform, etc. retailers on age restrictions on products"?age restrictions are everyday events in the marketplace. These examples also demonstrate that burdensome regulations about packaging of the products are not needed.

The effectiveness and workability of restrictions at the point of sale by age has been demonstrated in the American marketplace for years. The FDA should not ignore this demonstration. There is clear, strong and convincing evidence that age restrictions on sales are enforceable. If the FDA believes that some additional regulatory authority is needed to require the market to follow age restrictions at the point of sales, this should be done in emergency rulemaking and not be used as an excuse to further delay OTC sales.</5: 2.1, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.4.4>The ordinary events of the American marketplace clearly demonstrated that age restrictions at point of sale are practical. There is no evidence to suggest that age restrictions on products at the point of sales are ineffective.</6: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1, 8.3.1, 8.4.1>This question somehow assumes that different products would be sold in the same package. This is a patently ridiculous assumption. As argued earlier, the age of the purchaser does not change a product. Regardless of the age the purchaser, the product is the same. Again, FDA seems to be ignoring common sense to generate controversy and thus a reason to needlessly and inappropriately delay availability of this safe and effective drug over the counter.

The FDA could reasonably require that the age restrictions be displayed on the packaging for OTC sale. The FDA should not engage in the burdensome process of requiring one packaging for OTC sales and a different packaging for prescription sales. Clearly a packaging that shows OTC age restrictions should not cause any confusion in the mind of pharmacist about sale by prescription. FDA should not require separate packaging for OTC sales and prescription sales.</7: 8.1, 8.3.1, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be

inappropriate to do so?

. <8: 8.9>This question is another attempt to generate controversy needlessly. The question assumes that a meaningless distinction has been made and then assumes that the law recognizes the meaningfulness of the distinction and then asks the question whether legal sales would be inappropriate. The controversy suggested in this question exists only in the mind of the questioner.</8: 8.9>

GENERAL

GENERAL

<9: 3.2>The FDA acted irresponsibly in issuing the advance notice of proposed rulemaking. The FDA should have done an emergency rulemaking to address the subject of the proposed rulemaking. This advance notice suggests that the next step will be the issuance of proposed ruling. The use of bureaucratic steps to delay making a safe and effective drug available to the American citizens is unwarranted. </9: 3.2>

<10: 1.2.2>The questions in section II clearly miss the essence of the issue. In the press statement accompanying this notice, it is clearly that the rulemaking process is being used to delay over-the-counter (OTC) sales of the product known as Plan B. Since time is of the essence in the use of Plan B, using bureaucratic roadblocks to delay availability of a safe and effective drug deprives many citizens of the use of the drug during the period of the bureaucratic stalling. This stalling tactic is unethical and repugnant.

The question that should be addressed before all others is: Is there any reason to delay convenient access (and timely access is essential with the use of Plan B) to a safe and effective drug? The clear and unambiguous answer to this question should and must be NO! Emergency rulemaking is clearly the appropriate method to address any procedural questions that FDA perceives. In the absence of substantive reasons to delay convenient access to this safe and effective drug, the FDA's action should be to make this drug available as an OTC product as quickly as possible. </10: 1.2.2>

COMMENT NUMBER - 2005N-0345-EC325

2005N-0345-EC325 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Llewellyn, Heather

2005N-0345-EC325 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.4, 7.4.4>If an active ingredient in a drug has been ruled to be physically harmless enough for over-the-counter distribution, it should be marketed over the counter only. Rule-making codifications have already been set for drugs with active ingredients that have been ruled to be physically harmless enough for over the counter distribution but whose distribution might be deemed socially controversial. Please see the rule-making codification for alcohol and tobacco distribution. ID should be required to purchase it and guardians and police should be responsible for enforcing socially appropriate use. It is not the FDA's role to protect the public from physically harmless drugs or to monitor social use of drugs. The FDA's current "dilemma" is an egregious waste of tax-payer's dollars.</1: 3.8.4, 7.4.4>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

If an active ingredient in a drug has been ruled to be physically harmless enough for over-the-counter distribution, it should be marketed over the counter only. Rule-making codifications have already been set for drugs with active ingredients that have been ruled to be physically harmless enough for over the counter distribution but whose distribution might be deemed socially controversial. Please see the rule-making codification for alcohol and tobacco distribution. ID should be required to purchase it and guardians and police should be responsible for enforcing socially appropriate use. It is not the FDA's role to protect the public from physically harmless drugs or to monitor social use of drugs. The FDA's current "dilemma" is an egregious waste of tax-payer's dollars.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.5>I am not confused by the FDA's interpretation. The FDA administration, however, sounds like it's confused about what to do because it is caught between the scientific findings of the FDA's own scientists and the political wants of the Presidential administration that appointed it.</2: 4.5>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.5, 6.6.3>Since I am not confused, it would not help me. It would not help the FDA's administration either, because then it could no longer delay taking appropriate action on the drug, therefore, putting it right back between the findings of it's own scientists and the wants of Presidential Administration that appointed it. In addition, there is no need for new rulemaking, as the rule-making precedent has already been set by the distribution of alcohol and tobacco.</3: 5.5, 6.6.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.5.4>It is not the FDA's role to enforce it's rulings - that is the responsibility of distributors, guardians and the police.</4: 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

It is not the FDA's role to enforce it's rulings - that is the responsibility of distributors, guardians and the police.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 6.6.3, 8.1>Of course - but the package should have warnings, just like alcohol and tobacco do.</5: 6.6.3, 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 6.6.3>The package should have warnings, just like alcohol and tobacco do, preventing any circumstance that would be inappropriate.</6: 6.6.3>

GENERAL

GENERAL

COMMENT NUMBER - 2005N-0345-EC33

2005N-0345-EC33 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Collum, Mark

2005N-0345-EC33 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.1>Plan B should be either OTC or available to be prescribed by a pharmacist. Pharmacists can verify if a patient is above 16yo, and can then allow it to be dispensed. However, a licensed RPh should be the one making the decision. This will satisfy the requirements that it only be available to someone who is 16yo. It will allow a label to be generated and offer the RPh to counsel the patient regarding its use.</1: 1.2.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 3.1, 3.8.2>Yes. This should either be fully OTC or it should be classified into a category where RPh can prescribe and dispense it.</2: 3.1, 3.8.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.3.3>Yes. It is written entirely in legal jargon which most people cannot understand. In fact, even highly educated health professional must consult lawyers as to its interpretation. It needs to be worded such that a "regular" person can understand its provisions. Remove all legal jargon and replace it with intelligible phrases and words.</3: 4.3.3>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.2>NO! More rules only add to the confusion. Medicine & Pharmacy are too highly regulated as it is. More rules = more confusion.</4: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 7.4.1>Yes. If pharamcists are allowed to prescribe and generate a label for those greater than or equal to 16yo, anyone who receives it who is under 14yo must have received it from a phycisian. By making RPh generate their own prescription and treat it as such, there is a tracking method and accountability for anyone who receives the product.</5: 7.4.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.3.1.1>By allowing RPhs to treat Plan B as a member of their "prescribing class," you put the responsibility on their shoudlers. If someone under the age of 16 were to receive the product, it should have a physician's approval or the RPh would have violated his/her duties as a licensed professional and be subject to discipline.</6: 7.3.1.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.2>No. Their packaging should be different and distinct.</7: 8.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 8.6.4, 9.1.2>It is inapproriate to allow one single package to represent two products...that is deceptive to all parties involved.</8: 8.6.4, 9.1.2>

GENERAL

GENERAL

non

COMMENT NUMBER - 2005N-0345-EC34

2005N-0345-EC34 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Hudson, Ralph

2005N-0345-EC34 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.3>This question is asked twice in your webpage's form, with minor changes. In response to either wording, it does not make sense that birth control pills require a doctor's prescription, while an abortifacient drug may potentially be made available to teenagers without a doctor's professional guidance. An "active ingredient" is not being marketed for the same purpose in the case of the Plan B treatment, which is a high-dosage synthetic hormone treatment with the purpose of preventing implantation, not for the prevention of fertilization, which is the purpose of true birth control pills. The only valid comparison for allowing an active ingredient to be simultaneously marketed in both a prescription drug product and an OTC drug product is when the exact same active ingredient is being used for the exact same medical reason, in the exact same dosage. Allowing an abortifacient to be marketed OTC, while birth control pills require a doctor's prescription, simply because they both consist of the same synthetic hormone or combination of hormones (though in significantly different dosages) is disingenuous to the general public, by misrepresenting the completely different purposes for the drugs.</1: 1.2.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

This question is asked twice in your webpage's form, with minor changes. In response to either wording, it does not make sense that birth control pills require a doctor's prescription, while an abortifacient drug may potentially be made available to teenagers without a doctor's professional guidance. An "active ingredient" is not being marketed for the same purpose in the case of the Plan B treatment, which is a high-dosage synthetic hormone treatment with the purpose of preventing implantation, not for the prevention of fertilization, which is the purpose of true birth control pills. The only valid comparison for allowing an active ingredient to be simultaneously marketed in both a prescription drug product and an OTC drug product is when the exact same active ingredient is being used for the exact same medical reason, in the exact same dosage. Allowing an abortifacient to be marketed OTC, while birth control pills require a doctor's prescription, simply because they both consist of the same synthetic hormone or

combination of hormones (though in significantly different dosages) is disingenuous to the general public, by misrepresenting the completely different purposes for the drugs.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 1.2.3>When the interpretation is potentially misused, as it may be in the case of the Plan B drug, there is significant confusion (or rather concern) about the true intentions and motivations behind the decision to allow an abortion drug to be made available to teenagers, based on the illogical comparison of the acts of preventing pregnancy with the act of preventing implantation of a fertilized egg.</2: 1.2.3>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.1>It may dispel that confusion, if done correctly, but it will not "dispel" that confusion, as is written on your webpage.</3: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.5.4>This question requires a legal opinion, which is outside my qualifications. My layman's opinion is that, in the overly-litigious American society in which we now live, it is inevitable that there will be lawsuits brought in protest of age discrimination, unless a significant medical reason exists for the limitation.</4: 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.1, 7.3.2>By the same methods currently used to enforce the separation of over-the-counter from prescriptions.</5: 7.1, 7.3.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2>Only if the goal is mass confusion and the complete breakdown of requiring that any drugs are dispensed only by a doctor's prescription.</6: 8.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 1.2.4>Perhaps if the purpose is to terminate the life of an unborn child. </7: 1.2.4>

COMMENT NUMBER - 2005N-0345-EC343

2005N-0345-EC343 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Fisher, Julie

2005N-0345-EC343 - TEXT

Issue Areas/Comments

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 7.5.3>I very much doubt that the FDA would be able to prevent the sale of such a product to the prescription-only subpopulation by regulating pharmacies. What records are kept for OTC sales? None. And would nonpharmacy stores be able to carry the OTC product? What regulations would the FDA impose on convenience stores and grocery stores? </1: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<2: 7.2, 7.5.2, 7.5.3>I do not believe there would be any practical way to prevent the OTC product from finding its way into the prescription-only segment. Pharmacies will sell the OTC product to the prescription population because there will be no deterrent to doing so. Those in the OTC segment will purchase the product and pass it on to prescription-only recipients. While the later can and does happen with drugs currently available only by prescription, such transactions are illegal. Would it be legal for an OTC consumer to purchase the OTC product and then transfer it to a prescription-only consumer? How would a ban on the transfer be enforced? </2: 7.2, 7.5.2, 7.5.3>

COMMENT NUMBER - 2005N-0345-EC364

2005N-0345-EC364 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: McLeod, Doug

2005N-0345-EC364 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes it should and the decision should be made to allow this action. Especially if the scientific

evidence supports that decision.</1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 3.3.3>Yes it should allow active ingredients to be simultaneously sold as both an OTC and a prescription drug. This is especially so when the FDA experts have reviewed the drug and indicated that it should be available as an OTC product.</2: 3.3.3>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 1.2.2, 4.1>There seems to be when political pressure overules the science and expert opinion regarding the drug. For example the Plan B morning after contraceptive has been overwhelmingly rules as safe yet the FDA seems to be racting in response to political pressure rather than scientific evidence. This is clearly the wrong direction for the FDA.</3: 1.2.2, 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 5.3.1>So long as the rule allowed the practice and supported by the scientific evidence and advice of the FDA professional staff who should be independent of political influence.</4: 5.3.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.3.5>This decision should only be taken if there is hard scientific evidence that a subpopulaion would be harmed. A subpopulation could be by race, age, sex, ethnic origin etc. The FDA should not make a political,ethical or morality based decision to restrict access to a subpopulation unless the scientific study group advises it to do so for scientific reasons.</5: 6.3.5>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.2, 7.6>It could not, so do nnot try. If the drug is deemed safe by the scientific community for suitability for OTC, then do not apply further restrictions as to availability.</6: 7.2, 7.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1, 8.3.1>That is not so much a legal question as a marketing question. Often prescription drugs are dispensed in different containers than they are shipped to a pharmacy in. For example a large container of medicine is used to allocate to small vials for dispensing purposes. OTC products, on the other hand, are often packaged for theft protection, daily dosage packaging, colorful, informative packaging, sale price or incentive packaging (IE 50% more for free). I would answer YES to this question, but on practical terms, the packaging for the prescription product could change to adopt to an OTC style.</7: 8.1, 8.3.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.1.1>It may be inappropriate for a prescription drug to be packaged in an OTC package when the volume of the drug, or expected duration of consumption is different. For example, an OTC drug, such as the Morning After Contraceptive pill may be sold in single dosage OTC packaging, whereas the same drug could be sold in a daily dosage strength intended to match a womans menstrual cycle.</8: 9.1.1>

GENERAL

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<9: 1.2.2>I have never written to the Food and Drug Administration before, and was motivated to comment on this particular issue because of an apparent breakdown the FDA leadership to avoid political influences. In particular, the Plan B, morning after contraceptive drug issue is motivating me to state my outrage that the scientific community and staff of the FDA are overrules or ignored when political pressure is applied. This is unconcionable. The FDA decisions should be made on scientific evidence, and not by the political desires of a subpopulation. </9: 1.2.2>

COMMENT NUMBER - 2005N-0345-EC365

2005N-0345-EC365 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Deneris, Angela

2005N-0345-EC365 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.1>YES!!! We need to make this process much more simple and bring these medications to the American public sooner.</1: 3.8.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 1.2.2>YES!!! This is a safe medication which will lower the abortion and unplanned pregnancy rate

in this country. This medication has extensive study and has very few side effects.</2: 1.2.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1, 4.3.2>YES! I think the public and providers are very confused about the process and the length of time it takes to make a decision.</3: 4.1, 4.3.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 5.1>I would think so.</4: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.1, 6.6.3>YES! We do now with tobacco and alcohol. I see no reason that a pharmacist couldn't ask for ID. They do so now with Schedule I and II medications.</5: 6.1, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.1, 7.4.4>YES!!! This would not increase the amount of time or money in asking for ID.</6: 7.1, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1>YES! I see no reason for different packaging.</7: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.2.2>NONE</8: 9.2.2>

GENERAL

GENERAL

<9: 1.2.1>I feel this product should be available to every woman needing contraception, regardless of age. I believe we make it too difficult for people to get this product, which then needlessly subjects women to unwanted pregnancy. This is tragic. Too many lives are affected. Too many abortions happen that could be provented. Please pass this medication on to be OTC to EVERYBODY! </9: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC38

2005N-0345-EC38 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Scarpace, Sarah

2005N-0345-EC38 - TEXT

GENERAL

<1: 1.2.3>I am offering a comment specific to the change in status of Plan B to OTC. I am a clinical pharmacist and assistant professor. I have absolutely no qualms at all about dispensing Plan B OTC and counseling patients regarding the product; however, I am very concerned that should the drug be available OTC, that many women will not receive the appropriate triage necessitated in the cases of rape, especially HIV and STD testing, as well as social work and other psychological support interventions available in emergency rooms. This would especially be true in the case of date rape and rape by a person known to the victim, where she may feel ashamed and embarrassed to go to the ER. How would these circumstances be avoided?</1: 1.2.3> <2: 6.5.4>I also do not think that we can strictly enforce the sale of these products to only age 16 and I am not sure why the drug would not be safe to any young woman who has reached menarche as the ingredients are the same as the branded birth control pills Nordette (R), Lotrel (R), etc., which may be used by women younger than 16 to control painful menstrual periods/heavy flow. Does a 15 year-old rape victim not have the same rights as a 16 year-old?</2: 6.5.4> <3: 6.6.3, 7.5.3>If the drug is approved truly as OTC, where the patient could buy the product out in the aisles (as opposed to approving for "behind the counter" to be sold by a pharmacist only), would the store front cashier be responsible for deciding the appropriateness of "carding" a patient for the product to determine age? We know how effective these young adults are in regards to the sale of tobacco and alcohol! I also see a danger in not having some type of "screening" to ensure the safety of the patient in the respects mentioned above in regard to STD screening and social work support - the pharmacist can mention this during a counseling session but your average high school cashier working at minimum wage is not going to provide this level of attention (nor should they) to these patients. Please do not regulate the medication without considering the circumstances surrounding it. </3: 6.6.3, 7.5.3> <4: 3.8.2, 7.3.1.1>Yes, the medication itself is likely safe; however, there is special monitoring/intervention required for the medication which makes professional triage and not OTC availability in the best interest of the patient. The best scenario is to find a mechanism to ensure that these patients are seen by a physician in the ER, but the next best option is to at least utilize pharmacists as the fail-safe. Most pharmacists take this responsibility seriously; the recent media attention regarding pharmacists refusing to fill these prescriptions was in my view, embarrassing to the profession, but also highlighted a small minority of practice by pharmacists, probably equal to the percentage of physicians who hold similar ideologies. </4: 3.8.2, 7.3.1.1>Thank you for your valuable time in considering these comments.

Sincerely,

Sarah L. Scarpace, Pharm.D.
Assistant Professor of Pharmacy Practice
Albany College of Pharmacy
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Albany, NY 12208
phone: (518) 694-7226
fax: (518) 694-7302
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COMMENT NUMBER - 2005N-0345-EC399

2005N-0345-EC399 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Tufts, Gillian

2005N-0345-EC399 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes.</1: 3.1> <2: 1.2, 3.8.3>The manner in which many OTC drugs are used differs from the manner in which the prescribed drug of the same ingredients is used. For example, rare use of Plan B in the emergency situation has been found to be safe. The daily use of the same drug, with potential use for years, does require monitoring and education by a licensed prescriber. Although the drug used in both the emergent and preventative situations has been found to be safe, there are rare but potential health consequences with chronic use. In general, oral contraceptives have been taken by millions of women around the world and are safe.</2: 1.2, 3.8.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes, see question A.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>No.</3: 4.2> <4: 1.2, 3.8.4, 4.4.1>From the brief that I have available, I believe I understand the intent of the reasoning behind OTC use and prescribed use. Of importance here is the indication of the drug use. Plan B is to be used only in the emergent situation, after intercourse has occurred, to prevent an unintended pregnancy. The drug is not meant to be use daily to prevent. "The key distinction in these examples is that there is some meaningful difference between the two products (e.g., indication, strength, route of administration, dosage form) that makes the prescription product safe only under the supervision of a licensed practitioner." The previous quote is from the docket, I believe the key difference is the indication of the drugs' use.</4: 1.2, 3.8.4, 4.4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 1.2.1, 6.7>I do not believe it is necessary to limit the use of a drug, specifically Plan B, to subpopulation. Again, the drug is meant to be used in an intermittent fashion only, like taking tagamet HB for heartburn. Neither drug is meant to be used on a daily basis. That is where seeing the health care provider is indication and the information regarding the drug in the drug insert should reflect this.</5: 1.2.1, 6.7>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.5.3>I believe it would be difficult for the person actually selling the product to monitor and enforce the selling of a product limited by age. </6: 7.5.3><7: 1.2.1>In the case of Plan B, I believe that this may inhibit some from obtaining the drug much needed in an emergent situation!</7: 1.2.1> <8: 6.6.3, 7.4.1>Such enforcement would likely require that the drug be stored 'behind the counter', like cigarettes, and many women who would benefit from the intended use of the drug would not ask for it.</8: 6.6.3, 7.4.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<9: 8.2>No.</9: 8.2> <10: 8.6.1>As with many drugs that are available OTC and prescribed, the indication and manner in which the drug is taken differs. As with Plan B, the indication and number of pills required for the emergent versus daily use differs. If the number of pills needed and the manner in which the medication is taken differs then it follows that the packaging should differ. The OTC and prescribed product appear different because they are different. The intended use and manner in which the medication is taken is different between the two products.</10: 8.6.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<11: 8.2, 9.1.1>I do not believe the two products should be sold in a single package. If the intended use of the two products differs, then so should the packaging and the information in the package inserts.</11: 8.2, 9.1.1>

GENERAL

GENERAL

<12: 3.8.3>As a medical provider, I believe that it is safe to have two products be legally market to the general public.</12: 3.8.3> <13: 8.9>It is very important to have clear the intended use, how to use the medications, the side effects and what to do if the intended use has not resolved. Often the intended use for the OTC and prescribed product differs. For example, with oral contraceptives, the daily use is meant to prevent an unintended pregnancy, whereas the emergency contraceptive, such as Plan B, is meant ONLY for those situations where no preventative contraception has been used and intercourse has occurred. </13: 8.9><14: 3.8.1>Please consider the changes to the code 503B and permit the use of the

same ingredient in OTC and prescribed medications. I believe the availability of both products will well serve the general public. </14: 3.8.1>

COMMENT NUMBER - 2005N-0345-EC4

2005N-0345-EC4 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Bilz, Michael

2005N-0345-EC4 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.8>Has it done so for Ibuprofen? It is sold both ways today.</1: 3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Has it done so for Ibuprofen? It is sold both ways today.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

I don't know, is there?

C. If so, would a rulemaking on this issue help dispet that confusion?

<2: 5.5>I'm sure that it would - how long would it take to make a rule? Longer than it did when so many people were denied access to the Alzheimer's medication that sent so many people back into the darkness and so many families living with the torment of seeing a loved one suffer? There was a miss-step for the Agency, as it were.</2: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.7>Do they have a vehicle for enforcing it now? If so, what is it? Is it effective?</3: 6.7>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 6.6.3, 7.4.4>If there were an age limitation - it would become the responsibility of the Pharmacy provider to determine age - like we do for tobacco and alcohol. Now how does a fifteen year old girl prove her age without a parent? I sell tobacco to people only with a proper I.D. and I challenge everyone that looks younger than 27. Like Alcohol + Tobacco - why wouldn't underage persons solicit the help of someone of legal age to buy this for them? The controls you ask for here have historically had work-arounds since their inception.</4: 6.6.3, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.1, 8.4.1>Why not? They both do the same thing and the manufacturer sells these very same products in slightly more socially-conscious countries and would then raise the cost of the drug by creating alternate packaging for various applications - and the cost would be passed onto the end-user, not the drug company.</5: 8.1, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 9.2.2>I can't think of a situation where it would be an issue.</6: 9.2.2>

GENERAL

GENERAL

Dear FDA, I will start by saying that I respect your job and I feel the American consumer is safer, as a whole, for your agency's regulations on both food and drugs. I understand that it must be a difficult position to make these tough decisions regulating for people that cannot answer for themselves - and most of us are unaware of your role in our lives...as it should be. <7: 1.2.1>In regards to the Plan B Emergency Contraception ruling I believe that it is today, it was yesterday and it will be tomorrow a WOMAN's right to choose what is best for her body. No MAN should be allowed to legislate one way or another over a WOMAN's reproductive rights. Plan B E.C. has a specific application and it's use should NOT be regulated by the 'moral' or 'religious' convictions of any individual. Plan B should be on the shelf next to all other contraception, accessible to all persons. Yes, I agree that underage girls should be challenged for proof of age at the register - but first we need to have stronger Health + Sex Education in our school systems from an early age to allow all persons to be able to make an educated decision on what is best for their Body AND Mind. We're not stupid, we're just under-educated. Start education early and have an informed public. Plan B is important for everyone - I'm tired of supporting unwanted pregnancies through social programs that show children as a dollar figure to a poor family. Reform the social welfare systems and EDUCATE the population - STARTING TODAY...!! </7: 1.2.1>

Thank you for listening.

Sincerely,

Michael L. Bilz

COMMENT NUMBER - 2005N-0345-EC405

2005N-0345-EC405 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Kulshrestha, Vikram V

2005N-0345-EC405 - TEXT

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.1>Yes</1: 3.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 7.5.3>In my opinion, it will not be possible to ensure the misuse.</2: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.2>No.</3: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.2>No</4: 8.2>

GENERAL

GENERAL

<5: 8.5.4>It seems practically tricky to control the marketing of the same molecule for same indication in a single package as both prescription & OTC drug. In my personal opinion, a drug (molecule) can be sold as Prescription and OTC product with two different BRAND names. One brand can be marketed as a Prescription drug and the other one as the OTC, thus with two different Packaging. </5: 8.5.4>

<6: 7.5.3>But, the question is ?How the misuse of the same will be prevented by FDA, as the drug will be ultimately available to the subpopulation by a different route ?

So, it is not preferable to market same molecule as both a Prescription and OTC product for same

indication.

And it does not seem possible for FDA to enforce a check for limiting the sale of OTC product to a specific population even if the product is labeled for OTC and or Prescription. </6: 7.5.3>

COMMENT NUMBER - 2005N-0345-EC408

2005N-0345-EC408 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Labbe, Carl

2005N-0345-EC408 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.2>I believe that there are very sound arguments to initiate a rulemaking to define a transitional class of drugs that would be pharmacy-only drugs. Although there is some precedent for concurrent Rx and OTC marketing of drug products, there is much to be gained by defining a pharmacy-only class of drugs. Pharmacists already have the skills, knowledge and most importantly, the mechanisms to properly distribute medications based on specific medical and legal criteria.</1: 3.1, 3.8.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

See above comments

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes, the section is open to various interpretations.</2: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.1>Yes</3: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product

available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2>Not under current rules.</4: 6.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.4.1>Again, I suggest letting pharmacies, i.e. pharmacists, manage the distribution of medications that have been Rx and may not quite ready for the broad, unlimited distribution that comes with OTC status in the country.</5: 7.4.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.5.1>As I see it, under current regulations, different labeling is required.</6: 8.5.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.1>Certain, product-specific information or condition-specific information may need to be presented in different ways to different individual patients.</7: 9.1.1>

GENERAL

GENERAL

<8: 3.8.2, 7.4.1>It is a good time to give careful consideration to creation of a third Pharmacist Only class of medications in this country. Under our current system, medications make a giant leap from the very restricted and regulated prescription distribution system to the incredibly extensive non- prescription marketplace. Making some of these medications so widely available may not be in the best interest of patients' health. Granting pharmacists control over a specific group of prescription medications might serve to improve care in a cost-effective manner. Pharmacists know that they have tremendous impact on their patients' health when they advise and guide the selection and use of medications. Numerous studies have demonstrated the value in both dollars and outcomes when pharmacists are involved in drug therapy management. A third class of drugs would provide consumers with more choices and give them access to professional guidance toward effective health care. Of course, the added benefit would be that pharmacists would enhance the triage function that they already provide, referring patients for physician-provided medical care when indicated. A pharmacist-only class of drugs would be in the best interests of our patients and would have little negative impact on corporate profit margins or on physicians' ability to provide medical care. Actually, there is great potential to broaden the availability of consumer products and enhance the delivery of medical care. This is an idea whose time has finally come. The idea of a pharmacy-only class of drugs is also being considered and may serve as an important transitional step toward a more intelligent distribution system for the myriad of drug products available in this country. Think about the possibilities!

Remember, the purpose of the third class would be to improve access to beneficial medications, not restrict access to OTC products. </8: 3.8.2, 7.4.1>

COMMENT NUMBER - 2005N-0345-EC416

2005N-0345-EC416 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Thompson, Donald

2005N-0345-EC416 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.3, 3.1, 3.8.4>Yes. The rulemaking should state that an active ingredient cannot be simultaneously marketed in both prescription and OTC product forms. Either the concerns about biologic safety and regulatory safety are sufficiently low that there is no need for a prescription, or the concerns are sufficiently great to keep it prescription only. Biologic safety issues for estrogens and progesterones have always been enough of a concern that oral contraceptives have been available by prescription only. It seems to be a dilution of regulatory policy and responsibility to permit any estrogen/progesterone product to be available OTC</1: 1.2.3, 3.1, 3.8.4>.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes. The rulemaking should state that an active ingredient cannot be simultaneously marketed in both prescription and OTC product forms. Either the concerns about biologic safety and regulatory safety are sufficiently low that there is no need for a prescription, or the concerns are sufficiently great to keep it prescription only. Biologic safety issues for estrogens and progesterones have always been enough of a concern that oral contraceptives have been available by prescription only. It seems to be a dilution of regulatory policy and responsibility to permit any estrogen/progesterone product to be available OTC.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 2.2, 4.1>Yes. I do not understand FDA's interpretation of section 503(b) of the act. I applaud Commissioner Crawford's recognition that regulatory policy issues must consider more issues than simply the scientific safety concerns. Observations of human behavior strongly suggests that ulterior motives often lead to misuse and abuse of prescription, OTC, and illegal drugs and other substances, such as Scheduled narcotics, alcohol, and tobacco products, leading to a great degree of pain and suffering. FDA must consider all these issues and issue rules that protect vulnerable populations to the greatest extent possible.</2: 2.2, 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.1>Yes</3: 5.1>. See above.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2, 6.7>No, neither FDA nor state and local authorities would be able to enforce such limitations. Law enforcement and regulatory activities are often low on the priority list for local officials compared to violent crime, so such legal enforcement is very unlikely to occur.</4: 6.2, 6.7>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2, 7.5.3>I don't see how such a limitation could be enforced. Our nation has a long history of minors getting access to many drugs and substances that are not legal, such as alcohol and tobacco, for which there is only a personal desire for gratification. Prevention of pregnancy with OTC emergency contraception opens the door to sexual predators who could easily purchase the medication OTC, then require their victims to use it. The scientific literature is clear on adolescent decision making processes and risk taking for short term gain. FDA regulatory guidelines must protect this vulnerable population.</5: 7.2, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2, 9.1.1>No. If there is any rational reason for allowing an ingredient to be marketed both by prescription and OTC, the packages must be different, the labels must be different, the warnings must be different, and the limitations on access must be enforceable.</6: 8.2, 9.1.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.1>Anytime there are biologic or behavioral safety issues associated with access to the products, it would be inappropriate to sell such a product in the same package.</7: 9.1.1>

GENERAL

GENERAL

<8: 1.2.3>Prescription access to emergency contraception does not place an unreasonable burden on its availability. It protects vulnerable young women from sexual abuse and violence, to some degree, and requires all users to consider the possible outcomes of their actions. Healthy behaviors and healthy choices are to be strongly encouraged by our society and our governmental agencies, including responsible diets and exercise, reducing tobacco use, and moderating alcohol use. Increased access to emergency contraception is likely to increase the sexual abuse of vulnerable teenagers, and is unnecessary for responsible persons who are over 18 years of age.</8: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC418

2005N-0345-EC418 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Schulman, Marvin

2005N-0345-EC418 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.9.1>I can find no problem with allowing the same ingredient for both prescription and OTC. I believe this has already been done with many components, the only difference being dose levels. for example, folic acid tablets are OTC but at the 1mg level or higher, they require a prescription </1: 3.9.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes. I can find no problem with this . please see above

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No </2: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.1>Yes.</3: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.1, 7.4.6>Such a requirement is commonly done with cigarettes sold in Pharmacies. Enforcement is left to the local merchant.</4: 7.1, 7.4.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 7.5.3, 8.1>Why not. What is the issue here. If it is the same ingredient at the same dose, why would it remain a prescription. Noone will bother to obtain a prescription </5: 7.5.3, 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 9.2.2>None</6: 9.2.2>

GENERAL

GENERAL

<7: 4.3.3>I really don't understand the FDA's view of this matter. The issue is much simpler. If a product is safe for OTC sales, it should be available. It is irrelevant, If it also available as a prescription, in the same or a differnt package. </7: 4.3.3><8: 6.6.3>I also believe that few people will seek a prescription if the same product is available OTC. The enforcement issue is bogus. Currently, most pharmacies also sell cigarettes and are required not to sell them to children. The current means of enforcing this rule as well as the one that prevents sale of prescription drugs with a proper prescription should suffice.</8: 6.6.3>

<9: 2.1>It appears to me that the FDA has created some irrelevant issue to stall approval of Plan B because the politics surrounding this drug. It is not the FDA's job to worry about social or moral conduct but evaluate drugs and allow useful to available to those who need them. </9: 2.1>

COMMENT NUMBER - 2005N-0345-EC426

2005N-0345-EC426 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Duchon, Kathleen

2005N-0345-EC426 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.3>Yes, as a consumer and a woman, there should be guidelines as to under 16 years of age use. But, as an adult that option to buy a drug OTC should be available.</1: 3.1, 3.8.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 3.1>Yes, times are we a consumer can get a product in illegal ways. Why not make it a safe consumer choice?</2: 3.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>No, but it does need to be update as the world issues broaden and expand</3: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1, 6.6.1>Why not? They have enacted other new procedures such as ID for antihistamines. Why could the same implementation be put into affect for other drugs?</4: 6.1, 6.6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

see above

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.2>No, I would think to clarify the confusion you would have to mandate different packaging.</5: 8.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 9.1.1>When it is given to an under age consumer</6: 9.1.1>

COMMENT NUMBER - 2005N-0345-EC43

2005N-0345-EC43 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Lamermayer, Richard J

2005N-0345-EC43 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No.</1: 3.2> <2: 3.8.8>This would open up pandora's box as there would be a review of dozens (maybe hundreds?) of other molecules that might "need" to be reevaluated as to their prescription/OTC status.</2: 3.8.8>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>NO.</3: 4.2> <4: 4.4.2>Although there may SEEM to be so, such confusion is primarily claimed by those who are not entirely familiar with all the circumstances surrounding specific applications of Sec. 503(b).</4: 4.4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<5: 5.2, 5.4.2.2>Further rulemaking would merely open up additional areas of question and urge lawyers and medical personnel to find new avenues for advancing their personal (or constituent) agendas.</5: 5.2, 5.4.2.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<6: 6.1>Legally, FDA would probably be able to enforce such a limitation.</6: 6.1> <7: 7.2, 7.5.3, 7.5.4>In practice, this would raise the cost of prescription services and would probably not result in equitable and accurate enforcement.</7: 7.2, 7.5.3, 7.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<8: 7.2>Probably not, as mentioned above</8: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<9: 8.2>NO. </9: 8.2><10: 7.5.3>Any violation of the prescription product's sales would be virtually unenforceable from a practical standpoint.</10: 7.5.3>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<11: 6.5.4>If the drug were so HARMLESS as to be sold primarily OTC in the first place. But this begs the question, why sell it by prescription then? </11: 6.5.4>

COMMENT NUMBER - 2005N-0345-EC447

2005N-0345-EC447 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Anspach, Kurt

2005N-0345-EC447 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.3.3>If it were safe to take these pills without a prescription in one form then how can it not be for another use? That's a double standard. Most of the population that will be taking these pills won't understand that this shouldn't be done without being advised and supervised by a Doctor. </1: 3.3.3><2: 7.5.3>There wouldn't be any control over who buys these pills. Why fool ourselves saying let's put an age limit on them. After all it's possible to purchase anything at any time. </2: 7.5.3>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.5>Parts of the statement are good but how many people know the process of filing a complaint? This issue is a very important issue and it should be brought to the attention of the population through the media. </3: 4.5>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.2>no! </4: 5.2><5: 5.4.2.2> If there was a rulemaking how would the people know where to look for it? How many people know to go on the FDA website? </5: 5.4.2.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

no It wouldn't make any difference if the person wants them they will get them.

GENERAL

GENERAL

see attachment

2005N-0345-EC447-Attach-1.PDF 2005N-0345-EC447-Attach-1.PDF 2005N-0345-EC447-Attach-1.PDF 2005N-0345-EC447-Attach-1.PDF 2005N-0345-EC447-Attach-1.PDF

ATTACHMENT:

<6: 1.2, 10>IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CIVIL ACTION No. 05-810

MELISSA ANSPACH, KURT A. ANSPACH, KAREN E. ANSPACH,

Plaintiffs,

v.

CITY OF PHILADELPHIA, DEPARTMENT OF PUBLIC HEALTH, et al,

Defendants.

MEMORANDUM AND ORDER

JOYNER, J. June 27, 2005

Via the instant Motion, Defendants John F. Domzaliski, Louise Lisi, Maria Fedorova, Mary Gilmore, and the City of Philadelphia move to dismiss Plaintiffs' Complaint. Because Plaintiffs have failed to state a claim under federal law, this action must be dismissed for lack of federal question jurisdiction.

Factual Background

On January 26, 2004, Plaintiff Melissa Anspach visited a Health Center operated by the City of Philadelphia Department of Public Health. Melissa, who had engaged in sexual activity on January 23, 2004, believed that she might be pregnant and requested a pregnancy test. Plaintiffs allege that Melissa was told by a receptionist that she could not obtain a pregnancy test "because it was not family planning day." Melissa left the Health Center, but returned shortly thereafter at the prompting of a friend, who told Melissa to "ask for the morning after pill." Melissa followed this advice and was directed to the pediatric ward, where she provided her name and date of birth, indicating that she was sixteen years of age. See Complaint, ¶ 22-26.

Plaintiffs allege that Melissa next spoke with Defendant Maria Fedorova, a social worker, for approximately ten minutes, during which they discussed sexually transmitted diseases, birth control, and emergency contraception. Ms. Federova allegedly told Melissa that the Health Center could provide pills "that would prevent [her] from getting pregnant," and Melissa agreed to take these pills. Defendant Mary

Gilmore, a registered nurse, then took Melissa's temperature and blood pressure, and provided Melissa with emergency contraception marketed under the trade name Nordette. [Footnote 1: This method of emergency contraception, also known as the "morning-after pill," uses a combination of progestin and estrogen to prevent pregnancy. Depending on the phase of the patient's menstrual cycle, emergency contraception may prevent ovulation or fertilization. If fertilization has already occurred, emergency contraception may prevent ovulation or fertilization. If fertilization has already occurred, emergency contraception may alter the endometrium to prevent implantation of the fertilized egg. If a fertilized egg has already implanted in the endometrium, emergency contraception will have no effect. See <http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm>.] Nurse Gilmore told Melissa to take four pills right away and then four more in twelve hours. Plaintiffs contend that before Melissa took the pills, Nurse Gilmore consulted with Ms. Federova "to find out how Melissa should take the pills," and consulted with Defendant Jitendra Shah, a physician, to ask if Dr. Shah wanted to examine Melissa. After Melissa took the pills in Defendant Gilmore's presence, she allegedly asked whether the pills would make her sick. Nurse Gilmore reportedly consulted with Dr. Shah once again, who advised Nurse Gilmore to tell Melissa to drink ginger ale. See Complaint, ¶ 26-34.

After taking her second dose of pills at approximately 4:00 A.M. on the morning of January 27, 2004, Melissa experienced severe stomach pains and began vomiting. Melissa's father, Plaintiff Kurt Anspach, came to her room and found Melissa lying on the floor. Mr. Anspach contends that Melissa's face was swollen and red, and that Melissa asked if she was going to die. Upon learning that Melissa had taken emergency contraception, Mr. Anspach called their family physician and the poison control center, and took Melissa to the emergency room. Melissa was released from the hospital the same day, but returned because of sub-conjunctive hemorrhaging in her eye resulting from excessive vomiting. Melissa Anspach and her parents contend that the events described above have caused them to suffer severe emotional distress. See Complaint, ¶ 35-38.

Plaintiffs bring the instant action against Defendants, maintaining that their state and federal Constitutional rights were violated as a result of Defendants' actions. Mr. and Mrs. Anspach contend that they were deprived of their right to familial privacy when Defendants provided Melissa with medication without her parents' consent. Similarly, Melissa contends that Defendants' actions deprived her of the opportunity for parental consultation and guidance. She has also raised a claim of assault and battery against Defendants Federova and Gilmore for dispensing medication without Melissa's informed consent. Melissa contends that she was told that emergency contraception would prevent her from becoming pregnant, but was never informed that the pills could cause miscarriage or termination in the event she was already pregnant. Plaintiffs further bring claims of negligent supervision against Dr. Shah, and negligent and intentional infliction of emotional distress against the individual Defendants.

Standard of Review

In considering a motion to dismiss, a court must consider only those facts alleged in the complaint and accept all of the allegations as true. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3rd Cir. 1997). However, the court need not credit the plaintiff's "bald assertions" or "legal conclusions" where such conclusions are unsupported by the pleadings. *Morse*, 132 F.3d at 906. A motion to dismiss may only be granted where the plaintiff's allegations fail to state any claim upon which relief could be granted. *Morse*, 132 F.3d at 906.

Discussion

To state a cause of action for state deprivation of a constitutional right, a plaintiff must allege that he was deprived of a federal right by a defendant acting under color of state law. 42 U.S.C. § 1983; *Gomez v. Toledo*, 446 U.S. 635, 640 (1980). In Count I, Mr. and Mrs. Anspach contend that they were deprived of their fundamental right to direct the rearing and education of their minor child as a result of Defendants'

course of conduct. In Count II, Melissa Anspach alleges that Defendants deprived her of her right to parental guidance and advice in matters relating to medical care. Both counts arise out of the liberty interests granted by the Due Process Clause of the Fourteenth Amendment. Plaintiffs also allege that Defendants violated their First Amendment right to free exercise of religion by providing Melissa with a medication that can cause termination of a pregnancy, defined under Pennsylvania law as commencing with fertilization. 18 Pa. C.S. 3203.

I. Rights of Parental Guidance and Familial Privacy

It is well established that the fundamental right of parents to direct the upbringing and education of their children is protected by the Due Process Clause of the Fourteenth Amendment. *Troxel v. Granville*, 530 U.S. 57, 65 (2000); *Wisconsin v. Yoder*, 406 U.S. 205, 232 (1972); *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944); *Pierce v. Society of Sisters*, 268 U.S. 510, 534-35 (1925). This right, however, is not absolute. The state has a wide range of power to limit parental freedom in matters relating to child welfare. *Prince*, 321 U.S. at 167. Furthermore, the right of a parent to direct a child's upbringing cannot be understood in isolation. Minors, as well as adults, are protected by the Constitution and possess fundamental rights that may in some instances outweigh those possessed by their parents. *Carey v. Population Servs. Int'l*, 431 U.S. 678, 692 (1977) (quoting *Planned Parenthood of Central Missouri v. Danforth*, 428 U.S. 52, 74 (1976)).

A. No State Interference with Parent-Child Relationship

Even viewing the facts of the Complaint in their most favorable light, Plaintiffs have failed to state a valid claim for relief arising from violation of the above-described parental rights. Plaintiffs maintain that when Melissa Anspach visited the Health Center, Defendants were aware that she was only sixteen, but never asked Melissa whether her parents knew of her predicament, nor advised her to consult with her parents before deciding whether to take emergency contraception. Complaint, ¶¶ 27, 28. In Counts I and II of their Complaint, Plaintiffs conclude that Defendants' course of conduct "was intended to influence Melissa to refrain from discussing with her parents her possible pregnancy and what course of conduct was appropriate," and violated Mr. and Mrs. Anspach's rights "by usurping the parental role." *Id.*, ¶¶ 67, 68, 72, 77. This Court cannot credit Plaintiff's legal conclusions, however, as they are entirely unsupported by the factual allegations in the Complaint concerning Melissa's interaction with the Health Center staff. Plaintiffs do not maintain that Defendants instructed Melissa not to consult with her parents or otherwise prevented her from seeking their guidance and advice with respect to reproductive matters. At best, Plaintiffs have alleged only that Defendants failed to encourage Melissa to seek her parents' assent. Such passive failure on the part of a state agency and its employees cannot form the basis of a constitutional claim of the kind raised by Plaintiffs.

In the key cases defining the scope of the fundamental parental right to control a child's rearing and education, the Supreme Court has held that a state may not forbid parents from educating their children in accordance with their beliefs. See *Yoder*, 406 U.S. at 232-34 (compulsory high school education as applied to Amish minors); *Pierce*, 268 U.S. 510, 534-35 (compulsory education within the public school system); *Meyer v. Nebraska*, 262 U.S. 390, 400 (1923) (statute prohibiting teaching of foreign languages). Plaintiffs have identified no authority, however, to suggest that the scope of these cases can be expanded to allow constitutional claims against states that permit parental involvement but merely fail to take steps to encourage more active parental participation. This fundamental legal distinction was highlighted in 1980 by the Sixth Circuit Court of Appeals, in connection with a challenge to the Michigan Health Department's provision of contraceptive information and services to minors without parental notification. *Doe v. Irwin*, 615 F.2d 1162, 1168 (6th Cir. 1980), cert. denied, 449 U.S. 829 (1980). The Sixth Circuit found that earlier Supreme Court cases dealt only with states "either requiring or prohibiting some activity." *Id.* In contrast, the state of Michigan, in establishing a voluntary birth control clinic,

"imposed no compulsory requirements or prohibitions" affecting the rights of the parent- plaintiffs. *Id.* The court explained its findings as follows:

There is no requirement that the children of the plaintiffs avail themselves of the services offered by the Center and no prohibition against the plaintiffs' participating in decisions of their minor children on issues of sexual activity and birth control. The plaintiffs remain free to exercise their traditional care, custody and control over their unemancipated children. *Id.*

We find the Sixth Circuit's interpretation of Supreme Court precedent on the issue of parental rights to be compelling. See also *Parents United for Better Schs. Inc. v. Sch. Dist. of Pa. Bd. of Educ.*, 148 F.3d 260, 276 (3rd Cir. 1998) (favorably citing the reasoning of *Irwin* in upholding a voluntary condom distribution program in Philadelphia schools). In establishing a voluntary health clinic, the state of Pennsylvania has neither required that minors within the Commonwealth avail themselves of its services, nor prohibited parents from participating in their children's educational, moral, or physical upbringing. Thus, Plaintiffs have failed to state a constitutional claim for violation of Mr. and Mrs. Anspach's right to direct the upbringing of their minor child, Melissa. For the same reasons, Plaintiff Melissa Anspach has failed to state a constitutional claim for violation of her right to receive parental guidance.

B. No Parental Right to Be Notified of a Minor Child's Exercise of Reproductive Privacy Rights

Even if Plaintiffs' Complaint did allege facts sufficient to support a finding that Defendants' actions prevented Mr. and Mrs. Anspach from counseling their daughter, there is an alternative ground for dismissal of Plaintiffs' claims. There is simply no constitutional basis to support Plaintiffs' contention that parents have a constitutional right to be informed of their minor child's request for family planning services.

Minors, as well as adults, have a fundamental right to privacy in the intimate area of reproductive decision-making. See *Carey*, 431 U.S. at 692 (citing *Danforth*, 428 U.S. at 74). States that have adopted policies aimed at protecting this privacy right, however, often face challenges from parents alleging intrusion upon the sphere of familial privacy and parental guidance. In *Danforth*, for example, the Supreme Court considered the interplay between the reproductive rights of minors and the rights of their parents in the context of a Missouri law requiring parental consent to abortion for minors. *Danforth*, 428 U.S. at 74-75. Finding the absolute parental consent requirement unconstitutional, the Court held that a parent's independent interest in terminating or continuing a minor daughter's pregnancy is "no more weighty than the right of privacy of the competent minor mature enough to have become pregnant." *Id.* at 75. In a plurality opinion the following year, the Supreme Court found that the decision in *Danforth* "a fortiori foreclosed" any absolute prohibition on the distribution of contraceptives to minors without parental consent. *Carey*, 431 U.S. at 694. Thus, to the extent that Plaintiffs object to Defendants' failure to obtain the consent of Mr. and Mrs. Anspach before prescribing emergency contraception to Melissa Anspach, their constitutional claims must fail as a matter of law.

To the extent that Plaintiffs seek recovery on the basis of Defendants' failure to notify Melissa's parents of her request for emergency contraception, their claim must fail as well. There is absolutely no authority before this Court to support the proposition that a parent's right to be notified that their child has sought out family planning services outweighs the minor child's interest in reproductive privacy.

While the Supreme Court has upheld the constitutionality of parental notice requirements under some circumstances, the Court has never held that parents have a constitutional right to such notification, either with respect to contraception or abortion. [Footnote 2: Plaintiffs contend that the standards governing abortion should govern discussion of emergency contraception, because emergency contraception can result in the termination of a pregnancy, defined under Pennsylvania law as a fertilized embryo. See 18

Pa. C.S. 3203. This Court declines to determine whether emergency contraception is closer in kind to traditional methods of birth control or to chemically-induced abortion. For this reason, we will consider the law governing parental notification in the context of both abortion and contraception.] See, e.g., Lambert v. Wicklund, 520 U.S. 292, 297-98 (1997) (per curiam); Ohio v. Akron Ctr. for Reproductive Health, 497 U.S. 502, 510-11 (1990); H.L. v. Matheson, 450 U.S. 398, 409-10 (1981); See also Irwin, 615 F.2d at 1169 (finding that the opinions in Carey do not indicate that parents have a constitutional right to notification). Rather, the language used by the Supreme Court suggests that parental notification requirements pose significant constitutional challenges, and may be struck down if they do not provide minors seeking abortions with opportunities for exemption or judicial bypass. [Footnote 3: The Supreme Court has similarly held that statutes imposing an absolute requirement of parental consent are unconstitutional, finding that the failure to provide judicial bypass or other exemption procedures imposes an undue burden on a minor's right to choose. See Ohio v. Akron Center for Reproductive Health, 497 U.S. at 511; City of Akron v. Akron Center for Reproductive Health, 462 U.S. 416, 440 (1983); Bellotti v. Baird, 443 U.S. 622, 651 (1979) (plurality).] See, e.g., Hodgson v. Minnesota, 497 U.S. 417, 450-55, 461 (1990) (finding Minnesota's two-parent notice statute unconstitutional without procedures for judicial bypass); Lambert, 520 U.S. at 297-98 (upholding Montana notice statute with judicial bypass procedure); Ohio v. Akron Ctr. for Repro. Health, 497 U.S. at 510-11 (applying Bellotti bypass procedures to uphold Ohio notice statute); Matheson, 450 U.S. at 409 (upholding Utah parental notification law as applied to an immature, unemancipated minor seeking abortion); See also Planned Parenthood v. Heed, 390 F.3d 53 (1st Cir. 2004); Planned Parenthood of the Rocky Mts. Servs. Corp. v. Owens, 287 F.3d 910 (10th Cir. 2002); Planned Parenthood v. Miller, 63 F.3d 1452 (8th Cir. 1995).

Furthermore, numerous courts have held that parental notice requirements in the context of contraception and family planning services are inconsistent with Title X, which imposes a burden of confidentiality on providers of such services. 42 C.F.R. § 59.11; See, e.g., County of St. Charles v. Missouri Family Health Council, 107 F.3d 682, 684-85 (8th Cir. 1997); New York v. Heckler, 719 F.2d 1191, 1196-97 (2nd Cir. 1983); Planned Parenthood Fed. of Am. v. Heckler, 712 F.2d 650, 656-61 (D.C. Cir. 1983).

In light of the above authorities, Plaintiffs are wrong to suggest that they have a constitutional right to be notified of their daughter's request for emergency contraception. Thus, Counts I and II fail to state valid constitutional claims.

II. Right to Free Exercise of Religion

Plaintiffs also maintain that Defendants violated their right to free exercise of religion by providing Melissa with a medication that can cause termination of a pregnancy. Although the parties have not briefed this issue, this Court finds that Plaintiffs have failed to state a valid cause of action for violation of their rights under the Free Exercise Clause of the First Amendment.

In merely alleging that Defendants "gave [Melissa] a substance that, in some cases, may result in the termination of a pregnancy," and that Melissa would not have taken the pills had she known of this potentiality, Plaintiffs have failed to plead any constitutionally relevant injury in fact. See Complaint, ¶¶ 74, 80. Plaintiffs do not allege that Melissa was pregnant at the time she took the emergency contraception, nor do they allege that Defendants' actions actually resulted in the termination of a pregnancy in violation of Melissa's religious beliefs.

Furthermore, the facts of the Complaint, viewed in the light most favorable to Plaintiffs, do not suggest that Defendants "placed a substantial burden on [Plaintiffs'] observation of a central religious belief or practice." See Hernandez v. Commissioner, 490 U.S. 680, 699 (1989). Plaintiffs admit that Melissa voluntarily requested "the morning after pill," and do not allege that she made any inquiries as to the effect of emergency contraception on a fertilized ovum. Rather, Plaintiffs merely contend that Melissa

was misled by the designation "emergency contraception" in the literature provided by the Department of Health. Moreover, Plaintiffs do not maintain that Defendants compelled Melissa to take the pills, or otherwise prevented her from consulting with her parents or religious advisors regarding the implications of her decision.

Finally, it is well established that parental liberty interests are not violated merely because religious beliefs are implicated in the claim. *Irwin*, 615 F.2d at 1168 (citing *Prince*, 321 U.S. at 166).

Conclusion

This Court recognizes that parental guidance is invaluable to a child's moral, social, and religious development. Parental involvement is particularly important during the period of adolescence, when children struggle with weighty issues of peer pressure and sexuality. Within any family unit, parents and their adolescent children have a shared responsibility to engage in discussion of personal and family values, and to learn from each other's perspectives. These ideals are reflected in the Due Process Clause of the Fourteenth Amendment, which protects the fundamental right of parents to direct the upbringing and education of their children.

Plaintiffs interpret this parental right to require that public health centers disclose to parents a minor child's request for family planning services. In doing so, Plaintiffs stretch the boundaries of this constitutional doctrine to the breaking point. The Health Center's failure to notify Mr. and Mrs. Anspach of their daughter's request for emergency contraception in no way prevents Plaintiffs from discussing responsible sexual activity or religious doctrine at home. Furthermore, Mr. and Mrs. Anspach's rights under the Due Process Clause do not include the right to receive state notification upon their minor daughter's exercise of her fundamental right to privacy in reproductive decision-making.

In sum, Plaintiffs' allegations fail to state any constitutional claim upon which relief could be granted. As there is no federal question remaining before this Court, this action shall be dismissed for lack of jurisdiction.

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF
PENNSYLVANIA

CIVIL ACTION No. 05-810

MELISSA ANSPACH, KURT A. ANSPACH, KAREN E. ANSPACH,

Plaintiffs,

v.

CITY OF PHILADELPHIA, DEPARTMENT OF PUBLIC HEALTH, et al,

Defendants.

ORDER

AND NOW, this 27th day of June, 2005, upon consideration of the Motion to Dismiss filed by Defendants John F. Domzaliski, Louise Lisi, Maria Fedorova, Mary Gilmore, and the City of Philadelphia

(Doc. No. 6), and Plaintiffs' response thereto (Doc. No. 14), it is hereby ORDERED that the Motion is GRANTED and this action is dismissed for lack of subject matter jurisdiction.

BY THE COURT,

s/J. Curtis Joyner

J. CURTIS JOYNER, J.</6: 1.2, 10>

COMMENT NUMBER - 2005N-0345-EC47

2005N-0345-EC47 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Clason, Dennis

2005N-0345-EC47 - TEXT

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 6.1, 6.6.3>It seems rather clear that both State and Federal bodies regulate and enforce product restrictions to particular subpopulations. The legal age for alcohol consumption is 21 years in all 50 states, and this age limit is enforced by both the various States and by Federal agencies (e.g., Department of Defense). Many States have laws and regulations which control the distribution of tobacco products to those over an age limit, and they are able to enforce their laws and regulations. Other substances controlled in similar ways include inhalants (toluene-containing glues and aerosols) and spray paints.

Clearly, if it is permissible for State and Federal agencies to restrict distribution of certain compounds by age, it is both permissible and possible for the FDA to do so.</1: 6.1, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<2: 7.1, 7.4.4, 7.4.5>Of course it is. Age limits can be enforced for new drugs in the same way they are enforced for casually used drugs like nicotine and ethanol. Spot check purchase attempts by individuals who appear to be underage and have an underage ID would suffice to control distribution. The FDA can set appropriate fines and penalties for violation of the distribution rules it sets up.</2: 7.1, 7.4.4, 7.4.5>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<3: 9.1.1>If the indications were different for the OTC and prescription products, I would expect that

different packaging would be required and reasonable.</3: 9.1.1> <4: 8.4.1, 9.2.1>If the indications are the same for the OTC and prescription product, then I think that differentiated packaging is silly.</4: 8.4.1, 9.2.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

See above.

GENERAL

GENERAL

<5: 1.2, 2.1>This is without a doubt one of the silliest and most blatantly political exercises the FDA has ever engaged in. The political appointees in the Agency really ought to quit playing footsie and make a decision on the Barr application -- approve it, or disapprove it, but follow your own rules regarding applications. </5: 1.2, 2.1>

COMMENT NUMBER - 2005N-0345-EC49

2005N-0345-EC49 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Landauer, Christopher

2005N-0345-EC49 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.3>The FDA has a responsibility to determine what medications can be safely self administered. However in this case, the use of the medication will set a precedent that will be unheard of. There are ample methods of contraception available in the marketplace and there is no reason for a medication of this nature. It was unconditionable that the agency ever approved a medication of this nature in the first place, but now that it is approved, it should remain a prescription drug that doctors should only prescribe on a case by case basis.

I would hope that the agency would be responsible to ensure that this medication and any others like it remain prescription drugs.</1: 1.2.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.2, 6.5.1, 7.2, 7.5.2>No, the agency does not have the capacity to enforce a perscription program to any subpopulation. The agencies responsibility is to ensure that only safe, ethical drugs are allowed in the marketplace. The agency does not have the ability to enforce age limitations with respect to perscription drugs. Hence this drug product should only be perscribed by a medical professional.</2: 6.2, 6.5.1, 7.2, 7.5.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.5.1>No the agency does not have the authority to comply w/ this.</3: 7.5.1>

3

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<4: 1.2.3>This product should never be sold over the counter. That would be negligent of the agency to allow something like that to happen.</4: 1.2.3>

GENERAL

GENERAL

<5: 1.2.3>I think the agency is putting itself on a slippery slope with the decision on this issue. I think it would remain in the best interest of the general public to keep this and other medications as perscription drugs. This way a trained professional can make a rationale decision on the availability of this product.

This product does not have much redeeming value in general. </5: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC495

2005N-0345-EC495 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Stier, Christopher

2005N-0345-EC495 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

Yes. While the current interpretation seems reasonable, a lack of codification leaves open a great deal of subjectivity with respect to what is meant by a "meaningful difference" between a prescription product and an OTC product. This codification should go beyond simple differences (e.g., strength, dosage) and require that clinical trials form the basis for any OTC branding - in order to ensure the safety of the population or any subpopulation for which the OTC version is being made available.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.1>Yes.</1: 3.1> <2: 3.8.1, 3.11>While the current interpretation seems reasonable, a lack of codification leaves open a great deal of subjectivity with respect to what is meant by a "meaningful difference" between a prescription product and an OTC product. This codification should go beyond simple differences (e.g., strength, dosage) and require that clinical trials form the basis for any OTC branding - in order to ensure the safety of the population or any subpopulation for which the OTC version is being made available.</2: 3.8.1, 3.11>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1>Yes - to a degree.</3: 4.1> <4: 4.3.4>The interpretation is sound. However, there is confusion due to the lack of a documented "decision tree" around the process of FDA approval for the sale of an OTC product.</4: 4.3.4>

C. If so, would a rulemaking on this issue help dispet that confusion?

<5: 5.1>Yes.</5: 5.1> <6: 5.3.2>Document the "meaningful difference" for drug manufacturers and consumers. This will diffuse the effects of marketing, advertising, and labels that can be highly misleading. Men and women deserve to know the truth about drugs being marketed to them.</6: 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<7: 6.3.5>The answer would clearly depend on how the subpopulation was classified. Age restrictions, for example, could be enforced as a matter of law. </7: 6.3.5>

B. If it could, would it be able to do so as practical matter and, if so, how?

<8: 7.1, 7.4.4>Yes. Minors are not permitted to buy alcohol without proper ID showing proof of age. </8: 7.1, 7.4.4>

COMMENT NUMBER - 2005N-0345-EC5

2005N-0345-EC5 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Cunningham, Laura

2005N-0345-EC5 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>YES</1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

YES

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>YES</2: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.1>YES</3: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 7.1, 7.4.4>YES, BY MAKING STORES CHECK IDENTIFICATION BEFORE PURCHASE, JUST AS THEY DO WITH CIGARETTES AND ALCOLHOL. CASH REGESTERS AUTOMATICALLY STOP A SALE AND ASK FOR THE CUSTOMERS DATE OF BIRTH. </4: 7.1, 7.4.4><5: 7.4.1>PUTTING THEM BEHIND A PHARMACY COUNTER WOULD MAKE THEM AS INACESSABLE THEY WERE BEFORE BECAUSE PHARMACISTS WOULD THEN NOT DISTRIBUTE THEM DUE TO RELIGIOUS BELIFES.</5: 7.4.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.4.4>BY MAKING CASH REGISTERS CHECK DATE OF BIRTH</6: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1, 8.3.4>YES, WITH A DISCLOSURE</7: 8.1, 8.3.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.1.1>IF THERE WAS A DIFFERENCE IN PRODUCT INGREDIENTS</8: 9.1.1>

GENERAL

GENERAL

<9: 1.2.1>PUT THIS PRODUCT ON THE SHELF SO WOMEN MAY DECIDE FOR THEMSEVES WHAT IS RIGHT FOR THEM.</9: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC505

2005N-0345-EC505 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Padden, Phillip

2005N-0345-EC505 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.7.1>Check your congressional mandate. If it requires that interpretations be justified then yes, codifying your interpretation would be an extension of justification.</1: 3.7.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Again, Check your congressional mandate. If it requires that interpretations be justified then yes, codifying your interpretation would be an extension of justification.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.2, 6.5.4>No, but as a matter of law all America's should have equal access to drugs without any government restrictions/prohabitions. The constitutions allows for the regulation of interstate trade, not the restriction of it.</2: 6.2, 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.1, 7.4.4>Yes, follow the example of alchol and tobacco age restrictions.</3: 7.1, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.1>Yes</4: 8.1>

GENERAL

GENERAL

<5: 1.2.1>The release of Plan B as an OTC, should not be held up or restricted, of a young woman's access to the drug. </5: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC516

2005N-0345-EC516 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Katrib, Elise

2005N-0345-EC516 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.2>Yes it should allow Plan B to be available both in prescription and OTC drug form. But given that the pharmacists are allowed to choose which prescription you are allowed to receive, the OTC drug should marketed heavily.</1: 1.2.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 1.2.2>As long as the active ingredient is safe, market in both a prescription drug product and an OTC drug product.</2: 1.2.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1, 4.5>Yes, it seems that given enough pressure or money, a drug will be able to overcome FDA interpretation of any act.</3: 4.1, 4.5>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 3.8.3>The rulemaking should focus on safety. But also take into account that the same drug is widely available in other countries such as Canada and the Britain.</4: 3.8.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.1>Yes it is possible to sell to a subpopulation.</5: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 6.6.3, 7.4.4>How do we enforce the sale of tobacco and alcohol? Just check ID.</6: 6.6.3, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1>Yes</7: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.2.1>They may be sold in a single package if they have the same active ingredients.</8: 9.2.1>

GENERAL

GENERAL

<9: 1.2.1>I support the OTC version of the Plan B drug. I am actually surprised that the FDA is taking a longer time to examine this drug then others that have been declared safe to be sold as OTC drugs. I believe that the Plan B drug sold as an OTC will resolve many instances of conflict in pharmacies, regarding the right to have a valid prescription filled. I will keep checking for updates regarding this issue. </9: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC518

2005N-0345-EC518 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Kowalczyk, Brigid

2005N-0345-EC518 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.3>The morning after pill, which is potentially an abortifacient drug, should not be sold over the counter to anyone. It is a serious drug with a serious use that should not be trivialized by selling it to anyone who thinks they need it. There is no way to limit its application and avoid abuses which will be very damaging to the health of the women who take it as well as potentially causing an abortion, which is its only intent.</1: 1.2.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 1.2.3>the active ingredient in the morning after pill should not be allowed to be sold over the counter for any reason. If it is available by prescription there is some control over who decides to take it, some oversight to the application. OTC drugs can be and will be abused and used incorrectly often.</2: 1.2.3>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1>there is significant confusion. </3: 4.1><4: 4.5>No drug should be sold both by prescription and OTC.</4: 4.5>

C. If so, would a rulemaking on this issue help dispel that confusion?

<5: 5.1>Yes.</5: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<6: 1.2.3>How could that work? What subpopulation? Who decides who that "subpopulation" is? Only

prostitutes? Only teenagers under the age of 18? Only women between 18-24? Ridiculous. The decision to us MAP is a decision to take a drug to eliminate a condition. That condition is merely pregnancy, a normal natural consequence of intercourse. We do not recommend laxatives and bulimia and extreme exercise for overweight people who are also suffering the consequences of their act of eating, too much or the wrong things. But those items (laxatives) can be abused because they are OTC and we have no control over them. But that person is only hurting themselves. Someone who takes an OTC MAP will be hurting themselves and also removing a conceived embryo from the planet. This hurts the child (embryo is a child) and the planet and the effects of the OTC hormone will also hurt the woman who takes it.</6: 1.2.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 1.2.3>I answer questions, on a website, that come from young women who "accidentally" have sex with someone and not knowing where they are in their cycle or how likely it is that pregnancy could result, ask me if they should get MAP. And then if they "accidentally" do it again 2 or 5 days later, they ask the same question again! So many women, because they are scared (and doing the wrong thing) are going to think this saves them. They are going to think they are safe if they just do whatever they want and then take the MAP, especially if it's available OTC.</7: 1.2.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 8.2, 8.6.4>How confusing is that? One girl goes to her doctor and gets a prescription, the other goes to the local drug store and picks up the same box! One girl has some medical supervision in case there are adverse reactions (abortion is an adverse reaction but that won't be considered) and the other is on her own to consider her symptoms without any medical opinion to guide her. That's a good idea! NOT.</8: 8.2, 8.6.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<9: 9.1.2>All circumstances. Neither should be sold but if it will be sold and marketed (that's where the problem comes) then it should be something that women consider to be a serious drug with serious side effects, not something like Sudafed or antacids that anyone can pick up at any time without a medical diagnosis!</9: 9.1.2>

COMMENT NUMBER - 2005N-0345-EC52

2005N-0345-EC52 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Zahn, Steven

2005N-0345-EC52 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes.</1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

Yes.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes.</2: 4.1> <3: 4.5>It is not significant enough that different strengths of the same product are marketed as prescription or OTC. That gives the illusion of safety in taking increased doses of the OTC product knowing that there is an equivalent prescription dose available.</3: 4.5>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 6.1>Yes.</4: 6.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.2>No, not under the current regulations and its interpretations.</5: 6.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2>No. </6: 8.2><7: 8.6.2>There would be too much confusion among packaging, leading to errors in dispensing the wrong products or packaging.</7: 8.6.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.1.2>All circumstances. The OTC product would have the same potential for harm from misuse, or circumstances surrounding its use, in one subpopulation as in another.</8: 9.1.2>

GENERAL

GENERAL

<9: 3.11>It is not significant enough that different strengths of the same product are marketed as prescription or OTC. That gives the illusion of safety in taking increased doses of the OTC product knowing that there is an equivalent prescription dose available. The safety of all market strengths available of a particular product should be considered when evaluating a product's safety for OTC use. Also, limiting OTC sales of a product to population subgroups still exposes that subpopulation to possible harmful effects or circumstances due to misuse of the product. Potentiality of harmful effect of a product can also be realised from the circumstances in which a product is used, and not just toxicities from the product itself.</9: 3.11>

COMMENT NUMBER - 2005N-0345-EC522

2005N-0345-EC522 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Dolinski, Elizabeth

2005N-0345-EC522 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.2, 3.2, 3.8.8>The FDA should only rule on drug safety issues. I am very upset that the FDA is trying to pass moral judgement on the U.S. population. It has been determined to be medically preferable to make plan b available simultaneously available. Therefore, that is what the FDA should do.</1: 1.2.2, 3.2, 3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

The FDA should only rule on drug safety issues. I am very upset that the FDA is trying to pass moral judgement on the U.S. population. It has been determined to be medically preferable to make plan b available simultaneously available. Therefore, that is what the FDA should do.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.3.2>the FDA CAN make a drug both prescription and over the counter. That is clear to me and should be made clear to the public.</2: 4.3.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.5>the FDA CAN make a drug both prescription and over the counter. That is clear to me and should be made clear to the public.</3: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.7>the FDA has no right to make an OTC drug available only to a subpopulation. The only subpopulation separate the FDA has a right to regulate is minor versus adult.</4: 6.7>

B. If it could, would it be able to do so as practical matter and, if so, how?

The only subpopulation separate the FDA has a right to regulate is minor versus adult.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.1>YES, of course. </5: 8.1><6: 8.4.1>To require different packaging would raise the price for no good purpose.</6: 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 8.7, 9.1.1>For the same dose, it should always be appropriate. The ONLY reason it wouldn't be appropriate was if higher dosages were to be prescription. I.e. for ibuprofen.</7: 8.7, 9.1.1>

GENERAL

GENERAL

<8: 1.2.2, 2.1>I am deeply offended by the delay of approval of plan b. Why would the FDA want to take action that drives up the number of risky operations (abortions) for young women? especially when there is a safe contraceptive alternative? does the FDA intend to purposefully injure young women with this action?</8: 1.2.2, 2.1>

COMMENT NUMBER - 2005N-0345-EC526

2005N-0345-EC526 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Thompson, Sharon

2005N-0345-EC526 - TEXT

Issue Areas/Comments

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 6.2, 7.5.3>It would not be possible to regulate having "prescription" status for a particular subpopulation because it would be too easy to circumvent this. </1: 6.2, 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<2: 7.4.1, 7.5.3>It would need to be "behind the counter" in pharmacies, and pharmacists would need to regulate. However, even this seems like it would be easy to circumvent if something is a prescription item just for certain subpopulations.</2: 7.4.1, 7.5.3> <3: 7.4.6>For any subpopulation that is a minor, I would think a signature of a legal guardian would be necessary. </3: 7.4.6>

GENERAL

GENERAL

<4: 2.1>I would hope the FDA would never sacrifice safety for convenience. It seems like there is quite a push for convenience over safety, and my hope is that the FDA won't cave to the pressure. </4: 2.1>

COMMENT NUMBER - 2005N-0345-EC527

2005N-0345-EC527 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Ramirez, Robert

2005N-0345-EC527 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.3>Yes, if clarification is needed initiate a rulemaking interpretation. If a active ingredient scientifically shows that is safe and effective for the public and the only reason for the product not being available for the public is red-tape, then policy has to be amended.</1: 3.1, 3.8.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 3.3.2>If an active ingredient is proven scientifically that it is safe for public use in the same dosage there should not be any difference. Make the product OTC. If needed for clarification codify the ingredients and list them for dual markets.</2: 3.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.2>No. One this would be a enforcement nightmare. </3: 6.2><4: 1.2>Codify the active ingredients or have a resubmittal of the application and have physical development and size as the criteria for dosage for effectiveness.</4: 1.2>

GENERAL

GENERAL

<5: 1.2>Fundamental there is an age limit on the initial initial application. Does the scientific evidence show significant differences with regards to age? This should be the question. If not have the application resubmitted without age and included individual physical development and size. </5: 1.2>

COMMENT NUMBER - 2005N-0345-EC53

2005N-0345-EC53 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: McGhee, Tim

2005N-0345-EC53 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

It's very unclear to me how OTC status would not render completely irrelevant a drug's prescription status--especially when it's the same drug.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 4.3.4>It's very unclear to me how OTC status would not render completely irrelevant a drug's prescription status--especially when it's the same drug.</1: 4.3.4>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes, the FDA's interpretation would create legal confusion.</2: 4.1> <3: 7.5.3>That said, young people today are bright and would quickly figure out a way around the system/confusion. We don't need a second-tier market of these pills between younger and older teenagers.</3: 7.5.3>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 5.2>I find this to be unlikely.</4: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 7.5.3>As I mentioned in response to 1B, there would be no limitation. The FDA is trying to parse out a particular subpopulation into segments which are inherently fluid--teenage girls. Saying 15-year-olds need a prescription, and 16-year-olds don't?

The FDA may find it needs to draw an imaginary line dividing the two, but that line would not extend very far beyond the confines of the FDA into reality.</5: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.2>I do not believe it could.</6: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.9>The package doesn't change the contents, but it might change who is more likely to obtain the drug.

The tobacco industry was blasted for using "Joe Camel" that attracted young people to smoking. The moral of the story here is, changing the packaging would only increase who is likely to get the drug, not limit young people from getting the drug.</7: 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.2.1>Let's say the drug maker gets a green light to market the hell out of this drug--specifically for the 16-year-old girls and up market.

Continuing with the Joe Camel analogy, if they market the drug in areas to reach girls significantly under the specified age (such as 13, 14, 15), then the packaging in the marketing should match the prescription packaging, not the OTC packaging.</8: 9.2.1>

GENERAL

GENERAL

<9: 1.2.4>I don't believe this drug should be on the market at all.

As we have discussed in the cloning and embryonic stem cells debates, the union of egg and sperm is the beginning of life. I began there; we all began there.

This drug specifically thwarts the ability of that newly formed life from becoming the person God created them to be. This drug prevents the essential implantation of that life into the woman's body. That's killing it.

The use of this drug is wrong, and should not be endorsed by the FDA. </9: 1.2.4>

Thank you for your time, and for allowing me to speak.

Tim

COMMENT NUMBER - 2005N-0345-EC535

2005N-0345-EC535 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Rectenwald, Theodore

2005N-0345-EC535 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes.</1: 3.1> <2: 3.8.1>Clarity is necessary.</2: 3.8.1>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>No.</3: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1>Yes.</4: 6.1> <5: 6.6.3>This is already done, for instance, with tobacco and alcohol.</5: 6.6.3> <6: 1.2.3, 6.5.4>In the case of the abortifacient "morning-after-pill," direct OTC sales to minors without parental consent runs counter to every medical ethic currently practiced. Indeed, public health authorities will not even administer government-mandated immunizations without parental consent. To treat this matter differently would not only offer an absurd exception, but also engender a serious violation of parental rights and amount to an invasion of family privacy.</6: 1.2.3, 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 6.6.3, 7.1>Yes, in the same manner as sales of tobacco and alcohol are controlled.</7: 6.6.3, 7.1> <8: 1.2.3>On the other hand, kindly note that I am opposed to making this particular drug available in any but prescription form, if at all. It is dangerous and should not be available at all, let alone without a prescription.</8: 1.2.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<9: 9.3>On the (false) assumption that it should be legal, the packaging would be irrelevant.</9: 9.3> <10: 8.2, 8.5.4>However, differences in packaging would make control of violations (sales to minors, for instance) easier to detect and, perhaps, prosecute.</10: 8.2, 8.5.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

Same as above.

GENERAL

GENERAL

<11: 1.2.3>I am vehemently opposed to the availability of this abortifacient in general but, in view of the FDA's acceptance of it, would at least like to ensure that it continues to be accessible only by prescription. If this dangerous drug is foolhardily to be made available OTC, at a minimum access for minors ought to be restricted by the need for a prescription. </11: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC54

2005N-0345-EC54 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Rommel, Scott

2005N-0345-EC54 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.1>Yes, this would seem to be a required point considering the amount of drug therapies available and the numbers will only increase. In addition, when ever there are regulatory vagaries groups seems to always take advantage and promote unintended agendas.</1: 3.1, 3.8.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

Yes, see above.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes.</2: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.1>Yes.</3: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 3.8.7, 6.2>NO, This seems to be a problem waiting for a whole lot of money to be wasted on. Either a drug is over the counter or it is not.</4: 3.8.7, 6.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2, 7.4.1, 7.4.4>Most likely not, the only practical level of screening that may work is to have a drug OTC, but behind the counter where an ID is the only questioning limiting the drugs dispensing.</5: 7.2,

7.4.1, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2, 8.6.4>This would seem to be a problem waiting to happen. If this is to occur then the two packages should be different. It does not seem reasonable to require a possible enforcement protocol to account for an item with the same packaging with one being legal OTC and the other not.</6: 8.2, 8.6.4>
<7: 3.8.7>Either trust the majority of the population to do right and keep it all OTC or distrust and try to manage the minority and keep products behind a counter under strict control, both will have good and bad social consequences but one will cost more.</7: 3.8.7>

COMMENT NUMBER - 2005N-0345-EC555

2005N-0345-EC555 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Della Paolera, Mark

2005N-0345-EC555 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

No.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<1: 3.2>No.</1: 3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No.</2: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.2>NO, the FDA cannot guarantee that such age restrictions would be satisfied.</3: 6.2> <4: 7.5.3>Underage patients would still have access to the drug whether it is other persons of age purchasing it for them, theft, or cashiers selling it without certifying a person's age.</4: 7.5.3> <5: 1.2.3>Plan B needs to remain behind the counter.</5: 1.2.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2, 8.6.4>NO, confusion could occur with stocking issues. When a shipment of Plan B arrives, is it stocked in the front end of the store or in the pharmacy? Separate packaging is necessary.</6: 8.2, 8.6.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 7.4.1, 9.2.2>There is none. It needs to remain behind the counter.</7: 7.4.1, 9.2.2>

GENERAL

GENERAL

<8: 1.2.3>The marketing and selling of Plan B as an OTC product is a terrible idea. The general population need to have a greater understanding of the drug and granting it an OTC status revokes the importance of its use, how it is used, and how it acts to the consumer. There needs to remain a patient-healthcare professional relationship. Often when a product is granted OTC status, the public's perception is that the intervention of a healthcare provider is not necessary. Placing Plan B OTC prevents important aspects that need to be addressed to the patient. One such example is notifying patients of its mechanism of action. Many do not know that it prevents a fertilized egg from adhering to the endometrium and often choose to not perform this method of 'contraception' as they would view this as an abortion. Patients also need to be informed on potential side effects and need to guarantee that the patient is using it within 72 hours. When a product goes OTC, many patients will use a product against the manufacturer's recommendation. Having a pharmacist involved can help prevent such complications. Furthermore, the phrase 'emergency contraception' is a misnomer to many patients who may believe this is an item that could be taking regularly prior to each act of coitus. i.e., the public needs to know that there are safer and more effective means of contraception than purchasing Plan B.</8: 1.2.3> <9: 7.5.3>One final aspect to consider is that no one could guarantee that children under 16 would not have access to the drug. Cashiers could unknowing sell it to an underage person, it could be stolen, and it could be purchased by a person of age and given to the underage child.</9: 7.5.3> <10: 1.2.3>In summary, Plan B needs to remain behind the counter to protect the safety of patients by maintaining a patient-provider relationship.</10: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC56

2005N-0345-EC56 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Porter, Rebecca

2005N-0345-EC56 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No.</1: 3.2><2: 3.8.8> If the medication is not safe enough for OTC use then it should be sold only by prescription to maintain the safety for all parties. Making it OTC will make it available to the group for whom it is not acceptably safe.</2: 3.8.8> <3: 3.3.3, 7.5.3>There is too great a potential for this drug to be abused. There is more to this issue than carding the patient. Fake ids are easily found. Who will monitor these patients that are taking the prescription? Medications that are taken OTC are expected to be safe and not need a doctor's follow up.</3: 3.3.3, 7.5.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No. There is too great of a potential for this drug to be abused and lives to be put into danger. <4: 1.2.3>The use of this medication should be monitored by a responsible physician only.</4: 1.2.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.2>No.</5: 6.2> <6: 6.6.3, 7.5.3>Look at the amount of alcohol that is sold to minors. There will always be a way for the underaged to get this medications.</6: 6.6.3, 7.5.3>

COMMENT NUMBER - 2005N-0345-EC566

2005N-0345-EC566 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Burgess, Annette

2005N-0345-EC566 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

No.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.2>No.</1: 3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No.</2: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.2>No.</3: 5.2> <4: 1.2.3>There is a secondary danger of allowing this drug to go into an over-the-counter class. If this pill were allowed to become an over-the- counter medication, it could deny a woman the safety of conversing with her doctor the medical risks of taking it, deny the woman the privacy of deciding if she wanted to take the prescription or not, and might allow the woman's mate to buy the drug and coerce her to take it against her wishes, her health or that of her unborn child. To change this interpretation would not allow a woman to have a witness (i.e., the doctor who would writes the prescription) that she indeed did ask for this drug. Changing this drug's designation to Over-the-counter, would not give the woman the privacy to make her own choice in whether this drug was too dangerous to her health or not.</4: 1.2.3> <5: 6.5.4>To change the interpretation might bring legal consequences upon the FDA or the stores selling this drug if a wrongful death suit were initiated.</5: 6.5.4>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<6: 6.2>No.</6: 6.2> <7: 6.5.4>What would be legal consequences in a wrongful death suit to the FDA and the stores who carry this OTC medication?</7: 6.5.4> <8: 3.8.7>A subpopulation ruling would open a pandora's box to all kinds of hybrid requests that would tie up government as well as be a financial burden on stores which carried such products as they'd have to hire additional employees, etc. in an already stressful environment to provide timely prescriptions. Talk about back-log!</8: 3.8.7>

B. If it could, would it be able to do so as practical matter and, if so, how?

<9: 7.2>It couldn't.</9: 7.2> This would open the door to all kinds of age-related or hybrid

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<10: 8.2, 8.6.4>No, because of the harmful side effects of this drug.</10: 8.2, 8.6.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<11: 8.2>It should not be legal.</11: 8.2>

GENERAL

GENERAL

There is a secondary danger of allowing this drug to go into an over-the-counter class. If this pill were allowed to become an over-the-counter medication, it could deny a woman the safety of conversing with her doctor the medical risks of taking it, deny the woman the privacy of deciding if she wanted to take the prescription or not, and might allow the woman's mate to buy the drug and coerce her to take it against her wishes, her health or that of her unborn child. To change this interpretation would not allow a woman to have a witness (i.e., the doctor who would writes the prescription) that she indeed did ask for this drug. Changing this drug's designation to Over-the-counter, would not give the woman the privacy to make her own choice in whether this drug was too dangerous to her health or not. To change the interpretation might bring legal consequences upon the FDA or the stores selling this drug if a wrongful death suit were initiated.

No. What would be legal consequences in a wrongful death suit to the FDA and the stores who carry this OTC medication? A subpopulation ruling would open a pandora's box to all kinds of hybrid requests that would tie up government as well as be a financial burden on stores which carried such products as they'd have to hire additional employees, etc. in an already stressful environment to provide timely prescriptions. Talk about back-log!

COMMENT NUMBER - 2005N-0345-EC569

2005N-0345-EC569 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Tansley, Kathleen

2005N-0345-EC569 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>I feel strongly that the FDA should not initiate a rulemaking to codify their interpretation of section 503(b), about dual-marketing both a prescription drug product and simultaneously an OTC product. </1: 3.2>

<2: 1.2.3>Making Plan B over the counter would create numerous problems especially with regard to keeping it out of the hands of minors.</2: 1.2.3> <3: 7.5.2, 7.5.3>The FDA has no mechanism for enforcing a regulation that prohibits sale to minors. And enforcing this could not only cause serious controversy on both sides of the spectrum, but be very difficult to regulate.

I feel the FDA should step back and realize this, and not go further with this type of policy change.</3: 7.5.2, 7.5.3>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<4: 4.2>I myself, am not confused by 503(b) as explained on your web site here.</4: 4.2> <5: 3.8.8>But I have written my serious concerns above (see A), and see no logical reason for the FDA to change their policy on this issue, it would create serious controversy, difficulty, and perhaps even future lawsuits from consumers at the extreme.</5: 3.8.8>

C. If so, would a rulemaking on this issue help dispel that confusion?

<6: 3.2, 3.8.8>I believe the rulemaking should stay as it is. And not go change policy, allowing dual-marketing of both a prescription drug product and simultaneously an OTC product. The FDA should remain firm on this issue in this regard.</6: 3.2, 3.8.8>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<7: 6.2, 6.5.4, 7.5.3>Selective limitation of a product to a sub-population could bring on lawsuits from either end of the spectrum from disgruntled consumers, as well as media controversy on the issue, and a near insurmountable impossibility to enforce such a regulation.

This is a bad idea for the FDA to pursue.</7: 6.2, 6.5.4, 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<8: 7.2>No. I cannot see this happening.</8: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may

the different products be legally sold in the same package?

<9: 3.8.5>This again would be a cause for concern for the consumers, and controversy could arise, and laws must be changed, and I feel this is incorrect to do a 'blanket change of policy for reinforcement on dual-marketing drugs' in this manner.

What if other drugs arise in the future and likewise the drug companies supplying the consumers would want the same option, and what if there is cause for concern that this would be detrimental to the consumers by doing this? The FDA would then have to do 'damage control' and back-pedal on their policy on rulemaking if they follow this route. </9: 3.8.5>

COMMENT NUMBER - 2005N-0345-EC572

2005N-0345-EC572 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Naughton, John

2005N-0345-EC572 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.3>Why approve OTC use of a drug which is generally ineffective?

Morning-after pill access fails to cut pregnancy rate - January 5, 2005 </1: 1.2.3>

By Cheryl Wetzstein

THE WASHINGTON TIMES

<2: 1.2.3>Women's health care advocates have been urging the federal government to allow easy access to "morning-after" pills as a way to dramatically reduce unintended pregnancies. However, a study released today undercuts that argument by showing that young sexually active women who were handed packages of "morning- after" pills had pregnancy rates six months later that were virtually the same as women who had to go to drugstores or clinics to get the pills. "That was definitely a disappointing finding," said Tina R. Raine, lead researcher of the study of 2,117 women, which appears in today's Journal of the American Medical Association (JAMA). A core hypothesis, she said, was that two groups of women with easy access to "emergency contraception" (EC) would have half as many pregnancies as women who had to see a health provider to get the pills. Instead, all three groups of women had pregnancy rates of around 8 percent. Nevertheless, EC should still be available without a prescription, said Dr. Raine, a professor at the University of California at San Francisco. That's because the study also showed that when women had easy access to EC, they used the pills more often, but they didn't take more

sexual risks or get more sexually transmitted diseases (STDs), as some have feared. Given these findings, "it seems unreasonable to restrict access to EC to clinics," Dr. Raine and her colleagues wrote. Concerned Women for America analyst Wendy Wright, an opponent of EC, disagreed. "Why make [EC] easily available and put women's health at risk if it doesn't even reduce what the women fear, which is pregnancy?" she said. Emergency contraception refers to high-dose birth-control pills taken within 72 hours of unprotected sexual intercourse. The pills, used by 4 percent of women, can interrupt ovulation, fertilization or implantation. All but six states require a prescription to get EC. Most women's health advocates believe that half of the nation's estimated 3.5 million unintended pregnancies could be prevented if EC were widely available, especially to teens and college-age women. They believe the pills are safe and effective, and they have launched campaigns urging the federal Food and Drug Administration (FDA) to allow the nation's primary EC product, Plan B, owned by Barr Pharmaceuticals Inc., to be sold without a prescription. Opponents of EC, such as Miss Wright, worry that easy access to EC will encourage irresponsible sexual behavior and STDs.

Studies of EC in Britain show easy access to the pills causes "an increase in STDs and no decrease in the number of abortions," she said. In 2003, two FDA advisory panels recommended that the FDA approve Plan B for over-the-counter sales, but in May, the FDA declined, saying it was concerned about teens using the product without medical supervision. A spokeswoman for Barr Pharmaceuticals yesterday said they have resubmitted Plan B paperwork and are expecting another FDA response this month. The Raine study, conducted between 2001 and 2003, divided 2,117 sexually active women, aged 15 to 24, into three groups. One group received free packages of Plan B, another group was told how to get Plan B for free at drugstores and a third group was told how to get Plan B by appointment from a health clinic. A key hypothesis was that, six months later, women in the two groups with the easiest access to EC would have 5 percent pregnancy rates, compared with a 10 percent pregnancy rate expected for women who had to go to a clinic to get Plan B. But the three groups still got pregnant at about the same rate: Eight percent of the women with Plan B at home became pregnant, as did 7.1 percent of women with "pharmacy access" and 8.7 percent of women with "clinic access."</2: 1.2.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<3: 1.2.3>Why approve OTC use of a drug which increases the risk to women's health - abortion?

Nonprescription EC Linked to Rise, Not Drop, in Abortion Rates --Yet Advocates Continue to Push for Over-the-Counter Sales

Newly published figures on the number of abortions taking place in Britain show that the abortion rate has increased despite the availability of so-called "emergency contraception" (or, as critics call it, the "morning after abortion pill") which can be purchased without a prescription. The abortion rate has increased each year since Britain introduced nonprescription EC in Jan. 2001, with 2.1 percent more abortions taking place in England and Wales in 2004 than in 2003. EC is a high dose of contraceptive hormones that can act as an abortifacient if the woman has already conceived. U.S. abortion advocates have claimed that it will reduce the abortion rate by half. However, studies in Scotland and the U.S. (including a study of more than 2,000 young women that was published in the Journal of the American Medical Association this past January) have shown that selling EC over the counter has not reduced pregnancy and abortion rates, even when women are given the drugs in advance and are therefore more likely to use it. In addition, the teen pregnancy rate increased 31 percent in Sweden after nonprescription EC became available there. While abortion advocates have claimed that the rise in abortion rates in

Britain is due to other factors, critics say EC leads people to engage in more risky sexual behavior because they falsely think they are protected from pregnancy, leading to higher rates of unintended pregnancies, abortions, and sexually transmitted diseases. In addition, EC does not abort ectopic pregnancies and therefore women who use it may not realize they are still pregnant, putting their health and lives at risk.

The new figures come as the Food and Drug Administration announced it is delaying a decision on whether it will allow nonprescription EC sales in the U.S, citing a lack of data on the drugs' effect on teens and an inability to enforce regulations limiting nonprescription sales to women over the age of 17. Seven states currently allow nonprescription EC sales. Barr Laboratories, which markets EC under the name "Plan B" says it is planning to urge other states to allow the sales. The Planned Parenthood Federation of America has also said it will file a lawsuit against the FDA if over-the-counter EC sales are not approved. According to memos released as part of a lawsuit filed against Planned Parenthood in California, the organization stands to make considerable profit from over-the-counter sales of EC because of a deal the group struck with Barr allowing them to purchase the EC kits at a price below that of other retailers. Planned Parenthood's price on the EC kits averages below that of the competition, and Planned Parenthood watchdog group STOPP, the organization could make \$100 million or more in profits over the next five years if EC was made available over the counter.</3: 1.2.3>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

No comment

C. If so, would a rulemaking on this issue help dispel that confusion?

No comment

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

No comment.

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.2>Absolutely not.</4: 7.2> <5: 7.5.3>Older teens will buy the pills for younger teens.</5: 7.5.3>

COMMENT NUMBER - 2005N-0345-EC58

2005N-0345-EC58 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Venturella, Vincent

2005N-0345-EC58 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No. </1: 3.2><2: 3.8.4>There is no need to initiate any further rulemaking for codification of the action. It is quite clear in its present form.</2: 3.8.4>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No I believe the FDA's interpretation of the formal act for distinguishing the 2 parts of the issue needs no further clarification,

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>There is no confusion as I read Commissioner Crawford's thinking on the manner that the decision and/or interpretation that needs to be encompassed.</3: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

N/A

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1, 6.3.2>I do not see any deviation from the law(s) available to the FDA under the current FD&C Act that would prevent it from instituting this policy.</4: 6.1, 6.3.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.4.6, 7.5.3>As a practical matter, I do not envision an easy way to do this specifically for Plan B. It might be possible if the OTC portion was transacted in the manner that some exempt narcotics were handled in the periods prior to the 80s, when simple ledgers were kept for limited portions of the sale of exempts during a narrow window of time. However, as was obvious then, the signer was not always the subject end user and there was no proof that the dispensing act was aimed at the correct age group or ultimate patient.</5: 7.4.6, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may

the different products be legally sold in the same package?

<6: 8.2>No.</6: 8.2> <7: 8.6.3>There must be a distinguishing characteristic to provide for a value product. Same packaging would permit (and usually tempt) facile trading or swapping, defeating the original purpose of dual (dispensed) products.</7: 8.6.3>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.1.1>When one cannot be secure in the knowledge that the "Prescription Only" product will be available to only the restricted group.</8: 9.1.1>

GENERAL

GENERAL

<9: 1.2.3>I believe that the product known as Plan B should be for Prescription Use only (if used at all) so that it cannot be available to any consumer under the age of 17. I further believe this is the only rational approach given the data available. The 48-72 hour use limit for effectiveness can, I believe, be adequately handled in those situations that are truly emergency events by access to any of the "24 hour" local facilities that exist in most all communities.</9: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC586

2005N-0345-EC586 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Doran, Gregory

2005N-0345-EC586 - TEXT

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 6.2>No.</1: 6.2> <2: 7.5.3>You would NOT be able to enforce or prevent the illegal usage until the persons are injured by its usage. Let alone even for a 17 year old consumer may not be sufficiently informed of the risks of the drug. The greater fear is anyone using the drug without sufficient knowledge of the risks of the drug including the psychological predisposition (desperation) and postdisposition (negative side affects). Requiring a prescription will require the patient to confront their physician for advice and allow the phisician to properly educate the patient on its safe usage if it is safe for that patient.</2: 7.5.3>

COMMENT NUMBER - 2005N-0345-EC59

2005N-0345-EC59 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Leonard, Ruth Tehila

2005N-0345-EC59 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>I don't quite understand this question, but if you mean should you set a standard whether or not a product with the same active ingredient can be sold on and off the counter simultaneously I think the answer is yes.</1: 3.1><2: 3.3.2, 4.3.4> I can see no reason why an identical product will have to be given by prescription for one person and free for purchase to another. I suggest you allow certain people to carry open prescriptions for products they need regularly for a particular medical condition, but otherwise substances with the same active ingredients in the same doses that you do not deem safe for the entire population should not be sold to one segment over-the-counter and to another as a prescription.</2: 3.3.2, 4.3.4> <3: 1.2>Another issue that seems to loom large is that if you decide to allow this particular drug to function in both over-the-counter and prescription mode, what reason is there to keep regular contraceptive pills - that are a third as powerful as these similar drugs - from being approved for the same sale? I don't understand the logic here.</3: 1.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 7.5.3>I can only tell you from what we see here in Israel - where the morning-after pill is sold over the counter - that there is no way to control who buys it. I work with organizations that council teens and many middle-school and high-school students are saying that they now use the morning-after pill as a contraceptive since they do not need a prescription or parental consent to purchase it. A quick cursory jaunt into chat rooms specific to teen issues in Israel shows this is a rather popular view of the new solution to free sex.</4: 7.5.3> <5: 1.2.3>Many teens panic and take the morning-after pills (there are three you take in a row, I believe) twice or more in one cycle. How will you control this when you sell them over the counter? With a prescription medicine there is at least some control over how often the patient has access to a potentially damaging drug. </5: 1.2.3><6: 7.5.3>I have also been in supermarkets to buy wine and the cashiers have not asked for ID though I am young and could be mistaken for someone under 21. Over-the-counter meds will get even less attention from a teenage cashier.</6: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 7.2, 7.5.3>I don't believe there is an effective way of controlling over-the-counter med sales unless you can control who mans the cash-register. As you know, this is impossible.</7: 7.2, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 7.5.3>Why bother with making one prescription? Will a 13 year old not simply ask her older sister or friend to buy her the pills? If the packaging is the same, wh</8: 7.5.3>

GENERAL

GENERAL

<9: 1.2.3>Giving anyone hormonal treatments without strict medical supervision seems foolhardy and dangerous to me.</9: 1.2.3> <10: 1.3>Especially in light of recent deaths from unsupervised use of RU486 pills.</10: 1.3>

COMMENT NUMBER - 2005N-0345-EC6

2005N-0345-EC6 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Goodman, Evan

2005N-0345-EC6 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

If we assume that Plan B has not been shown to be safe without prescription for children under 17, then the new regulations should be considered. A drug that can be very helpful to women and is only denied based on ideology instead of science should be made available by any truly scientific health organization.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.1, 3.8.3>If we assume that Plan B has not been shown to be safe without prescription for children under 17, then the new regulations should be considered. A drug that can be very helpful to women and is only denied based on ideology instead of science should be made available by any truly scientific health organization.</1: 3.1, 3.8.3>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 3.9.1, 4.2, 7.5.3>I am not aware of confusion within the act; however, I do know that other drugs are over-the-counter and prescription when used in different ways. In doing that, it seems far less easy to regulate a drug that can be bought over the counter by anyone for the prescription use as long as they know what prescription drug it corresponds to.</2: 3.9.1, 4.2, 7.5.3> <3: 6.6.3>By allowing a drug to have an age restriction, if it is truly based on health issues, the drug can be regulated in much the same way as tobacco and alcohol.</3: 6.6.3>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 5.1, 5.3.2>If there is confusion on any issue, wouldn't making a rule to dispel the confusion take it away. I don't believe this question is even worth asking.</4: 5.1, 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.1, 6.6.3>Regulations based on age have existed in this country since its onset. Voting was the first restriction, tobacco and alcohol have legal ages for purchase at stores across the country.</5: 6.1, 6.6.3> <6: 7.4.4>In the same store as a pharmacy, often beer is sold and so are cigarettes. Both of those require the vendor to check ID. Plan B could easily implement this precaution, and if making a box say must check ID on it isn't enough, the barcode could make the register beep to check ID and have the cashier have to push a button if the ID has been checked.</6: 7.4.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 6.6.3>Similar methods to alcohol and tobacco could easily be used to regulate the sale of drugs.</7: 6.6.3> <8: 7.4.6>The box could have obvious differences such as labelling and shape to make sure the cashier realizes that he has to check ID.</8: 7.4.6> <9: 7.4.4>Furthermore, as implemented for alcohol at some cash registers, the register itself could beep to check ID when the barcode is scanned, and the cashier would have to check the ID before pushing a button to ok the sale.</9: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<10: 8.9>I don't understand why it wouldn't be legal, but it may in fact, at present, not be. And, even if it is illegal, the pharmacy could hold different packaging for the same medicine in the back as the over-the-counter version. Again I point to tobacco and alcohol as examples of packaging restricted to younger age groups.</10: 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be

inappropriate to do so?

<11: 8.1, 9.1.1>Prescription and non-prescription Plan B, assuming they are two products for legal purposes, are the same exact drug and do not need different warning labels or precautions. So, it would only be inappropriate to put them in the same package if all warnings were not on the single package and if it did not specify the age restriction for distinguishing purposes.</11: 8.1, 9.1.1>

GENERAL

GENERAL

<12: 1.2.1>Abortion is legal in this country, so not selling Plan B, even if it is put in the category of an abortion drug, because abortion is morally wrong to some people would be poor judgment. This point is especially true considering separation of church and state in addition to the privacy issues brought up by Roe vs. Wade. </12: 1.2.1><13: 6.5.4>Furthermore, the FDA is supposed to approve drugs that are found to be safe and effective. Aspirin, for example, is safe and effective, but only for people over a certain age. It is not safe for young people because it can cause Reye's syndrome, but is still marketed over the counter to all age groups. So, I put it to you, if you want to be hypocritical by limiting one drug that you claim might be dangerous to children and don't limit another known to be dangerous, say so, and give a good reason for it.</13: 6.5.4> <14: 2.1>I honestly think the FDA has made a big mistake in waiting this long, and if you are not in fact doing it for political, moral, or religious reasons, I would like a better explanation.</14: 2.1>

COMMENT NUMBER - 2005N-0345-EC609

2005N-0345-EC609 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Billingsley, Daniel

2005N-0345-EC609 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 6.5.4>I do not believe that products should be offered in OTC as well as prescription because of the confusion this would cause as to use and dose.</1: 6.5.4>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC

drug product?

I do not believe that products should be offered in OTC as well as prescription because of the confusion this would cause as to use and dose.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>I believe there is a lot of confusion.</2: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.2>I don't believe a new rulemaking on confusing rule would help. </3: 5.2><4: 3.3.3>I just believe if a product is safe enough to OTC then a prescription should not be required.</4: 3.3.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.2, 6.5.4>The enforcement would not fall to the FDA, it would fall on the entity selling the product.</5: 6.2, 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.2>The FDA could not enforce this limitation.</6: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.2>What would be the distinction in product? Would this not cause more confusion?</7: 8.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 8.2>I don't believe the two products could be sold or packaged in a single package. </8: 8.2>

COMMENT NUMBER - 2005N-0345-EC61

2005N-0345-EC61 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Card, Alan

2005N-0345-EC61 - TEXT

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No. No further rulemaking is required to allow for simultaneous Rx/OTC marketing, and the sudden question about the matter is doing a grave disservice to the FDA.</1: 3.2><2: 2.1> It appears to be (and, frankly, let us all admit: it is) simply a delaying tactic being employed against the Plan B emergency contraceptive for purely political reasons. The reputation of the FDA as an unbiased arbiter, which bases its decisions solely on scientific has suffered a terrible blow as a result of this deeply misguided policy, and public trust in this institution is too important to be squandered.</2: 2.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No. No further rulemaking is required to allow for simultaneous Rx/OTC marketing, and the sudden question about the matter is doing a grave disservice to the FDA. It appears to be (and, frankly, let us all admit: it is) simply a delaying tactic being employed against the Plan B emergency contraceptive for purely political reasons. The reputation of the FDA as an unbiased arbiter, which bases its decisions solely on scientific has suffered a terrible blow as a result of this deeply misguided policy, and public trust in this institution is too important to be squandered.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2, 4.4.2>No. If there were, it would have come up long before now</3: 4.2, 4.4.2>.<4: 2.1> This supposed question is obviously nothing more than a politically motivated delaying tactic, a rearguard action of partisan politics vs science.</4: 2.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<5: 5.4.3>There is no significant confusion to be dispelled.</5: 5.4.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<6: 6.1, 6.6.3>Of course this plan would be enforceable under law, just as age restrictions on the purchase of tobacco and alcohol are enforceable under law. The legal powers of the FDA are more than broad enough to allow for this.</6: 6.1, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 6.6.3, 7.1, 7.4.2>Absolutely. I would recommend the wholesale borrowing of state statutes regulating tobacco sales as the basis for regulation and enforcement.</7: 6.6.3, 7.1, 7.4.2>

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 8.1>Certainly. There is nothing whatsoever to prevent it.</8: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<9: 9.3>None, provided that the labeling requirements for the OTC product were the same as for the prescription product. We thereby ensure that the consumer is, under all circumstances, guaranteed the most complete data upon which to base his/her decisions with regard to the use of the product.</9: 9.3>

GENERAL

GENERAL

<10: 2.1>I am writing today primarily to express my deep revulsion for the politicization of the drug regulation process I have witnessed with regard to the Plan B emergency contraceptive. Neither the science (in the case of the first delay) nor the law (in the case of the present delay) provide any justification whatsoever for the absolutely singular treatment this drug has received. The only POSSIBLE reason for the continuous obstructions it has faced is that there are policy makers in the FDA who are basing their decisions not upon what is best for the health of the American public, but upon what is best for the political goals of the Republican Party. This subversion of an honored American institution cannot be allowed to continue. The confidence the American people have in the FDA is based on the belief that the agency will make the best decisions it can on the basis of the best scientific data available. It is based on the notion that they can rely upon the FDA to examine that data WITHOUT political, religious, personal or financial bias. It is a matter of trust... and that trust is being betrayed. I implore you, before you do any further damage to the FDA and to the long-term health of the American public (how effective will you be, if no one listens anymore?) to please, please, PLEASE return to making rational policy decisions without regard to politics. </10: 2.1><11: 1.2.1>This should have been, as they say, a 'no brainer.' The drug is safe. It is effective. Its side effects are minimal; many other OTC drugs are more risky than this. Move on this application. Move on it today. And make the right choice to begin rebuilding confidence in the FDA. Thank you.</11: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC610

2005N-0345-EC610 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Koch, Frances

2005N-0345-EC610 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>I think that the FDA should make rules about when a drug can be sold as both prescription and OTC</1: 3.1>. <2: 3.8.4>The current usage - where the molecule/drug is used for different purposes/doses it is either prescription or OTC - seems intelligent enough. </2: 3.8.4><3: 3.1>I think that actually codifying this would be good. </3: 3.1><4: 3.3.3, 7.5.3>Making sure that OTCs are safe enough to be used without the supervision of a physician must continue in the interests of public safety. Studies show that the American population routinely doubles, triples, even quadruples the recommended dosage on OTC medications - particularly pain medications. We have seen some medications go behind the shelf (pseudoephedrine) because of the misuse of the product. In this particular case of Plan B, it would be VERY easy for the product to be misused (18 year old buying it for a distraught 15 year old friend). People typically don't read instructions, they don't read warnings, they don't read about side affects. They just want to pop a pill and make it (pain, congestion, whatever) go away. How many people with high blood pressure will take Sudafed when the packaging says not to? At least with a prescription, they have the chance to speak with their physician. Their physician knows what they are taking, and knows their health history. Any medication that can cause severe reactions should be controlled. </4: 3.3.3, 7.5.3><5: 3.11>And I think that the studies for this should be conducted by someone other than the drug company and that the FDA should consider the results of ALL studies on a drug BEFORE it is approved for OTC status. Lighter doses of prescription medications as OTCs is helpful to the public and the pharmacies. But allowing a prescription to become an OTC must be done with careful, careful consideration, and with the EXPECTATION that the dosages available OTC will be at least doubled by the average consumer.</5: 3.11>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

This is the same as the box above - question and answer). I think that the FDA should make rules about when a drug can be sold as both prescription and OTC. The current usage - where the molecule/drug is used for different purposes/doses it is either prescription or OTC - seems intelligent enough. I think that actually codifying this would be good. Making sure that OTCs are safe enough to be used without the supervision of a physician must continue in the interests of public safety. Studies show that the American population routinely doubles, triples, even quadruples the recommended dosage on OTC medications - particularly pain medications. We have seen some medications go behind the shelf (pseudoephedrine) because of the misuse of the product. In this particular case of Plan B, it would be VERY easy for the product to be misused (18 year old buying it for a distraught 15 year old friend). People typically don't read instructions, they don't read warnings, they don't read about side affects. They just want to pop a pill and make it (pain, congestion, whatever) go away. How many people with high blood pressure will take Sudafed when the packaging says not to? At least with a prescription, they have the chance to speak with their physician. Their physician knows what they are taking, and knows their health history. Any medication that can cause severe reactions should be controlled. And I think that the studies for this should be conducted by someone other than the drug company and that the FDA should consider the results of ALL studies on a drug BEFORE it is approved for OTC status. Lighter doses of prescription medications as OTCs is helpful to the public and the pharmacies. But allowing a prescription to become

an OTC must be done with careful, careful consideration, and with the EXPECTATION that the dosages available OTC will be at least doubled by the average consumer.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<6: 4.1, 4.3.3, 4.3.4>I think that there is some confusion built into the act because it does not directly define when a product/drug/molecule is allowed to become an OTC. And when they are allowed to become both OTC and prescription at different usages or doses, there is still some confusion about safety, use, etc. It gives the average consumer a false sense of security that no matter how much they take, a medication will not hurt them. The studies show that misuse and overmedication are rampant with OTCs. I also think that considering having the same exact medication as a prescription and as an OTC is a misinterpretation of the act.</6: 4.1, 4.3.3, 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

<7: 5.1>I think that a more defined set of rules would help alleviate the confusion.</7: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<8: 6.2, 6.6.3>I do not think that this would be possible. The accessibility of alcohol and cigarettes to minors - despite strict laws on the books - shows that in practice, limitations to subpopulations is not a practical solution. </8: 6.2, 6.6.3><9: 7.5.3>The ability to enforce the law would be basically non-existent, and therefore, the hoped for protections for any subpopulation that would come through requiring a prescription would not, for practical purposes, be in place.</9: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<10: 7.2, 7.5.3>It is ludicrous, insane, irresponsible to think that this would even be practical.</10: 7.2, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<11: 8.2>NO. Again, that is totally irresponsible, insane, ludicrous.</11: 8.2> <12: 8.6.4>If you ever actually went down that path you'd have to have some way to determine the difference in the general population, or you would NEVER be able to enforce the controls.</12: 8.6.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<13: 9.1.2>It would NEVER be appropriate to do so. Under ALL circumstances it should be considered inappropriate to sell them in a single package.</13: 9.1.2>

GENERAL

GENERAL

This did not show up on the next page, so I am also attaching it as a Word file.

<14: 1.2.3>All women MUST have a prescription to get birth control pills. Why would you think that another form of birth control should be any different? This is also a pill that has had a lot of controversy over its safety. It should NEVER be put out as an OTC. </14: 1.2.3><15: 7.5.3>There is no way of enforcing any laws that would keep an older person from giving it to a younger one that required a prescription.</15: 7.5.3> <16: 3.3.3>In addition, it essentially induces an abortion - of sorts. When you see a physician, they know your health history, they can tell you the benefits and the consequences. They can tell you of any potential problems to look for and when to come back or go to the hospital. The typical American does not even read the dosage information on a bottle of ibuprofen. If they hurt they take some, if they hurt a lot, they take a handful. Americans act like every OTC is safe - no matter how they take it or whom (age, weight, medical history, medicines being taken) they give it to. </16: 3.3.3><17: 7.5.3>Putting any medication on the shelf and behind the shelf is a mistake because of the lack of practical and EFFECTIVE enforcement (think alcohol, cigarettes and teenagers). </17: 7.5.3><18: 1.2.3>Putting a medication that could cause serious side effects on the shelf is an even worse choice. I encourage you to treat Plan B the same way you treat ALL OTHER birth control medications and leave it as a prescription for ALL ages. </18: 1.2.3><19: 4.5>And I also encourage you to clarify section 503(b) of the act so that any OTC MUST be a "non-prescription" dose that can be taken at multiple times the recommended dose without harm or has an alternate presentation and use (ex. Benedryl pills or Benedryl in itch cream). And codify the act so that the same dosage of a medication cannot be BOTH prescription and OTC. </19: 4.5><20: 1.2.3>I encourage you to look at ALL of the studies about Plan B usage, the increase in STDs and abortions in populations where it is easily available, and at the potential for harm in the medication when you are trying to decide if it should be made OTC. And do NOT make your judgements based on what other countries are doing. Many other places thought they were going to get one type of behavior with easy access to Plan B, and they got another one entirely. And please remember that women are usually the losers in the STD game, and where abortion or easy fixes for uneducated sex are readily available, the STD rate goes up. You will not be doing the female population any favors by making Plan B an OTC medication.

If you release Plan B as an OTC, you will be doing the American public, particularly the young women of America, a great injustice. </20: 1.2.3>

Thank you for your time and consideration.

Signed,

A hopeful mother of 2 young girls.

COMMENT NUMBER - 2005N-0345-EC623

2005N-0345-EC623 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: DeWitte, Conrad

2005N-0345-EC623 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.3>Yes. It would inform the voting and pharmaceutical consuming public to understand how such decisions are analyzed and made, including the medical purpose for creating at once a controlled and an uncontrolled distribution channel for the same product.</1: 3.1, 3.8.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes. As stated above, it would inform the voting and pharmaceutical consuming public to understand how such decisions are analyzed and made, including the medical purpose for creating at once a controlled and an uncontrolled distribution channel for the same product.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1, 4.3.2>Yes. For the layman and even for the well-informed layman, there appears to be a non-sensical aspect to this aspect of FDA regulations.</2: 4.1, 4.3.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.3.2>Potentially, yes. The rule making language should be developed so as to inform the public and thus strengthen understanding and public support for FDA decisions.</3: 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.6.3>This would seem to be "possible" to make this distinction and a common analogy would be the ability to enforce laws regarding the sale of alcoholic beverages to adults but make those same products illegal for sale to minors.</4: 6.6.3> <5: 7.5.3>But aside from the appearance of this possibility, the record of thousands or millions of violations of laws prohibiting the sale of liquor to minors suggests that in fact such limitations would be ineffective except as "political cover" for craven and unethical governmental administrators.</5: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.5.3>As outlined above, this would seem to be "possible" to make this distinction and a common analogy would be the ability to enforce laws regarding the sale of alcoholic beverages to adults but make

those same products illegal for sale to minors. But aside from the appearance of this possibility, the record of thousands or millions of violations of laws prohibiting the sale of liquor to minors suggests that in fact such limitations would be ineffective except as "political cover" for craven and unethical governmental administrators.</6: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.6.4>If the FDA would seek to undermine public confidence in its purpose and effectiveness then such a plan should be pursued.</7: 8.6.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 1.2, 9.3>It would be inappropriate to sell a highly dangerous drug as an Over The Counter formulation and such would be the case with the "morning after abortion pill." The FDA's interest in product packaging has been historically to ensure or at least further the goal of safety (i.e. tamper resistance, or cleanliness protection, or warning labeling, or reduction of light exposure), but this question seems entirely designed to accommodate a product marketing consideration which suggests a cavalier attitude of FDA administrators with respect to the health safety of American consumers. Consideration of these aspects of this issue argue for aggressive scrutiny and change in the senior administrative personnel at FDA.</8: 1.2, 9.3>

GENERAL

GENERAL

<9: 1.2.3>FDA would abandon its purpose and thus its right to exist (and thereby also its claim for public support) by approving a drug as an OTC product which has the power and purpose of terminating an existing human life (e.g. this is NOT preventative, but would in fact only be used if in fact the existence of pregnancy was known for certain to exist). The formerly, Pure Food and Drug Administration was created entirely to protect intended or potential users of pharmaceutical products.</9: 1.2.3> <10: 3.3.2>Only pharmaceutical products with the potential for minimal health hazard should be offered as Over The Counter formulations.</10: 3.3.2> <11: 1.2.3>In this instance the proposed product poses severe health risks including potential death for the consumer and near certain death for the intended target of the drug. It is by definition lethal or at least potentially lethal. There is zero justification for approving the availability of such a product in the least or essentially completely uncontrolled commercial environment.</11: 1.2.3><12: 7.4.2> It is well known that communities supported by families all over the nation enforce heavy guard over the potential of even common and well understood pharmaceuticals which may be administered or otherwise made available to children or minors. Aspirin is absolutely unavailable to a child under twenty-one years of age in all of our public schools without specific control and approval.</12: 7.4.2><13: 1.2.3> The FDA discards its authority to command any respect for its pronouncements if this powerful and absolutely dangerous drug is approved for uncontrolled distribution (i.e. as an OTC drug) in the face of an entire nation's effort to make pharmaceuticals available only in the most carefully controlled and well advised setting. There is no medical reason, no practical reason and no ethical justification for approval of this proposal to make an abortion drug available Over The Counter.</13: 1.2.3>Conrad J. DeWitte Fullerton, CA

COMMENT NUMBER - 2005N-0345-EC626

2005N-0345-EC626 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Peer, Gerald

2005N-0345-EC626 - TEXT

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.1, 3.8.1>The FDA should clearly define its policy. Its previous position, that a substance cannot be both prescription and OTC for the same indication, is rational and defensible and should be codified.</1: 3.1, 3.8.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2, 4.4.2>Not in the past. Confusion is building due to special interest pressure.</2: 4.2, 4.4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.1>Yes</3: 5.1>.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.6.3>With difficulty. Such a ruling places pharmacists in the same role as alcohol dealers, cigarette sellers and pornography peddlers: limiting exposure of the young to influences that could "corrupt youth."</4: 6.6.3> Why else would an age limit be imposed? And why would FDA want to approve a drug that would "corrupt youth?"

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 6.5.1>Extension of law enforcement by FDA on the general population complicates its mission and enlarges the obtrusive arm of government into private lives.</5: 6.5.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.9>How you package this product makes little difference. Any attempt to sell the same product as OTC and prescription makes a mockery of the prescription process.</6: 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.2.2>None</7: 9.2.2>

GENERAL

GENERAL

<8: 1.2.3>Plan B is a bad idea. It is, by design, a lethal drug. To make this available without prescription cheapens the entire public safety mission of the FDA</8: 1.2.3>.

COMMENT NUMBER - 2005N-0345-EC65

2005N-0345-EC65 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Ray, Amy

2005N-0345-EC65 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes</1: 3.1>, <2: 8.6.2>although it is dangerous to market as both OTC and prescription status due to possible double dosing, overdosing, and lack of appropriate medical guidance regarding diagnosis and treatment.</2: 8.6.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.2>No</3: 6.2>. <4: 7.5.3>The front line for such enforcement is pharmacists and they would not be able to adequately recommend, dispense and monitor subpopulations without significant work environment changes.</4: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2, 7.5.2, 7.5.3>It would not be practical since the paperwork, manpower and danger to the patient being diagnosed improperly or using inappropriate doses would far outweigh the positive nature of easier access to medication</5: 7.2, 7.5.2, 7.5.3>.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2>NO</6: 8.2>! <7: 8.6.2>They should be separate to avoid confusion that could lead to serious overdose, improper usage and lack of control of health professional in recommending and dispensing appropriate medications and doses.</7: 8.6.2>

GENERAL

GENERAL

<8: 1.2.3>Plan B possesses far too much risk of danger to women's health to be listed as OTC status. It is highly irresponsible for any health professional or human being to advocate the use of medication that may so seriously harm an individual without proper diagnosis, physical examination and properly informed patient consent. </8: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC654

2005N-0345-EC654 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Kortebein, Peter

2005N-0345-EC654 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes, if the benefit is clearly defined to those who would benefit from such an interpretation.</1: 3.1>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1, 4.3.4>Yes, when applied to the particular application concerning "Plan B".</2: 4.1, 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.1, 5.3.2>It would help to clear up the issue regarding the controversy over age of the women and why those older than 16 "benefit" from OTC status and those under 16 might be harmed by OTC status.</3: 5.1, 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 7.5.3>Enforcement would obviously be the main issue and should raise the question of the reality of those doctors who would make such drugs available under pressure from parents of minor women who may have conceived a child.</4: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.1, 7.5.3>No, it would not be able to monitor the use of such drugs adequately as a practical matter.</5: 7.1, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1, 8.9>It would not make a difference if the packaging contained language that indicated that two applications existed for the same product.</6: 8.1, 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.3>This question would be resolved by the debate in a rulemaking discussion.</7: 9.3>

GENERAL

GENERAL

<8: 1.2.4>

By all means the product in question should be correctly termed an abortifacient, since it can act to prevent the implantation of a fertilized egg into the uterine wall, and the product labeling should contain such information. This raises the question as to why it was approved in the first place since it is a lethal drug. </8: 1.2.4>

COMMENT NUMBER - 2005N-0345-EC66

2005N-0345-EC66 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Baird, Debora

2005N-0345-EC66 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

Yes

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.1>Yes</1: 3.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes</2: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.1>Yes</3: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1>Yes</4: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.4.1, 7.4.4, 7.4.6>Allow pharacists to card those purchasing the drugs and the purchaser must sign a form stating "met age requirements". </5: 7.4.1, 7.4.4, 7.4.6><6: 7.4.5>Recourse for illegal purchase can be turned over to the local authorities for processeccution</6: 7.4.5>.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.2, 9.1.1>No, different strengths of product, different and separate packaging.</7: 8.2, 9.1.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.1.1>None as long as "Plan B" Morning After pill is sold in a different strength and dosage, they are not the same.</8: 9.1.1>

GENERAL

GENERAL

<9: 1.2.1>PLEASE ALLOW THE OVER THE COUNTER SALES OF PLAN B (MORNING AFTER PILL). THIS WILL REDUCE THE NUMBER OF ABORTIONS AND GIVE WOMEN THE FREEDOM OF CHOICE THEY SHOULD HAVE. </9: 1.2.1>

THANKS!

COMMENT NUMBER - 2005N-0345-EC668

2005N-0345-EC668 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Vrankar, Anna

2005N-0345-EC668 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.3.2>No, if an active ingredient needs the supervision of a physician because of potential side effects, drug interactions, or because there might be physical conditions which would render taking such an ingredient unsafe, it should remain "prescription only"</1: 3.2, 3.3.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

No, see above

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>no</2: 4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.5>only if the rule made it clear that if a prescription is required, it is universally required.</3: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2>NO</4: 6.2>!<5: 6.6.3, 7.5.3> Is the ban on tobacco sales to minors enforceable? Absolutely not.</5: 6.6.3, 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.2>NO</6: 7.2>

GENERAL

GENERAL

<7: 1.2.3>Please protect our children's health! Keep these potentially dangerous prescription drugs available by prescription only</7: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC671

2005N-0345-EC671 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Friedl, Mary Frances

2005N-0345-EC671 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

no, the policy in effect now is adequate

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.2, 3.8.4>No, the policy in effect now is adequate. </1: 3.2, 3.8.4><2: 3.8.8>A change in this policy could result in decreased safety for OTC drugs. It would shift policy definition from the scientific to the political arena.</2: 3.8.8>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>no</3: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 5.2>no</4: 5.2>.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.2, 7.5.3>No, the population under limitation would simply approach the population not under limitation in order to purchase the drug through a third party. The decision of whether or not to give the drug to the subpopulation would be made, not by physicians, but by individual OTC purchasers.</5: 6.2, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 7.2>No.</6: 7.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.2>Under all purposes.</7: 9.1.2>

GENERAL

GENERAL

This is one can of worms that the FDA should not be opening. <8: 3.8.4, 3.8.8>Under the current circumstances, some drugs are OTC and some are not because it is presumed that proper use of prescription drugs requires specialized knowledge that is not available to the general public. Without this knowledge, the public cannot truly give individual and personal consent to the possible consequences of the use of the prescription drug. If these drugs are made OTC, the only source of information available to consumers will be via inadequate package information or through the recommendation of the pharmacist.

Any change in the current policy is going to negatively impact both the safety of the public and the role of pharmacists. Patients will become mere consumers and pharmacists will become amateur physicians. </8: 3.8.4, 3.8.8>

COMMENT NUMBER - 2005N-0345-EC677

2005N-0345-EC677 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Gordon, Jennifer

2005N-0345-EC677 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>If this means that it should change its rules to allow the simultaneous marketing of 'Plan B' as an OTC and prescription drug, than no. See below.</1: 3.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Same as above. See below.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

See below.

C. If so, would a rulemaking on this issue help dispet that confusion?

See below.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.2>Without any real knowledge of law, I believe that a law must be reasonably enforceable to be real

law.</2: 6.2> See below. <3: 6.5.3>Also, with respect to limiting OTC 'Plan B' to women over a certain age, how does this stand legally with the resistance to parental notification laws for minors who wish to obtain abortions? If, as many claim, it is illegal (violation of 'privacy') to require minors to notify parents before obtaining an abortion, and since they don't need a prescription to undergo a major surgical procedure, why should they not be allowed to decide on their own about taking 'emergency contraception?' It seems very contradictory.</3: 6.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.2>Absolutely not. </4: 7.2><5: 6.6.3, 7.5.3>Just as minors easily purchase tobacco, alcohol and other drugs, 'prescription-only' for under 16/17 year old women would be a joke. Not only could minor women get friends and boyfriends to purchase this drug OTC, parents who wish to avoid the hassle and expense of going to the doctor would also purchase the drug for their daughters. </5: 6.6.3, 7.5.3><6: 7.6>Moreover, what would prevent men who are already breaking the law by having relations with minors from using this drug to cover up their crimes? This is already the problem with the striking down of parental notification laws for minors procurring abortions. The men who responsible for these pregnancies are able to pressure their victims into abortions without the parents ever knowing what is happening. This drug would make that abomination even easier.</6: 7.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.2, 8.5.4, 8.9>This question is grammatically confusing. Does it mean that the prescription and the OTC products will be sold together 'in the same package,' or that they will be sold separately in the same packaging? Since the former doesn't make any sense, I assume it's the later, in which case, I think it makes sense to sell them in different packages, so that there is some ability to distinguish between when the drug was procured as a prescription and when it was procured OTC. Since it would be illegal for minors to procure the OTC version of the drug, it seems important to be able to make this distinction.</7: 8.2, 8.5.4, 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

Again, this question indicates that the first interpretation of "in the same package" above was correct. How is it possible to sell a prescription and a non-prescription in a single package?

GENERAL

GENERAL

Above, I answer the questions which have been posed by the FDA. <8: 1.2.4>What I have not stated so far is my objection to selling "Plan B" at all. "Emergency contraception," like the Pill, employees an abortifacient as its secondary effect. And as this "Plan B" is even stronger than the Pill, it would be causing many more early-term abortions.

It seems a gross violation of the FDA's purpose to approve the sale of a drug that is not used to heal or cure anything, but rather to take life. And as studies have already shown, the "Morning After Pill" has not succeeded in reducing the number of unintended pregnancies or abortions. It also provides absolutely no protection against STDs. It's another "safe-sex" fable that will lull even more young women (and men)

into a dangerous mentality of sex without consequences. The FDA, by approving "Plan B" would be exposing women to more risks of health and life, not improving health care for women. Not only would it be immoral to approve the sale of this drug, it would also be pointless, as it has not been shown to have any practical value in the reduction of "unwanted" pregnancies. If there are strong moral reasons NOT to approve the drug and NO practical reasons to approve it, the FDA will be acting both immorally and illogically if it approves the sale of "Plan B." </8: 1.2.4>

COMMENT NUMBER - 2005N-0345-EC678

2005N-0345-EC678 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Socha, Kathleen

2005N-0345-EC678 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

No. <1: 1.2.3>A drug so powerful that it can kill a person shouldn't be sold at all. But if you must, then by prescription only for all ages.</1: 1.2.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

Yes. <2: 3.9.1>I take a drug sold both ways. I buy by prescription because my insurance pays for it that way.</2: 3.9.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>No.</3: 4.2> <4: 4.4.2>I think the problem lies in trying to limit the age to purchase the OTC drug.</4: 4.4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<5: 5.2>Only to you.</5: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<6: 6.2, 6.6.3>You can't even prevent kids from buying cigarettes or alcohol. What are you thinking?</6: 6.2, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 7.2>Not possible.</7: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 8.6.2>It would make it easier for the kids to get the right one.</8: 8.6.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<9: 9.1.1>When the product can kill a person. Adults die from this drug too.</9: 9.1.1>

COMMENT NUMBER - 2005N-0345-EC680

2005N-0345-EC680 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Schulz, Stan

2005N-0345-EC680 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No.</1: 3.2> <2: 3.8.8>This would open the floodgates for evermore trivial excuses to market products which have been judged dangerous enough to require professional oversight -- through a prescription.</2: 3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding

when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No. This would open the floodgates for evermore trivial excuses to market products which have been judged dangerous enough to require professional oversight -- through a prescription.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.5>No confusion regarding present practice; plenty of confusion over what may happen in the future.</3: 4.5>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 5.2>No.</4: 5.2> <5: 5.4.2.2>It would only change a simple "esy/no" issue into a complex one requiring measurements (of age, for instance) or status (married or not), and set the groundwork for requiring additional bureaucratic action (for instance, requiring proof of age)and the possibility of fiviolous lawsuits based on the decision of a drugstore clerk.</5: 5.4.2.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<6: 6.2, 6.5.4>Probably not. It would result in lawsuits challenging the right to restrict sales; challenging the appropriateness of the cutoff age, alleging age discrimination.</6: 6.2, 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 7.2>No.</7: 7.2> <8: 7.5.3>As a practical matter, any young girl could find a friend over the age of 16 who could buy the drug and give it to the youngster. Also, any young MAN over the age of 16 would gladly buy the drug for his underage lover.</8: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<9: 8.1, 8.4.1>Sure. The packaging would make no difference --- it's the person making the purchase who makes the difference.</9: 8.1, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<10: 8.9>There are not "two products". They would be the same with just different locations and sales restrictions.</10: 8.9>

GENERAL

GENERAL

<11: 3.3.2>Any product which has been judged sufficiently dangerous to warrant professional supervision via prescription -- should not be presented to the public without such protection. </11: 3.3.2><12: 7.5.3>It opens the product to many forms of abuse -- purchase of the product by one qualified person for the use of another unqualified person; purchase of multiple packages of the product for over-use "just in case"; purchase of the product with intent to resell it at a profit to an unqualified person, etc. </12: 7.5.3>

COMMENT NUMBER - 2005N-0345-EC691

2005N-0345-EC691 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Carter, Thomas

2005N-0345-EC691 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

I am not sure what the interpretation is. <1: 1.2.1, 1.2.2>I will say that I support OTC status. Short of that, I support a dual OTC/prescription status.</1: 1.2.1, 1.2.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

I am not sure what the difference between "act" and "action" is - may I suggest including some background in "plain english" for those of us who are interested laymen, but not lawyers? Otherwise, see my answer for the first question.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes - I am not even sure what it is!!</2: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.1>It would seem so, although I do not know what the ramifications of such a rulemaking would be.</3: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1>Yes, I believe so.</4: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.1, 7.4.3, 7.4.4>I assume the "subpopulation" would be legal minors, under the age of 16-18. The limitation could be enforced by having undercover "minors" attempt to purchase the product OTC. Such practices are engaged in voluntarily by some retailers, e.g. Wal Mart IDs purchases of spray paint and alertness aids.</5: 7.1, 7.4.3, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1>This question is a little beyond my knowledge, but on the face of it, I believe so.</6: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.1>If it is determined that a special package, i.e. instructions designed to be easily understood and targeted to minors, is needed for the prescription package.</7: 9.1.1>

GENERAL

GENERAL

<8: 1.2.1, 1.2.2>Once again, I believe that per the original recommendation, this drug should have been given OTC status. Short of that, I would support a dual OTC/prescription status. </8: 1.2.1, 1.2.2>

COMMENT NUMBER - 2005N-0345-EC7

2005N-0345-EC7 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Dawson, Jennifer

2005N-0345-EC7 - TEXT

Issue Areas/Comments

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 6.1>Yes, the limitation would be easily enforceable.</1: 6.1> <2: 6.4.1, 6.6.3>Such limitations already exist for medicines like nicotine-replacement therapy, as well as for other controlled substances such as tobacco and alcohol.</2: 6.4.1, 6.6.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.1, 7.4.1, 7.4.4>Pharmacists could be required to check IDs for customers. If pharmacists can be trusted with dispensing addictive and potentially dangerous pharmaceuticals, clearly they can be trusted to check to ensure customers are of legal age.</3: 7.1, 7.4.1, 7.4.4> <4: 6.6.3, 7.4.3, 7.4.5>If there was concern that pharmacists were not carding customers, undercover operations could be used as they are with tobacco and alcohol, and fines could be levied.</4: 6.6.3, 7.4.3, 7.4.5>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.1, 9.1.1>I see no problem with selling prescription and OTC medicines in the same package, so long as their distribution is controlled.</5: 8.1, 9.1.1>

GENERAL

GENERAL

<6: 1.2, 2.1>I hope that the FDA rules promptly on this issue. American women have been waiting too long for emergency contraception, which is clearly safe and effective, to be on drugstore shelves. </6: 1.2, 2.1>

COMMENT NUMBER - 2005N-0345-EC710

2005N-0345-EC710 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Devine, Naomi

2005N-0345-EC710 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC

drug product?

<1: 3.8.8>If the products are identical and for identical uses, all should be regulated.</1: 3.8.8>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1, 4.3.4>Yes, there is confusion. It is hard to understand why a drug should be prescription for some and over the counter for others.</2: 4.1, 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

Perhaps.

2

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.2, 7.5.3>No. In practicality, this type of restriction would be nearly impossible to enforce.</3: 7.2, 7.5.3>

GENERAL

GENERAL

<4: 1.2.3>All other forms of birth control pills are available only by prescription. Why would this one be sold over the counter? It is dangerous and irresponsible of the FDA to allow a drug to be sold over the counter when the Agency has determined that it is unsafe for a large sub-population. Especially in this circumstance, where this sub-population would be highly interested in the drug. If this drug is unsafe for those under 17 -- it should not be sold over the counter at all.</4: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC716

2005N-0345-EC716 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Hager, Joseph R

2005N-0345-EC716 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC

drug product?

<1: 3.2>NO!</1: 3.2> 1. <2: 8.5.4>There is no way to control the dispensing that "medicine" if packaged the same.</2: 8.5.4> 2. <3: 1.2.3>As a parent, I object to a "birth control" drug being made available as an over the counter drug for my daughter under the age of 18 because I am still responsible for her health and safety, and her development, and a birth control drug available to her over the counter would usurp my parental authority</3: 1.2.3>. 3. <4: 7.5.3>Allowing an active medicinal ingredient simultaneously marketed in both a prescription drug and an OTC drug product would leave the use of the drug open to misuse/abuse.</4: 7.5.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No! See above answer.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

Not able to make a knowledgeable response.

C. If so, would a rulemaking on this issue help dispet that confusion?

Unknown.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.5.4>I say that the pharomicist/pharmacy/store is in danger of being prosecuted because they unintentionally/inadvertantly sell an OTC drug to some one who was authorized the drug only by prescription.</5: 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.2>No!</6: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.9>Are you asking a legal question of non-legally trained people?</7: 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 8.9>Without a parent's approval.</8: 8.9>

COMMENT NUMBER - 2005N-0345-EC717

2005N-0345-EC717 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Gorini, Joseph

2005N-0345-EC717 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2>First, please consider whether or not the FDA should be answering this question with regard to Plan B. Plan B should not be considered to fall under the FDA's concern for 'health and safety.' See General Comment.</1: 1.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

First, please consider whether or not the FDA should be answering this question with regard to Plan B. Plan B should not be considered to fall under the FDA's concern for 'health and safety.' See General Comment.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>If the FDA applies section 503(b) it would create confusion by seeming to accept Plan B as falling under FDA's concern for 'health and safety.' See General Comment.</2: 4.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.2>Rule making on this issue with regard to Plan B would confuse the proper understanding of 'health and safety.' Plan B should not be considered to fall under the FDA's concern for 'health and safety.' See General Comment.</3: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a

matter of law?

What is the FDA's experience with other abortifacients?

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.2>No!</4: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

I would hope not!

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<5: 9.1.2>Always.</5: 9.1.2>

GENERAL

GENERAL

<6: 1.2>In and unusual exchange this week in the US Congress, among the highest ranking UN officials admitted that the term "reproductive health" does not include abortion, at least in the context of the recently decided Millennium Summit Declaration. The exchange came during a hearing of the US House Committee on International Relations when Congressman Chris Smith questioned Mark Malloch Brown, senior adviser to UN Secretary General Kofi Annan. Smith asked Brown three times if "reproductive health" included access to abortion. Brown finally admitted that it did not.</6: 1.2>

COMMENT NUMBER - 2005N-0345-EC73

2005N-0345-EC73 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Ricci, Stephen

2005N-0345-EC73 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes</1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

Yes

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes</2: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.1>It is more likely</3: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.7>Not without a means to verify the end-user of the product, as is with a valid RX signed by a licensed practioner for a single patient</4: 6.7>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2>I do not believe it is likely even as a practical matter.</5: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2, 8.8>This is the case with one particular ingredient: Meclizine 25mg tablets are currently either labeled for RX or OTC distribution. The package must be labeled accordingly, as so it cannot be produced by a manufacturer in 'the same package' unless it is one labeled for OTC</6: 8.2, 8.8>

GENERAL

GENERAL

<7: 1.2.3>I as a licesnsed healthcare practioner do not approve of the sale of Plan B as an OTC entity.</7: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC76

2005N-0345-EC76 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Rosati, Lucia

2005N-0345-EC76 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.5>I believe it is acceptable to consider drugs on a case-by-case basis.</1: 3.8.5> <2: 1.2>In the case of Emergency Contraception/Plan B, I can appreciate the concerns about selling to minors.</2: 1.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

I believe that if a drug is considered safe when used appropriately, it should be sold as over-the-counter -- period. <3: 7.4.4>If there are concerns regarding the age of purchasers/users, leave it up to the individual retailer to "proof" the person if they so wish. </3: 7.4.4><4: 1.2.1>I don't see any disadvantage, however, to an individual using Plan B even if they're 15 years old. At least, a pregnancy will not result, which is much worse.</4: 1.2.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<5: 4.1>Yes. </5: 4.1><6: 1.2.1, 2.1>The drug should have been allowed based on its safety -- nothing else. You don't see cigarettes being sold prescription to minors, but over-the-counter to adults. And cigarettes are much worse. The only reason you are hesitating to rule on this drug is because of the religious concerns of certain segments of the population. I believe that that violates the rights of American women who would benefit from its availability.</6: 1.2.1, 2.1>

C. If so, would a rulemaking on this issue help dispel that confusion?

<7: 3.8.5>Maybe so; but again, I think each drug should be considered on a case-by-case basis. In most cases, I don't see why a drug would be safe only for certain people. Either it's safe or it isn't.</7: 3.8.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<8: 6.1>The FDA through the pharmacy chains would be able to enforce it just as they enforce any other prescription medication.</8: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<9: 7.1>How does it normally enforce the sale of prescription drugs? However, the drug would have to merit regulation. </9: 7.1><10: 1.2.1>In the case of Plan B, there's no reason why it cannot be available over-the-counter to any woman seeking it, no matter the age.</10: 1.2.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<11: 8.1, 8.4.1>Certainly. I don't see why packaging would have to change. Only the manner in which it is sold would have to change.</11: 8.1, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<12: 9.2.2>I cannot think of any.</12: 9.2.2>

GENERAL

GENERAL

<13: 1.2.1>I think the time has come to make Plan B contraception available to women over-the-counter. This is a safe drug and would reduce the number of unwanted pregnancies, and therefore, the number of abortions. I urge you to act quickly on this. It has taken long enough and has been found to be safe.</13: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC762

2005N-0345-EC762 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Long, Laura Jean

2005N-0345-EC762 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC

drug product?

<1: 3.2, 3.9.1>The FDA has already approved the use of drugs in both simultaneous prescription form and over the counter form, ie. Claritin. I argue that such allergy drugs are still only used by allergy sufferers, not the entire population, and yet they are available for use by all.</1: 3.2, 3.9.1> <2: 2.1, 3.2>Denying the approval of Plan B as an over the counter drug, especially after being so overwhelmingly approved for such use in clinical recommendations, appears to be a direct (embarrassing) cow-tow to a particularly vocal political minority. No ruling is necessary if the panel on the FDA would take responsibility for their positions as scientists and attempt (and act) as objective voices for the health of the public (rather than the interests of lobbying groups, be they political or pharmaceutical).</2: 2.1, 3.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

This question is the same as the previous question with minor change (act - action, marketed - market). My answer still stands.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>No, there is not significant confusion.</3: 4.2> <4: 1.3, 2.1>Your interpretation of the 503(b) text is just an excuse to delay the approval of a safe drug for the OTC market (where was the need for clarity on 503(b) when truly dangerous drugs like Vioxx and Celebrex were so hastily approved?). In failing to rule objectively you disappoint your public and endanger their health.</4: 1.3, 2.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<5: 5.2, 5.4.2.2>I fear that rulemaking on this issue would only further codify the opinion driven barriers which prevent scientific recommendation from being heeded.</5: 5.2, 5.4.2.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<6: 6.2>No.</6: 6.2> <7: 6.5.4>Limiting the sale of an OTC product to a particular subpopulation (in this case, the "subpopulation" being HALF the population, ie. women) by making it prescription only is tantamount to discrimination.</7: 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<8: 7.2>It would not be able to do so as a practical matter. </8: 7.2>This question presupposes making an OTC drug prescription only is "a practical matter" when the drug is only used by a segment of the population. It may be argued that all drugs are only used by a segment of the population, when they so need them. This question also presupposes that the FDA's job is to regulate drugs for "practical matters". I find this presupposition appalling. <9: 1.2.1>I am challenged as to whether I should lose my faith in the FDA as an objective, regulatory commission with the best interests of the American public at heart. It is impractical to continue to keep a safe drug prescription only, especially when its effectiveness is so

dependent upon a crucial time- window - 72 hours, but the sooner, the better. By continuing to keep Plan B as prescription only, you are patently interfering with the effectiveness of this drug, by making it difficult and time-consuming for the drug to be obtained by those who need it.</9: 1.2.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<10: 8.1>Yes they may legally sold in the same package. </10: 8.1><11: 8.9>In fact, a more useful law would be one preventing pharmaceutical companies from artificially inflating the price of either the OTC or prescription version.</11: 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<12: 9.2.2>I find no circumstances in which it would be inappropriate to do so.</12: 9.2.2>

GENERAL

GENERAL

<13: 1.2.1, 2.1>It is reprehensible that the FDA has delayed the approval of a drug (Plan B) that has been proven safe and highly recommended by clinicians for use over the counter. I dare to hope that the panel will grow a spine and rule on this and all other future drug recommendations from an objective motivation, untainted by politics or profit. In continuing to deny safe drugs, such as Plan B, on the market to those who need them, you are effectively endangering the health of the public.</13: 1.2.1, 2.1>

COMMENT NUMBER - 2005N-0345-EC77

2005N-0345-EC77 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Carlson, Brent

2005N-0345-EC77 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes.</1: 3.1> <2: 1.2.2>Access without a prescription in the 17 year old and above is reasonable and will help prevent unwanted pregnancies.</2: 1.2.2>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.2>No.</3: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1>Yes.</4: 6.1> <5: 7.1, 7.4.1, 7.4.4>You could either require identification at the point-of-sale or require dispensing by a pharmacist (with ID).</5: 7.1, 7.4.1, 7.4.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

See "A".

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2, 8.3.1>The "legend" would have to be modified to read "for patients under 17 years of age".</6: 8.2, 8.3.1>

GENERAL

GENERAL

<7: 1.2.2>This appears to be a compromise that will at least provide easy access to prevention of unwanted pregnancies for women 17 or older until a more effective "treatment" is approved.</7: 1.2.2>

COMMENT NUMBER - 2005N-0345-EC779

2005N-0345-EC779 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Macdonell, Megan

2005N-0345-EC779 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.9.1>There are many medications that have the same active ingredient available in both a generic/OTC method as well as through prescription. With that said I am also unaware of the guidelines by which these decisions are made, however I do not personally see it as a problem. I believe that there should be a "re-wording" of section 503(b).</1: 3.1, 3.9.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.6.3, 7.4.1, 7.4.4>I believe that a controversial product like Planned B should be placed behind the counter (at the register) to control the buyers age of this product. I am from Oregon, and here our legal age to buy cigarettes is 16 years of age. I believe that if this product was kept behind the counters (literally) that this will prevent theft and the ID's of the buyer can be checked before the product can be purchased. If the consumer does not have a Drivers License or and ID with their birthdate on it, then I believe they should need a form of proper identification that includes their date of birth.</2: 6.6.3, 7.4.1, 7.4.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<3: 7.1, 7.3.1.2, 7.4.4>I do not believe that the process I described above is unpractical or difficult to accomplish. I believe that cashiers just need to be trained at looking for proper ID's (which generally they are) as well as the use of discretion while serving these consumers.</3: 7.1, 7.3.1.2, 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.1>I believe that they should be allowed to be sold in the same package.</4: 8.1> <5: 8.3.4>I also believe that perhaps the packages that are sold in stores should have information about the risks of this medication and facts about why this is called emergency contraception, and that it in no circumstance should replace normal contraceptive measures. The subpopulation under 16 who would get it through prescription will have their doctors explain these facts. So I do not believe that it would hurt to have an extra precautionary measure included in the OTC meds.</5: 8.3.4>

GENERAL

GENERAL

<6: 1.2.2>I believe that making the Planned B birth control available without a prescription to women age 16 and older is a progressive measure. I believe that the girls under 16 should seek a health practitioner for this medication so that they can be properly notified about the risks that are involved as well as the term "emergency". I believe this way, perhaps they can get the help they need, while also getting information about how to help their bodies and perhaps receiving another form of protection for the

future.</6: 1.2.2> I also believe that perhaps the packages that are sold in stores should have information about the risks of this medication and facts about why this is called emergency contraception, and that it in no circumstance should replace normal contraceptive measures. The subpopulation under 16 who would get it through prescription will have their doctors explain these facts. So I do not believe that it would hurt to have an extra precautionary measure included in the OTC meds.

COMMENT NUMBER - 2005N-0345-EC788

2005N-0345-EC788 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Philips, Thomas

2005N-0345-EC788 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

Not in the case of Plan B.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.2>No.</1: 3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>Yes.</2: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.2>No.</3: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1>Probably.</4: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.5.3>Very difficultly.</5: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.4.1>This is an absurd question: after some time people will know the way (ex. a friend or relative with the required age of 17 years) how they can buy it OTC and the different package for prescription will be of no use.</6: 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.2>Any.</7: 9.1.2>

GENERAL

GENERAL

<8: 1.2>One of the main arguments for providing an OTC version of Plan B and similar products is a presumed reduction in the number of needed pregnancy terminations of unwanted pregnancies. Similar products have been approved for OTC use in several countries in Europe (Great Britain, Belgium, France,...), many times with this same argument of reducing the absolute number of pregnancy terminations. In september 2000 Norlevo was introduced as an OTC product on the Belgian market. Now on a total population of 10 million persons more than 100.000 units are used each year. The number of pregnancy terminations has increased significantly since then: 14923 in 2000, 16707 in 2003 (an increase of 21%). The number of OAC remained stable in that period and there was a major increase in pregnancy terminations in the 12-20year age group. Recent (unpublished, 2004-2005) numbers indicate an even higher increase. The same trend has been seen in Great Britain.</8: 1.2>

<9: 1.2>Is it possible to publish (or email) the review of scientific studies on wich the Center for Drug Evaluation and Research or CDER, has based its conclusion that the available scientific data are sufficient to support the safe use of Plan B as an over the counter product?

And what fisiologic argument is given to withhold it to women 16 years old and not to women who are 17 years and older?

Are there any large scale studies on the metabolic and cancerogenic long-term effects of these products included in this review?

In recent years there has been seen an increase in early (30-40years age group) and often very aggressive forms of breast cancer: have there been any studies undertaken to link the use of morning-after pills as one of the possible causes? </9: 1.2>

Thanks,

Thomas Philips, MD

COMMENT NUMBER - 2005N-0345-EC793

2005N-0345-EC793 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Kuskey, Garvan

2005N-0345-EC793 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

(See statement below in the comments section

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<1: 4.1>yes</1: 4.1>

2

B. If it could, would it be able to do so as practical matter and, if so, how?

GENERAL

GENERAL

<2: 3.1, 3.10>If 5% testosterone -- a completely benign substance -- must be written on a triplicate prescription, then why not this more dangerous preparation? Or the reverse: if this drug can be marketed without a prescription to those over sixteen years of age, then why can't 5% testosterone be marketed to elderly men who need HRT? The FDA designated low-dose testosterone a dangerous drug specifically because of its abuse by body builders. And yet, body builders don't use 5% preparations. In fact, they can and do easily buy much more concentrated products in Mexico.</2: 3.1, 3.10> <3: 1.3>Because you have listed low-dose testosterone as a controlled substance, this relatively cheap substance is now priced beyond the reach of many senior men: up to \$250 for a one month's supply. I recommend that you promptly de-list it so that those needing this soy-based bioidentical hormone can purchase it over the counter for closer to \$25 for a one month supply. Or does that make too much sense?</3: 1.3>

COMMENT NUMBER - 2005N-0345-EC80

2005N-0345-EC80 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Cahoon, Clifton

2005N-0345-EC80 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>no</1: 3.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

no

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.3.4>That is hard to justify or explain. It is my opinion that medications which are prescription should not therefore have a simultaneous non- prescription status.</2: 4.3.4>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.4.2.2>I think it should continue to stay legend vs non-legend and not allow a ruling which would not only put the particular drug at hand to be confusing but there would be too much leeway to allow multiple drugs be given OTC status.</3: 5.4.2.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 3.8.7, 6.5.4>This is making it too confusing. I think they should not allow this subpopulation seperation legal. It presents too many future regulations, regulatory parties, audits, etc. Yes a drug may make OTC status but the monetary and regulatory burden placed therefore on the public would be enormous. The drug would in essence be able to be free of that burden while then the burden rests on

taxpayers and retail workers to pay for this drugs audits and regulations. Very unwise when the drug is for such a limited population that the burden is then placed on the general public. Let the population for whom the product is designed for seek to carry the burden by seeking a physician visit and prescription given. This is a ridiculous request by a drug maker, it is obvious they will make the money, market the product and then pass the burden of regulation and audit to the taxpayer. Abuse.</4: 3.8.7, 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2, 7.5.2>No, no, no. I have explained my rationale above. They would place the burden on society as a whole for such a small population for whom it serves. It is not practical no matter how much the drug company said they would monitor it, in the end we would end up paying for it as taxpayers. Very inappropriate shuffle of burden.</5: 7.2, 7.5.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2, 9.2.2>Not at all.</6: 8.2, 9.2.2>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

see above

GENERAL

GENERAL

<7: 2.1, 3.8.8>This is a matter that the FDA must continue to monitor and not make a drug manufacturer the controlling party. Do not allow drugs with such specificity as being subpopulation separated to become the burden of all public buyers. The people who seek such specific medications must continue to seek to establish a physician/patient relationship or pharmacist/patient relationship where legal to do so in order to meet criteria. Let only those trained in health care specific to the disease decide the appropriateness of therapy, not allow the general public to make that determination. It is a shift of burden that must be kept with the FDA and regulated by legend drug rules, and not allowed to be made a public responsibility to determine appropriateness of therapy. It only opens a large decentralization of appropriateness of regulation, appropriateness, and cost. </7: 2.1, 3.8.8>

COMMENT NUMBER - 2005N-0345-EC81

2005N-0345-EC81 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Schmierer, Ann

2005N-0345-EC81 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.4, 3.9.1>I think there are a number of drugs available OTC that are similar and used for exactly the same indications as prescription drugs (i.e. Claritin OTC, Prevacid OTC), and there should be no distinction made between the interpretation for these drugs, so why the confusion on Plan B? I believe there is a very distinct political motivation behind this issue being raised. If the product is proven safe and effective by the FDA for OTC, it should be made available to consumers that want it.</1: 3.2, 3.8.4, 3.9.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

No. See above comments. FDA has made their recommendation, so follow it.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.4.2>I think it may be inappropriate for the public to make comments on "FDA's confusion" on the interpretation. I believe there are adequate historical cases and precedence for a number of OTC formulations and similar drugs only available via prescription, all proven safe and effective by the FDA for dispensing to patients and consumers. This is a political position taken by the Commissioner and the office of HHS, and I believe he and the office should stand down and let the FDA do their job.</2: 4.4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.4.3>I am unaware of the definition for the word "dispel" in the English language that is worded in the question, and may be used intentionally to really incite "confusion". If the appropriate word was intended to be "dispel", I believe there are adequate rules within the Federal Register for the FDA to do its job, and do not have a problem with their interpretation of what has been entered into the code of law governing FDA.</3: 5.4.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 1.2.1, 6.5.4>If the FDA has ruled that this product is safe and effective for OTC designation, they should make the product available to customers. Do pharmacies (or the FDA) restrict the sale of condoms or contraceptive jelly to a 5 year old? Should pharmacies (or the FDA) restrict the sale of condoms or other contraceptive items to a 10 year old? At what age is it appropriate to sell OTC contraceptive items...who cares. If they are needed by a specific consumer, they have OTC designation, why should

there be a gender bias against females that want this product? What about girls that are raped by a stranger, their brother, cousins or fathers that would like to have some control over their reproductive system? Give females the control their own decisions on this matter, especially when there is an FDA sanctioned product available that is deemed safe and effective for OTC use.</4: 1.2.1, 6.5.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.4.1, 7.4.4, 7.5.4>If the FDA Commissioner, Secretary of HHS, and the President would like to interfere in this FDA issue, and as a result there are restrictions placed on this product, I think the recent ruling on pseudoephedrine-containing pills being available as OTC, but in limited quantity and behind the counter at a pharmacy can make an example of how to deal with this situation. Make it available in a set limited quantity that can be obtained from a pharmacist by asking at the counter. If there is some age restriction imposed, then have the person produce proof of age, such as an ID card or driver's license to provide that information. I feel that by producing such information is an invasion of privacy as the pharmacist would know the identity and could possibly interfere with a personal matter by obtaining such information for an OTC product. Are there HIPPA restrictions on pharmacy personnel having access to patient information (and interference with a request for an OTC drug) that can guide this train of thought?</5: 7.4.1, 7.4.4, 7.5.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.3.1>Typically, OTC and prescription formulations have different packaging, and I believe it is appropriate to do so if it is deemed necessary to have pertinent health and usage information clearly displayed on the packaging. Typically, prescription packages do not come with detailed use information, e.g. a pill bottle filled at a pharmacy, but pharmacies may provide additional information about the drug by including a drug package insert or sheet. In this particular case you may want to have clearly displayed information ON THE OUTSIDE OF THE PACKAGE on how to use the product (i.e. route of administration, etc.) so there is no confusion for someone that is considering the purchase of the OTC product and whether it is appropriate for them. There should be adequate information available, as for cold remedies, for people on certain medications or or have certain health conditions that it is not recommended for use.</6: 8.3.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.1>See above comments concerning existing health conditions or medication that the person is taking that could jeopardize their health, or interfere with know medications (if that information is know at this time). Examples of an OTC product that have warnings are numerous, such as aspirin not recommended for those with a history of intestinal bleeding or clotting disorders, or cold remedies that can adversely affect asthma sufferers.</7: 9.1.1>

GENERAL

GENERAL

<8: 1.1>I consider the delay in the availability a blatant display of political interference by the FDA commissioner, the commissioner's office, the Secretary of HHS, and the president of the United States. I and many within the US public, believe the integrity of Secretary Leavitt, Commissioner Crawford, and

the organizations they 'lead' are irreparably damaged by caving in to political pressure and presidential mandates. If people do not want to use this product for political or religious reasons, individual women have the right to make that choice. Many states have spoken on the issue and have drafted bills within their legislative bodies to make Plan B available to the consumers in their states. Large bodies of people have spoken through these state legislative actions, and their opinion on the availability of this product quite obvious.

I think it is time for Secretary Leavitt and Commissioner Crawford to stand up and support the scientific evidence provided and reviewed extensively by the FDA, support the lawful process outlined in the Federal Registry that guides FDA, stop interfering with a company's product for political reasons, and make this product available. The longer this drags on and the more delays imposed by the Secretary, Commissioner and President, the more damage you do to instituting a SCIENTIFICALLY-BASED FDA process, damage to commerce by interfering for political gain, discrimination against poor women by denying access to Plan B OTC, discriminate against women that do not have access to adequate healthcare (a doctor's needed prescription and payment of drugs) due to the lack of insurance, and risk the alienation of women of the United States. These delays and obstructions will only damage the reputation of the stated government individuals, and the organizations they are representing. </8: 1.1>

<9: 1.2.1>The law is clearly stated, the FDA has thoroughly reviewed the product's safety and efficacy, so stand down and let this product proceed to consumers that choose to use it. Do not make this an issue of women wealthy enough to travel to states or countries where this product may be freely available in the future, or only those with medical insurance coverage. I believe this is a blatant discriminating act towards poor and uninsured women of the United States. Give these women OTC options that do not require a prescription that they do not have access to or the means to pay for as long as the product is safe and effective. Condoms and contraceptive jellies are not enough--bring this option to the the consumer, and let THEM make the choice. No one would be forcing anyone to use this product, but it should be made available to women that feel this treatment is appropriate and compatible with their health care. </9: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC811

2005N-0345-EC811 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Camron, Kiera

2005N-0345-EC811 - TEXT

GENERAL

The comments below were published in the "Tallahassee Democrat" on September 9, 2005. The author is Kiera Camron, responding to an editorial by Mary Ann Lindley.

<1: 1.2.3>Mary Ann Lindley calls the morning-after pill, or ?emergency contraception? (EC), a ?blessing.? Apparently, her definition of ?blessing? and mine are opposites.

Many descriptions of the various methods of EC call these regimens ?mega-doses? of the chemicals

found in daily birth control pills. (For example, the "Plan B" EC kit's two pills, to be taken 12 hours apart, contain the same amount of levonorgestrel that a birth control pill user would ingest in about 20 days.) It follows, then, that EC users could experience many of the same serious side-effects that birth control pill users can experience (blood clots, strokes, heart attack, tumors, even an increased incidence of sexually transmitted disease) and then some: add inconvenient nausea and vomiting and even the potentially fatal ectopic pregnancy. Women who have historically suffered from a variety of health issues or who smoke are more vulnerable to the dangerous side-effects of EC.

EC is also contraindicated for routine contraceptive use, so it's not safe to use over and over again in the place of other contraceptives. But women's lifestyle choices could be significantly altered if they have some sense of "safety" because they perceive EC to be a "back up." Poor choices and risky behaviors are associated with sexually transmitted disease infection, including HIV, and particularly among people under age 25, where two-thirds of STD infection occurs. Some sexually transmitted diseases are viruses that a woman will carry with her for the rest of her life; some cause dramatic damage to women, including sterility and cervical cancer. EC provides no protection whatsoever against these sexually transmitted diseases.

EC doesn't stop at harming women; it harms the most defenseless among us, newly conceived boys and girls. Although Ms. Lindley claims that EC does not cause very early abortions, the FDA and the Alan Guttmacher Institute say that it can interfere with the implantation of early embryos. Both concur that, among several mechanisms, EC may work by either interfering with an embryo's movement through the fallopian tube toward implantation in the uterus or by changing the lining of the uterus, making it inhospitable to the embryo. That new life is lost to his or her parents, and to the world. What is worse, he or she is lost without anyone's knowledge because EC proponents obscure the truth about this mechanism of the drug. </1: 1.2.3>

<2: 3.1, 3.8.3>Despite all of these risks, proponents are agitating (loudly) for these drugs to be made available over the counter, available without the advice of a medical professional who would provide vital education and assessment of a woman's risk. The well-being of Americans is at stake; it is the FDA's responsibility to ensure the involvement of medical professionals and prevent the over the counter sale of EC.

Planned Parenthood claims that EC will prevent 1.7 million unintended pregnancies and prevent 800,000 abortions each year in the United States, yet studies in the prominent medical journal *The Journal of the American Medical Association* and others in countries where EC has routinely been used for years show no change in pregnancy rates with over the counter availability of EC. So why the stubborn promotion of EC? What agenda could possibly justify the exploitation of American women?

I, for one, am thankful for the FDA taking the time to look more carefully at this dangerous drug. With any luck, they will conclude that over the counter EC is one "blessing" America can do without.</2: 3.1, 3.8.3>

COMMENT NUMBER - 2005N-0345-EC813

2005N-0345-EC813 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Wagner, Patricia

2005N-0345-EC813 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 8.6.2>If an active ingredient is marketed in both prescription and OTC forms the packaging and advertising should be clearly different. Assuming that people with no medical training can differentiate carefully nuanced differences invites an increase in drug induced adverse effects that will eventually lead to a distrust in the pharmaceutical industry by the general population.</1: 8.6.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 3.1, 8.6.2>The FDA should issue an interpretation of section 503(b) that requires that when drugs are simultaneously marketed as both prescription and OTC their packaging and advertising must be so dissimilar that the ordinary customer will identify them as two different products.</2: 3.1, 8.6.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.6.3, 7.5.3>Over the last several decades we have had laws forbidding the purchase of tobacco and alcohol by those under age. It has been very difficult to enforce and is frequently circumvented by simply having an older friend or acquaintance make the purchase. As it has become increasingly common for adult men to seek out minor females as sex partners, how will they be prevented from purchasing OTCs and using coercion to convince their "girlfriends" to use them or even slipping them into their food or drink without their knowledge?</3: 6.6.3, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.5>It would seem to be an invitation for lawsuits against pharmaceutical manufacturers. </4: 8.5>

COMMENT NUMBER - 2005N-0345-EC82

2005N-0345-EC82 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Fogelgren, Katharine

2005N-0345-EC82 - TEXT

Issue Areas/Comments

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 1.2.1, 6.5.4>I am really struggling with your stance on this issue. Why was age 16 years first chosen (by the manufacturer), and then increased by FDA to age 17 years? Upon what cognitive/decision-making abilities (or other) human FEMALE developmental empirical evidence were either age chosen based? In case you folks didn't know, the average age of menarche in the US human female is far, far below age 16 or 17. There are thousands (probably many more) unintended pregnancies annually in US young women aged below 17 years. What about their rights to obtain such an important, life-altering medication? In many states, they have long ago been granted medical decision-making rights to seek reproductive healthcare without parental/guardian consent; apparently there is sufficient evidence to support that even a 12 year old female has the cognitive skills to avail herself of this type of service. Granted, in most clinics there is healthcare provider oversight of the learning process... I am concerned that a large (and very vulnerable) subpopulation who perhaps really is able to comprehend the risks/benefits of such a critically important treatment option is being summarily denied the opportunity to do so with the FDA's age qualification of 17 years. Then again, I can certainly foresee all the products liability, med-mal & various other varieties of attorneys just biding their time to file suit with the first "bad" outcome... No easy answers to this one, I know. </1: 1.2.1, 6.5.4>

COMMENT NUMBER - 2005N-0345-EC827

2005N-0345-EC827 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: O'Hagan, James

2005N-0345-EC827 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding

when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

Yes it should. FDA rules are much more readily available as meaningful information to typical consumers.

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.1>Yes it should.</1: 3.1> <2: 3.8.3>FDA rules are much more readily available as meaningful information to typical consumers. </2: 3.8.3>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1>Information regarding this interpretation is not well understood by the general public today. </3: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 5.1, 5.3.1>A rule making on thi sissue helps significantly because of the clear, concise language which typically accomponies such rulemaking on the FDA site. While other information is also available on the site, a rulemaking is a more formal, dated document which is often used as a starting point by other stakeholders in creating their own communications. </4: 5.1, 5.3.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 1.2.3, 7.5.3>I am not qualified to answer that question, but I do know, firsthand, that there is already active lawbreaking and misrepresentation going on in society with respect to this medicine and that removing it from prescription for even a small subset of the population will have the practical impact of removing it from prescription for everyone. </5: 1.2.3, 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.2>Clearly not.</6: 7.2> <7: 7.5.3>Look at methamphetamines and alcohol as examples! </7: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 7.4.3, 8.5.3>It would be far preferable to have different National drug codes: then pharmacies could program POS systems and pharmacy automation systems to help police the use. </8: 7.4.3, 8.5.3>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be

inappropriate to do so?

<9: 8.6, 8.6.3, 8.6.4>Why do you want to encourage someone with a prescription, likely subsidized by an insurance plan, to begin sharing their medicine with someone else? If it is legal for this drug, how will you communicate that it is illegal for other drugs? </9: 8.6, 8.6.3, 8.6.4>

COMMENT NUMBER - 2005N-0345-EC83

2005N-0345-EC83 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Smith, Rodney

2005N-0345-EC83 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.3.2>No. How can a drug be both, especially when the Rx form is of a HIGHER concentration?</1: 3.2, 3.3.2>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No.</2: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.1>Yes.</3: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.2>No.</4: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may

the different products be legally sold in the same package?

<5: 8.2>No.</5: 8.2>

GENERAL

GENERAL

<6: 1.2.3>How can a drug be both OTC and Rx, especially when the proposed OTC dosage is higher than the Rx dosage?

This drug should not be available to minors. That is reason enough to keep it as an Rx.

What about the pharmacists who might refuse to dispense it? </6: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC839

2005N-0345-EC839 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Jago, Laura

2005N-0345-EC839 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.4>As been the process for a long time, the FDA has a statute that an active ingredient may not be simultaneously marketed in both prescription and OTC drug product. This should stand as is, and not be modified just for this one product. FDA makes these regulations for sound reason and should not be overturned just because a case arises with political interests. I am a pharmacist and what I do is guided by, and I rely on, these statutes. The FDS should stick by its regulations, which have worked so well over time.</1: 3.2, 3.8.4><2: 3.8.8> It would be confusing to have a drug both marketed as prescriptions only and over the counter, especially when there is no difference in the drug or packaging. </2: 3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<3: 3.2, 3.8.4>Again, a single active ingredient should not be marketed both as prescription only and over

the counter. FDA should stick by their policy which has been in place for many years, without prior incident. They should not make an exception or worse, initiate rulemaking to change this. </3: 3.2, 3.8.4>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2>No.</4: 6.2><5: 7.5.2> there would have to be extensive regulations as to its access. many pharmacists are crunched for time as is. see below. </5: 7.5.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<6: 7.5.3>It might prove difficult to determine who is eligible to receive the OTC item versus the Rx item-ie, how can we be sure that the person intending consumption falls over the age of 16 or 17?</6: 7.5.3> <7: 7.4.1>In this case, pharmacists would have to control the sale, maybe including the OTC product behind the counter although still OTC. </7: 7.4.1><8: 7.4.4, 7.5.3>We would have to ask for identification, which may prove difficult if the person does not have a drivers license yet (age 16 or 17 may not have one yet).</8: 7.4.4, 7.5.3> <9: 1.2.3, 6.5.3, 7.6>Another issue is that many pharmacist currently have the option NOT to dispense emergency contraception (the case in Maryland),due to religious beliefs. These pharmacist would also carry this into the process of selling the item OTC. Pharmacists who currently object to dispensing the prescription Plan B would also object to dispensing this item OTC. Taking away that right to object by allowing OTC sale would forfeit the current right to object which has been ruled on, and allowed as long as the Rph refers the patient to another pharmacy who is willing to fill the prescription. Personally, as an Rph with CVS practicing in MD, I was given the opportunity to object to dispensing/filling prescription Plan B, which I enthusiastically took. Allowing this product to go OTC would obliterate this right of mine to refuse to dispense, since I object to its use in those over the age of 17 as well. </9: 1.2.3, 6.5.3, 7.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<10: 8.2>no.</10: 8.2>

GENERAL

GENERAL

<11: 1.2.3>Allowing this product to be available OTC, even to a limited population (ie, those over age 17) would be horrific. Having this product OTC would promote unsafe sexual activity overall, increasing the cases of sexually transmitted diseases. When a child/adolescent knows that there is a quick, easy and widely available way to "repair" their situation, they will not take the precautions that they will without this method being so widely available. There is already significant morbidity and mortality associated with STDs. We as a nation are fighting hard and spending billions of dollars on a cure for AIDS, and this move from Rx to OTC will only make the AIDS epidemic worse. When there are no repercussions for actions, they will engage in these actions-when a patient knows there is a product over the counter to prevent pregnancy right after she engages in unprotected sex, she will. Having this product available OTC will only increase unsafe behavior, and decrease personal responsibility for ones actions (unsafe sex).

Yes, studies that have shown evidence to the contrary, but they have been short term in nature, with only a few months to a year in follow up and not powered sufficiently. People will see they do not have to take the full responsibility for their actions, and will be less careful with sex knowing there is a security blanket. This means those who use the product will use it repeatedly, which is not its intended use. Over time having this product available OTC will inevitably lead to increased (unlabeled) use, misconduct and unsafe sexual practices increasing sexually transmitted disease and morbidity and mortality. </11: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC85

2005N-0345-EC85 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Oyola, Sandra

2005N-0345-EC85 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1, 3.8.1>Yes. This would clarify the regulations for any future products that may be sold either as prescription or OTC.</1: 3.1, 3.8.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

Yes, same comment as above.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>I do not feel there is.</2: 4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.3.2>Yes, because consumers and manufacturers will have a better understanding of the regulations.</3: 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product

available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2>I do not believe so. I do not agree with limiting sales to a subpopulation.</4: 6.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.6, 8.7>This could be very confusing to consumers and even health professionals. For example, Zantac OTC is clearly marked as being OTC, yet it has the same ingredient as the prescription product. This information is included on the packaging. It could also affect insurance coverage/reimbursement.</5: 8.6, 8.7>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 8.9>Persons of other countries who buy the product here in the U.S. It may be illegal in their country to obtain the medication without a prescription, or, the regulations of their country may require separate and distinct packaging.</6: 8.9>

GENERAL

GENERAL

<7: 1.2.2>I certainly hope the FDA does not succumb to the will of the religious right in this country. If a product is deemed safe, and can help people, it should be allowed to be sold to a consumer. Moral beliefs should not be the deciding factor whether or not medications can be sold over the counter. Perhaps in the near future, pharmacists can privately counsel patients on the proper use of Plan B when a purchase is made. Although Plan B is not a substitute for birth control, it can help reduce the number of unwanted pregnancies in this country, and help women retain their reproductive rights. </7: 1.2.2>

COMMENT NUMBER - 2005N-0345-EC860

2005N-0345-EC860 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Oberst, Sara

2005N-0345-EC860 - TEXT

Issue Areas/Comments

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product

available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 6.1>Yes, the FDA should be able to sanction pharmacists or pharmacies that are not in compliance.</1: 6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<2: 7.1, 7.4.3, 7.4.5>It should be able to take complaints and/or perform random visits to pharmacies. Any found to be acting illegally should be warned with an ultimate penalty of a fine and/or suspension of license.</2: 7.1, 7.4.3, 7.4.5>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<3: 8.1, 8.3.1, 8.3.4>Yes, as long as the appropriate warning is on the outside of the package.</3: 8.1, 8.3.1, 8.3.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<4: 9.1.1>If the drug caused a severe reaction in one subgroup of the population. By severe I mean death or permanent damage to one's health.</4: 9.1.1>

GENERAL

GENERAL

<5: 1.2.1>Everyone agrees that unplanned pregnancy is a problem in this country. This includes teens, women who've been raped and those whose contraceptive methods fail. As a matter of public health, it is imperative that women have the ability to easily access emergency contraception. By providing this option the number of abortions performed in the US, which has remained steady at about 1.5 million for 15+ years, would decrease; there would be less women and children living in poverty; and rape victims would more easily recover from their assaults. In the case of EC the FDA MUST listen to the scientific evidence. Any other decision would greatly diminish the integrity of the association. </5: 1.2.1>

<6: 1.2.1, 6.6.3>Although I believe that all subgroups should have access to OTC EC, any improvement over the status quo would be welcomed. Perhaps few prescription drugs are treated in this manner, but there are many other examples of assigning age restrictions on substances. Of course with tobacco, for instance, some adolescents under the age of 18 will end up purchasing a pack of cigarettes, but this is a small minority. And because no woman truly wants to use EC it is unlikely that any age restrictions would be broken.</6: 1.2.1, 6.6.3>

COMMENT NUMBER - 2005N-0345-EC870

2005N-0345-EC870 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Vander Bleek, Luke

2005N-0345-EC870 - TEXT

Issue Areas/Comments

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.2>NO</1: 3.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No</2: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.2>NO</3: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 7.3.1.1>If FDA were able to allow these products for sale only in establishments already under FDA jurisdiction e.g. pharmacies, medical clinics, enforcement would seem plausible. However, if FDA allowed the marketing of this class of products by retailers not currently bound by FDA regulation, e.g. mass marketers, enforcement would be tenuous.</4: 7.3.1.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.3.2>Practicality would be dependent on the structure of the business entity allowed to offer these items for sale.</5: 7.3.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 3.8.8, 8.6.4>A prescription product would assume the patient has had the benefit of a medical examination and consultation of a willing physician and pharmacist.

An OTC product which could be acquired in a self service environment would necessarily carry the responsibility to inform the patient of proper use, mechanism of action, and the dangers of not submitting

themselves to routine medical examinations to detect diseases. In the case of emergency contraceptive marketing, and despite the most comprehensive labeling, I believe that many young sexually active women will not recognize the value of routine gynecologic exams. These women will likely never submit themselves to routine gynecologic exams and public health will suffer.</6: 3.8.8, 8.6.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.2.1>Two products could be packaged in a single package technique, only when a substantial review of the impact of marketing the product over the counter would reveal that all other public health issues would either improve or remain unchanged.</7: 9.2.1>

GENERAL

GENERAL

<8: 1.2.3>Over the counter status of any drug should require research to assure that public health will be improved or at a minimum, not jeopardized by the OTC status. In my experience as a community pharmacist, many women submit themselves to a gynecologic exam only when necessary to receive a contraceptive prescription. Since many diseases and other health conditions are discovered and consequently treated pursuant to routine exams, I believe public health will suffer from the otc status of emergency contraceptives, regardless of age requirements. </8: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC882

2005N-0345-EC882 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Vander Bleek, Peter

2005N-0345-EC882 - TEXT

GENERAL

See attachment

2005N-0345-EC882-Attach-1.DOC

ATTACHMENT:

To whom it may concern:

<1: 1.2.3>I am a concerned citizen. Allow me to preface my comments with the following information from the web site of Barr Labs, the manufacturer of Plan B(R).

www.go2planb.com/ForConsumers/AboutPlanB/HowItWorks.aspx

"Plan B(R) is approved by the FDA and contains the hormone levonorgestrel, the same hormone in the birth control pills that healthcare professionals have been prescribing for more than 35 years. The

difference is that Plan B(R) contains a larger dose of levonorgestrel than the amount found in a single birth control pill."

As are you, I am certain that this is an over-simplification of the issue. I ask you, would Barr Labs tell prospective customers that an anticoagulant, Warfarin, which they also happen to sell, is safe because it is only rat poison-the only difference being the dosage level? Certainly not, but Barr leaves this bit of information out of its Warfarin literature. I infer that it would be too dangerous to Barr Labs for its consumers and prospective consumers to realize one important thing about pharmacology: that the effects of a drug therapy are often as dependent on the dosage level of a drug as they are on the drug itself.

In the above consumer information, Barr states that Plan B(R) simply "...contains a larger dose of levonorgestrel than the amount found in a single birth control pill." In my opinion, Barr Labs and its marketing team are attempting to capitalize on the public's lack of awareness of the importance of dosage.

In fact, the action of the drug is very much different from a "birth control pill." Note Barr's clever use of information from its web site:

Plan B(R) works like a regular birth control pill. It prevents pregnancy mainly by stopping the release of an egg from the ovary, and may also prevent the fertilization of an egg (the uniting of sperm with the egg). Plan B(R) may also work by preventing it from attaching to the uterus (womb). It is important to know that Plan B(R) will not affect a fertilized egg already attached to the uterus; it will not affect an existing pregnancy.

It is important to note that the antecedent of "it" (highlighted in the third sentence) appears to be "egg." "It," however, refers to a fertilized egg. This information was very cleverly worded by Barr to do nothing but mislead the public. Whether one knows that life begins when a sperm meets an egg, or argues that it begins at some other arbitrary point, it is clear that Plan B(R) does not work "like a regular birth control pill," as stated by its manufacturer. </1: 1.2.3>

<2: 3.8.8>It is a certainty that the general public's understanding of the intricacies of how drugs act on the body varies a great deal-from very little to expert. Not many of us have had advanced training in the study of pharmacology or have a working knowledge of advanced chemistry. For this reason, I believe that the average prospective consumer of this drug is vulnerable to this company's aforementioned sales propaganda. I am certain that OTC approval of Plan B(R) would be tantamount to unleashing Barr Labs and its "misinformation sales machine" on an unaware public.

At this time, the public is safeguarded by the knowledge, training and consultation of its doctors and pharmacists. If Plan B(R) were to reach the OTC shelves, these safeguards will have been sacrificed-in my opinion a risk to public health. </2: 3.8.8>

<3: 1.2.3>Please continue to take Barr Labs and their comments about Plan B(R) with the proverbial "grain of salt." As you can see in the literature they present to the public, Barr is not above sacrificing important information about their product as a means to an end: expanded sales of a product that is very much different from traditional contraceptives. Based on Barr's current conduct, there is no indication that FDA approval of Plan B(R) for OTC sales will spur their corporate philosophy-and consequently the information they offer consumers-to change. In such a case, I predict an even more blatant campaign of misinformation.

Being men and women of Science-and being charged with the awesome responsibility to safeguard public health-it is incumbent upon you at the FDA to weigh the risks of this drug's effects on the general public. I am certain that an OTC version of Plan B(R) will tout itself-as has its prescription counterpart-as a

"regular birth control pill." This false information is a risk that our public simply cannot afford.

Based on these concerns, I urge the FDA to deny Plan B entry into the OTC market.</3: 1.2.3>

Respectfully,

Peter M. Vander Bleek

COMMENT NUMBER - 2005N-0345-EC895

2005N-0345-EC895 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Holden, Karen

2005N-0345-EC895 - TEXT

Issue Areas/Comments

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.1, 3.8.3>If a there is evidence that a prescription drug poses a particular risk to a particular subgroup of the population, then the FDA may impose added restrictions for that group, including marketing the drug simultaneously as OTC and prescription. However, the definition of risk should encompass only safety or efficacy of the particular medication, and should be based on accepted evidence. Any other basis or concern used to deny access to medication to a particular subgroup is beyond the legitimate interest of the FDA.</1: 3.1, 3.8.3>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.3.4>The confusion arises from FDA's seeming to ignore the advise of its professional staff and instead to bow to political pressures from the religious right.</2: 4.3.4>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.5>Only if the rulemaking were based on legitimate concerns about the SAFETY and EFFICACY of a particular medication in a particular subgroup. Rulemakings done for the sole purpose of social engineering at the behest of religious concerns is insidious and likely unconstitutional. It would increase confusion over the role of the FDA, and lead to lawsuits.</3: 5.5>

COMMENT NUMBER - 2005N-0345-EC896

2005N-0345-EC896 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Guy, Katie

2005N-0345-EC896 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 7.5.3>If a drug has a limitation for one group of individuals and not another, being simultaneously sold as a prescription and an OTC drug will open the door for those individuals the FDA has put the limit on to easily obtain the drug illegally through a relative or friend and putting them in danger. I strongly oppose this action.</1: 7.5.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 7.5.3>This would be extremely hard to enforce by law. Any GIRL 16 years or younger can easily have a friend or relative purchase the drug OTC for them. If, as a result of this act, the child fell ill the FDA would be responsible.</2: 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<3: 8.5.4>This action would add even further confusion to the scenario. Having them sold in the same package would make it virtually impossible to determine if the minor child had obtained the drug lawfully, through a prescription.</3: 8.5.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<4: 9.1.1>In the circumstance of the drug Plan B it would be unequivocally inappropriate to do so!!</4: 9.1.1>

GENERAL

GENERAL

<5: 1.2.3>I am adamantly opposed to the sale of 'Plan B' over the counter to anyone of any age. Your letter refers numerous times to females 16 years old and younger as 'women', I would like to emphasize that these are children, girls, not women. At the very most they are young ladies or young women. One should be careful in his choices of words. 'Plan B' is a drug that can have serious consequences to anyone taking it. This drug should always be taken under the care of a doctor if it remains legal. Hopefully, one day soon, society will shift towards the view that drugs that cause abortions and end perfectly healthy pregnancies should be made illegal. But until then this drug needs to be strictly regulated. Liberalizing it's use will only harm women, not help them. </5: 1.2.3>

COMMENT NUMBER - 2005N-0345-EC9

2005N-0345-EC9 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Corder, Traci

2005N-0345-EC9 - TEXT

Issue Areas/Comments

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<1: 6.5.4>I feel it is unlawful to with hold certain medications to a subpopulations. They are either safe or they aren't safe. There is no biochemical difference in this subpopulation.</1: 6.5.4>

COMMENT NUMBER - 2005N-0345-EC90

2005N-0345-EC90 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Townsend, Elisha

2005N-0345-EC90 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding

when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.1>With respect, I believe the FDA has created this situation with its previous decision which denied over the counter access of EC because it felt that there were not enough studies proving the drug was safe for those 16 and under. To approve the current application, would create a situation where a completely safe drug has been denied to a section of the population. I can see issues of discrimination arising. However that is not a reason to deny access to those who are 17 and older. My suggestion would be to revisit the previous ruling and fully approve access. Short of that you must change your interpretation to allow for the discrimination you have already set in place.</1: 1.2.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

Yes. It could also allow the FDA to review a previous ruling when it creates this type of situation.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.5>There are other drugs that have age limits such as tobacco and alcohol. However both of those have proven negative side effects, and are not also prescription.</2: 4.5>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.5>I'm not so sure. We are trying to change the rules so that our discrimination against young women seems o.k. They are able to consent to their own reproductive healthcare, and thus should be able to purchase this over the counter medication. If you start bending the rules, it opens up the flood gates as you pointed out in your letter. Of course this contradicts my previous statements, but this whole situation is contradictory.</3: 5.5>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.1>They could, but they should not.</4: 6.1>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.2, 8.6.3>If you are planning on enforcing the legality of who can have it, you must have different packaging and the pills should look different as well.</5: 8.2, 8.6.3>

GENERAL

GENERAL

What a pickle you have made. Just deny the whole thing so the public can really see where the FDA loyalties lie. After all, you must know that many consider this pill to be an abortifacient.

COMMENT NUMBER - 2005N-0345-EC903

2005N-0345-EC903 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Kopp, Margaret

2005N-0345-EC903 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2, 3.8.8>No. The FDA is so thoroughly biased and under the influence of politics that any rule that it makes at this time will be in the interest of politics, and not in the interest of good medicine, nor in the interest of the public sector.</1: 3.2, 3.8.8>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

This comment section appears to be identical to the one above it, except that there is a grammar error in this one. They are both identified as the "1. A." comment, with very similar wording.

"A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?"

and

"A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?"

Please note that in the second "1. A." comment, in the following passage "when an active ingredient can be simultaneously market in both a prescription drug product...", the appropriate verb should be "marketed", not "market".

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2, 4.4.2>No. It is very clear that the FDA is making the interpretation that is preferred by White House, without regard to actual safety and efficacy of the drug in question. I am not at all confused. I am, however, deeply offended by the actions of the FDA, in hijacking this drug as part of a political agenda.</2: 4.2, 4.4.2>

C. If so, would a rulemaking on this issue help dispel that confusion?

If you are sensing confusion, it is probably due to the spelling errors on your website where comments can be submitted. To help clear up the confusion, let me suggest to you that "dispel" is spelled d-i-s-p-e-l, NOT d-i-s-p-e-t.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 7.5.3>No. The subpopulation in question would simply find a person who meets the preferred criteria to obtain the OTC product for them.</3: 7.5.3>

B. If it could, would it be able to do so as practical matter and, if so, how?

Yes. A simple solution to this problem would be to require a prescription for young women age 16 and under. They will then get an older friend to buy the drug for them, and everyone will be happy, sort of. Young women are used to having their rights trampled, so they will not realize the extent to which they have been denied their rights until they are much older.

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.3.1>It depends on whether the written patient instructions accompanying the package could be made clear and un-ambiguous under those circumstances.</4: 8.3.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<5: 9.1.1>If there were patient instructions that would apply to prescription use that do not apply to OTC use, and this could not be made clear in the patient instructions, then it would be inappropriate to sell the item in the same packaging.</5: 9.1.1>

GENERAL

GENERAL

<6: 8.9>Many OTC drugs are sold with clearly labelled instructions "under age two, ask your doctor", or "under age 12 ask your doctor". I see no reason why this OTC drug could not be labelled in a similar

fashion. </6: 8.9>

<7: 1.2.1>We should consider whether the prescription requirement for this drug should be removed entirely. If it can be safely sold without a prescription, then clearly IT CAN SAFELY BE SOLD WITHOUT A PRESCRIPTION.

Removing the prescription requirement for the drug would eliminate what appears to be a major source of confusion.</7: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC91

2005N-0345-EC91 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Hawkins, Susan

2005N-0345-EC91 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No</1: 3.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>I do not believe so.</2: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<3: 6.2, 7.5.3>I don't see how it's possible. You talk of selling only to women. Yes, women will be the

ones taking the drug, but a man may purchase the drug for his partner. You cannot know whether his partner is 17+ or not.</3: 6.2, 7.5.3>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<4: 8.5, 8.9>Yes, they can but to have any possibility of regulation you would probably need to have different packaging. This brings up an issue of the possibility of a pharmacy running out of one type (Rx vs. non) and not being able to sell the one they do have in its place. It can make inventory an issue. Additionally you have pharmacists who refuse to dispense drugs of this nature to anyone.</4: 8.5, 8.9>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

see comment above.

GENERAL

GENERAL

<5: 1.2.1>It's either safe or it isn't. It's been approved for Rx and appears to be safe enough to be OTC. I don't think age should be a consideration here. This is not going to encourage promiscuity, but it may prevent some unwanted/unnecessary pregnancies and the difficult decision/action of having an abortion. This is a drug that is available in other parts of the world without this quandry. I'm not really certain what our issue is. </5: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC921

2005N-0345-EC921 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Aengst, Jennifer

2005N-0345-EC921 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 6.5.1>The FDA should determine that product can be both sold as a prescription and OTC. Even though neither the FDA nor the pharmacies are able to regulate whether the consumer is within the age

category that the drug is available for, the FDA's responsibility in this case is just to make recommendations not necessarily to enforce them. The individual consumer still has rights.</1: 6.5.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<2: 3.1, 3.8.1>Yes, the FDA should codify its interpretation of this act, so that it can address the numerous cases of drugs ingredients that are present in both prescriptions and OTC sales.</2: 3.1, 3.8.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.1>Yes.</3: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<4: 5.1, 5.3.2>Yes it would but rulemaking needs to be flexible enough so that it can accomodate particular states...certain states are more progressive than others, in terms of letting consumers determine whether they can have access to medicine, that remains controversial in other states.</4: 5.1, 5.3.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.2, 6.5.4>No I think that's an inappropriate use of the FDA's power. Targetting a particular subpopulation is discriminatory...either the medicine is available OTC to everyone or it's not. It's questionable that the FDA would want to determine which population can have access or not. Either it is available or not...education and warnings can certainly be there, recommendations are appreciated, but if something is going to be available OTC, that means that the FDA has to let go of any sort of control of who buys it.</5: 6.2, 6.5.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

I'm not sure about that...

COMMENT NUMBER - 2005N-0345-EC93

2005N-0345-EC93 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Burns, Ben

2005N-0345-EC93 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.3.3, 3.9.1>i dont see a problem with it, they already partially do it with naproxen, by having lower doses in the over the counter drug aleve. it would allow cunsumers who could purchas it, as well as allow organizations like planned parenthood, who could prescribe it to low income falmilies.</1: 3.3.3, 3.9.1>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1>yes there is a lot of confusion over it.</2: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.1>it probably would.</3: 5.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.5.4>it would acually be a kind of age descrimination. if the younger kids want it, because they are having sex, wouldn't we want them to use it instead of them geting pregnant, and possily having more burdens on the social services than there is now.</4: 6.5.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.6.2>no, it would cause confusion.</5: 8.6.2>

GENERAL

GENERAL

<6: 1.2.1>i think that if the morning after pill was available to women otc, there would be a lot of demand for it, because people do some dumb things at times, like when they are drunk. also, say they are using condoms to begin with, and it rips, this would be a product that would give them piece of mind knowing, ok, i can still take this, and i wont get pregnant. they wont have to have all the worry and stress until they

find out, ok, im not, or oh god, i am. </6: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC94

2005N-0345-EC94 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Wurtz, Richard

2005N-0345-EC94 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>YES</1: 3.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

YES

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>NO</2: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 4.2>NO</3: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<4: 6.2>NO</4: 6.2>

B. If it could, would it be able to do so as practical matter and, if so, how?

<5: 7.2>NO</5: 7.2>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.1>YES</6: 8.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<7: 9.1.1>WHEN THERE IS AN AGE LIMITATION. THE SOURCE OF THE DRUG AS PRESCRIPTION OR OTC IS THUS SKEWED AND PHARMACIES COULD VOUCH THAT THEY SOLD IT PRESCRIPTION RATHER THAN AN OTC PURCHASE.</7: 9.1.1>

GENERAL

GENERAL

<8: 1.2.3>THE PARTICULAR DRUG IN QUESTION I.E. PLAN B SHOULD NOT BE SOLD OVER THE COUNTER. THE MISUSE OF THIS DRUG AND ITS FORCEFUL USE IN MINORS WILL BE WIDESPREAD. AS WITH TOBACCO AND ALCOHOL THE ABUSERS OF THIS DRUG WILL PRIMARILY BE MINORS. THIS IS AN ABSOLUTELY RIDICULOUS PROPOSAL AND SHOULD BE CONDEMNED. AS A PRIMARY CARE PHYSICIAN WHO WITNESSES THE MISUSE OF OVER THE COUNTER DRUGS ON A DAILY BASIS, NOT TO MENTION THE MISUSE OF PRESCRIPTION HORMONES, THE IDEA OF PLAN B GOING OTC IS FRIGHTENING. THIS REGULATORY COMMITTEE SHOULD BAN THE OTC SALE OF PLAN B AS A PUBLIC HEALTH DISASTER COULD ENSUE WITH ITS RELEASE. </8: 1.2.3>RICHARD P. WURTZ MD

COMMENT NUMBER - 2005N-0345-EC940

2005N-0345-EC940 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Mock, Suzanne

2005N-0345-EC940 - TEXT

Issue Areas/Comments

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<1: 3.8.3>This should be spelled out very clearly for practitioners and pharmacists, alike, so they cannot misunderstand the language. Selling this product as both a prescription product and an OTC product should not be much different from what is happening now with physician/pharmacist agreements regarding many medications.</1: 3.8.3>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<2: 6.1>I believe this could occur.</2: 6.1> <3: 7.4.1>Pharmacists are law-abiding citizens like most other people of this country. Handing out PlanB like candy is not ethical or lawful and most pharmacists would not be willing to do this. Enforcing this law would not be an issue for this medication.</3: 7.4.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.4.6>This could occur, as well. Already, pharmacists are allowed to dispense this medication with a previous written consent from a licensed physician and later receive a written prescription. A questionnaire for the patient wishing to receive this medication would not be impractical for a pharmacist to go through with the patient.</4: 7.4.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.6.4>The same active ingredients that are sold both over-the-counter and by prescription, such as ibuprofen, do not have the same packaging. It would be best for both legal and reasonable practices to be sold under different packaging. This would make it easier for the pharmacist to differentiate between the two products.</5: 8.6.4>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<6: 8.6.4, 9.1.2>I think having the same packaging for the medication would make the pharmacists' job more difficult. I don't believe that it would be appropriate under any circumstances for this product to be dispensed in the same packaging.</6: 8.6.4, 9.1.2>

COMMENT NUMBER - 2005N-0345-EC95

2005N-0345-EC95 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Trubow, Marshall

2005N-0345-EC95 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes</1: 3.1>, <2: 1.2.1>me thinks you'r making a mountain out of a molehill with this roundabout issue on whether to allow Plan B to be OTC. The FDA's subcommittee previously recommended placing Plan B on the OTC list, only to have the political process intervene. There appear to be many interested parties in this debate, but in reality it comes down to the prolife vs abortion rights advocates, and it is clear that science is the loser when these issues become politized as this one has. If women's health were truly the issue, the data would say this is a "no brainer". It's safety has been shown, and if we really want to avoid having our patient's chose between an abortion or an unwanted pregnancy, then Plan B should be available OTC. The packaging is not the same as the already approved prescription items, and should not preclude this from being available</2: 1.2.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

<3: 3.1, 3.9.1>Yes-you have already done this. You can obtain Ibuprofen as an OTC 200 mg tablet, but it is also available as a prescription in 600 and 800 mg doses.</3: 3.1, 3.9.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<4: 4.1>Yes</4: 4.1>

C. If so, would a rulemaking on this issue help dispet that confusion?

<5: 5.2>Doubtful. We don't need more rules- we need some basic common sense to prevail, and have the politicians stay out of this.</5: 5.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<6: 6.7>Would it really need to? </6: 6.7>

COMMENT NUMBER - 2005N-0345-EC951

2005N-0345-EC951 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Brass, Kathryn

2005N-0345-EC951 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.2>No.</1: 3.2> <2: 2.1, 3.8.4>The FDA's interpretation of this rule has, up until this decision, been consistent for many years; care needs to be taken that political pressures are not entered into the interpretation, but the rule itself is straightforward.</2: 2.1, 3.8.4> <3: 1.2.1>Furthermore, the unnecessary process of codifying new rules will only prolong Plan B coming to market as an over-the-counter medication.</3: 1.2.1> <4: 3.9.1>There are numerous examples of discretionary drugs (nicotine, alcohol) that are marketed to/available only to subpopulations; they provide more than enough precedent to move forward with the ruling without codifying it. </4: 3.9.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<5: 4.4.2>The only confusion resulting from the FDA's interpretation of this section of the act stems from the FDA's deviation from precedent established by our scientific understanding of drug effects on women of reproductive age.</5: 4.4.2> <6: 1.2, 4.5>In every previous ruling, the FDA has considered women of reproductive age as one group when looking at the safety and efficacy of a product. The arbitrary separation here into 'adolescent' women and 'adult' women is unsupported by the scientific literature, particularly in light of studies which find no differences in the frequency or risk of unprotected sex in young women provided emergency contraception in advance. On the contrary, these teens are more likely to use emergency contraception with unprotected coitus, and to use it earlier after the event, making it more effective. In addition, no decreases have been seen in consistent condom use in the teens that had unrestricted access to emergency contraception. Furthermore, studies in both the US and the UK indicate that teens are not more likely to use emergency contraception as a regular birth control method, nor are they more likely to engage in risky sexual behavior as a result of improved access to the drug. </6: 1.2, 4.5>

<7: 1.2, 10>1. Raine T, Harper C, Leon K, Darney P. Emergency contraception: advance provision in a young, high-risk clinic population. *Obstet Gynecol.* 2000;96:177.

2. Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *J Pediatr Adolesc Gynecol.* 2004;17:87-96

3. Glasier A, Baird D. The effects of self-administering emergency contraception. *N Engl J Med.* 1998;339:174

4. Ellertson C, Ambardekar S, Hedley A, Coyaji K, Trussell J, Blanchard K. Emergency contraception: randomized comparison of advance provision and information only. *Obstet Gynecol.* 2001;98:570-575

5. Jackson RA, Bimla Schwartz E, Freedman L, Darney P. Advance supply of emergency contraception. Effect on use and usual contraception? a randomized trial. *Obstet Gynecol.* 2003;102:87-16

6. Belzer M, Yoshida E, Tejirian T, Tucker D, Chung K, Sanchez K. Advanced supply of emergency contraception for adolescent mothers increased utilization without reducing condom or primary

contraception use. J Adolesc Health. 2003;32:122?123

7. Blanchard K, Bungay H, Furedi A, Sanders L. Evaluation of an emergency contraception advance provision service. Contraception. 2003;67:343?348

8. Cicely Marston, Howard Meltzer, Azeem Majeed. Impact on contraceptive practice of making emergency hormonal contraception available over the counter in Great Britain: repeated cross sectional surveys. BMJ, doi:10.1136/bmj.38519.440266.8F (published 11 July 2005) </7: 1.2, 10>

C. If so, would a rulemaking on this issue help dispel that confusion?

<8: 5.2, 5.4.1>Rulemaking on this issue is unlikely to help dispel the confusion mentioned above, as the confusion stems largely from the FDA's arbitrarily redefining the population of reproductive-age women, and moving away from precedent, not from an incomprehensible or ill-defined law. </8: 5.2, 5.4.1>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<9: 6.1, 6.6.3>As mentioned above, such limitations on alcohol and tobacco are widespread and enforceable. </9: 6.1, 6.6.3><10: 6.6.1>State and Federal bodies alike have engaged in enforcing laws such as the one the FDA proposes, and it would not be outside the legal powers of the FDA to both impose and enforce this law. </10: 6.6.1>

B. If it could, would it be able to do so as practical matter and, if so, how?

<11: 7.4.5>As a practical matter of enforcement, a fines system could be set up to punish those who violate the distribution laws that result from this ruling.</11: 7.4.5> <12: 7.4.4>Requiring photo ID from consumers for sale of such products would be an obvious first step.</12: 7.4.4> <13: 6.6.1>Precedent for this in the pharmaceutical industry already exists in many states ? the sale of over-the-counter pseudoephedrine is now often restricted to those over 18 and requires showing a photo ID.</13: 6.6.1> <14: 7.4.3>Periodic ?stings? with underage-looking consumers (similar to those performed in bars and convenience stores) would provide sufficient deterrent for selling to ?minors.?</14: 7.4.3> <15: 7.5.4>While the issue of older friends and acquaintances buying the products for minors remains, this is a challenge for practical enforcement of any law that subdivides a population into those who can and cannot purchase certain products. </15: 7.5.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<16: 8.1, 8.4.1, 9.1.1>One might conclude that the two products should not be sold in the same package in order to differentiate those purchased with a prescription and those purchased over the counter. However, the likelihood that a young teen will be caught standing on the street corner with her non-prescription-style package of emergency contraception is low, and the idea is absurd. There is no logical reason for these two products to be packaged differently, as the dosage and usage are exactly the same. </16: 8.1, 8.4.1, 9.1.1><17: 3.9.1, 8.8>Claritin is currently offered over the counter, but some patients continue to obtain prescriptions in order to purchase it at a reduced price with a co-pay, and these packages do not differ.</17: 3.9.1, 8.8> <18: 8.4.1>In fact, separate packaging might encourage consumers to think (erroneously) that the two are different or should be used differently. </18: 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

N/A

GENERAL

GENERAL

<19: 1.2.1, 2.1>This latest delay in bringing Plan B to the over-the-counter market is absurd and flies in the face of scientific evidence-based medicine. The previous decision on Plan B was made with complete disregard for the wealth of literature regarding how Plan B might be used. This current decision on Plan B has made a regulatory mountain out of a molehill in an attempt to impose new rulemaking and delay the advent of Plan B as an OTC drug even further, despite its proven safety and efficacy.

The entire purpose of the Food and Drug Administration is to serve as the unbiased evaluator of drugs and devices ? to mediate and mitigate the influences of all parties who might want to take advantage of the consumer for their own gain, or who might unwittingly impose significant risks on any given patient population. In the current climate, the FDA cannot afford to continue to lose the public trust by politicizing this issue. Already the public is wary of the FDA?s commitment to their health, and indefinite foot-dragging on the issue of emergency contraception does not do the FDA?s public image any favors.

As a medical professional in training, I am ashamed that such obvious political interference should have a place at the FDA. The governmental agency designed to protect the American public with regard to what they put in their bodies should be above such games. By proxy, health care providers, too, will bear the brunt of patients? mistrust in the FDA ? we must prescribe medications ?approved? by the FDA, and patients will wonder how confident we can really be about those drugs.

Move forward on the Plan B application, and dispense with the politics. The resignation of Susan Wood is evidence enough that something is drastically wrong at the FDA, and the public needs reassurance that the agency will put science over politics, public interest over political agenda. Plan B belongs on drug store shelves where it can be utilized to reduce the number of unintended pregnancies in the US, a number that far exceeds any other country in the developed world. As a physician in training, I implore the FDA to reconsider this ruling and move forward on the Barr application. </19: 1.2.1, 2.1>

COMMENT NUMBER - 2005N-0345-EC96

2005N-0345-EC96 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Etter, Eleanor

2005N-0345-EC96 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 1.2.2>The real question is whether Plan B is safe and effective for over-the-counter use by women over the age of 16. FDA's own scientists determined that to be the case before the first delay. Consequently, the FDA should approve such use immediately. Then, if the FDA would like to initiate a rulemaking to codify its interpretation of section 503(b) and if that is the most important way for the FDA to spend its resources right now, it should do so. Any other course of action would unnecessarily subject women who would choose to use Plan B to higher expenses and more inconvenience. And, not insignificantly, it would undermine the trust of the majority of Americans in the FDA.</1: 1.2.2>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

<2: 1.2.2>It's already clear that at least in the case of Plan B, that it should be allowed.</2: 1.2.2>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<3: 4.5>I would think people are wondering whether the FDA still adheres to its policy of basing decisions on science as opposed to ideology. When the FDA's scientists recommend one course of action and the agency acts against that recommendation, the public's trust of the agency is understandably undermined.</3: 4.5>

C. If so, would a rulemaking on this issue help dispel that confusion?

<4: 2.1, 5.2>No. Using "rulemaking" to delay approval would not help.</4: 2.1, 5.2>.

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.6.3>Assuming making a product available to a subpopulation is legal, the enforcement would be fairly straightforward. And, certainly there are currently drugs available that are for use by adults only. The marketing of those drugs does not seem to cause a problem. Currently, almost all pharmacies sell products which only a subpopulation can purchase (eg, tobacco products) and they do it very effectively. Also, alcohol is currently available to adults only and it is effectively sold to only a subpopulation with far less supervision than there would be in a drug store.</5: 6.6.3>

B. If it could, would it be able to do so as a practical matter and, if so, how?

<6: 7.4.4>Similar to alcohol sales: If the customer appears to be below a certain age (perhaps 26 to give a 10 year margin), they would be required to show proper photo ID. Alcohol sales are controlled fairly effectively in such a manner and without the oversight of a pharmacy. If this works for alcohol, a

substance which can cause death in the use in sufficient amounts and is subject to abuse, then the marketing of Plan B, which young people would get no special abuse pleasure from, could be handled in the same fashion.</6: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<7: 8.1, 8.4.1>Of course. Doing otherwise would cause unnecessary expense to women.</7: 8.1, 8.4.1>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.2.2, 9.3>None. Although, it would be unethical to charge more for Plan B dispensed by prescription rather than over-the-counter.</8: 9.2.2, 9.3>

GENERAL

GENERAL

<9: 1.2.1>Choosing to end an unplanned pregnancy is surely one of the most difficult decisions a woman ever has to make. Unfortunately, every day many women are forced to make that decision. Easy and low cost access to Plan B will help spare hundreds or perhaps thousands of women that awful dilemma and further reduce the incidence of abortion in our country. Further delay in its approval not only causes women unnecessary expense and inconvenience but serves to increase health risks for them if they choose to end an unintended pregnancy with an abortion. Choose science over ideology - release the stranglehold on Plan B and approve its over-the-counter use now.</9: 1.2.1>

COMMENT NUMBER - 2005N-0345-EC97

2005N-0345-EC97 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Brakman, Anita

2005N-0345-EC97 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 2.1>While I fear the rulemaking process is just another delay tactic regarding the approval of Plan B,

if this will help women access this important medication, than the process should begin as soon as possible.</1: 2.1>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously market in both a prescription drug product and an OTC drug product?

No. The ruling only has to take into account the case at hand, and not all future drugs. Additionally, if and when studies show Plan B safe and effective for women under 16, the medication should become available to them as well.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.2>No.</2: 4.2>

C. If so, would a rulemaking on this issue help dispet that confusion?

<3: 5.2>No</3: 5.2>. <4: 5.4.2>There is no confusion, only politically motivated delay.</4: 5.4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.1>Yes.</5: 6.1> <6: 7.4.4>Such age limitations are already in place for purchasing cigarettes and alcohol. Similar age limits exist for everything from renting a car to voting.</6: 7.4.4>

B. If it could, would it be able to do so as practical matter and, if so, how?

<7: 7.4.4>This could be simply enforced by asking consumers for proof of age and identification. </7: 7.4.4>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<8: 8.6.2, 8.6.3>It is advisable to use different packaging to help ease enforcement and prevent mistakes in distribution.</8: 8.6.2, 8.6.3>

GENERAL

GENERAL

<9: 1.2.1>Dear Commissioner Crawford, I am deeply disappointed that the decision on whether to make Plan B, emergency contraception, available in pharmacies has once again been delayed. As the FDA's own panel has decided that this medication is safe and effective, I can only conclude that this delay is politically motivated, and not tied to any real concerns over women's health. I called my Senator and

asked her to block your confirmation until you agreed to decide this matter, and I was pleased at the earlier announcement that a decision was forthcoming on September 1st. I took this to mean that you would finally make a decision, and hopefully one based on the FDA's own recommendations. Today Secretary Leavitt took the opportunity to mince words, saying that only "action" was promised, and that a delay is such an "action." Additionally, while I believe this medication should be available to all women, including those under 17, it is ridiculous to me that any question comes up over how to ensure Plan B is distributed only to those who are of legal age. I have bought cigarettes in pharmacies in the past, and never found it to be a confusing or difficult process to enforce the age limit by producing identification. To me, this is just another empty line of reasoning.

Emergency contraception is a safe, effective medication that could prevent unintended pregnancies and abortions in this country, yet it is being kept from women under the guise of concern for their own safety. This is a medication that is more effective the sooner it is taken, and getting a prescription is a major barrier to this process. Most women do not even have a primary care physician, and most physicians wait times for appointments are up to a week. Even women who use hotlines like 1-800-NOT-2-LATE have experienced difficulty when they have prescriptions called in when pharmacists then refuse to honor them.

I can see this delay only as an effort to police women's sexuality, and pander to abortion opponents in the radical right. Don't you agree that we should all try to prevent unintended pregnancy in the first place?

Please make your decision soon. Please decide based on evidence for safety and efficacy, and please stop making excuses and delays. </9: 1.2.1>

Sincerely,

Anita Brakman
712 Sackett St
Apt 1F
Brooklyn, NY 11217

<10: 10>Croxatto, H.B. et al., 2004. Pituitary-ovarian function following the standard levonorgestrel emergency contraceptive dose or a single 0.75-mg dose given on the days preceding ovulation. *Contraception* 70(2004): 442-450.</10: 10>

<11: 10>De Santis, M. et al., 2005. Failure of the emergency contraceptive levonorgestrel and the risk of adverse effects in pregnancy and on fetal development: an observational cohort study. *Fertility and Sterility* 84(2), August 2005.</11: 10>

2005N-0345-EC97-Attach-1.PDF 2005N-0345-EC97-Attach-2.PDF 2005N-0345-EC97-Attach-1.PDF 2005N-0345-EC97-Attach-2.PDF 2005N-0345-EC97-Attach-1.PDF 2005N-0345-EC97-Attach-2.PDF 2005N-0345-EC97-Attach-1.PDF 2005N-0345-EC97-Attach-2.PDF 2005N-0345-EC97-Attach-1.PDF 2005N-0345-EC97-Attach-2.PDF 2005N-0345-EC97-Attach-1.PDF 2005N-0345-EC97-Attach-2.PDF 2005N-0345-EC97-Attach-1.PDF 2005N-0345-EC97-Attach-2.PDF

COMMENT NUMBER - 2005N-0345-EC98

2005N-0345-EC98 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Keys, Lori

2005N-0345-EC98 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the action regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.8.4, 3.9.1>As a pharmacist and public health practitioner, I do not see where the confusion lies. According to information available at 21CFR Part 310 for Docket 2005N-0345, the current interpretation of the Act includes a differentiation between OTC and Rx drugs by indication (among other things, including strength, dosage form, and route of administration). The meaningful difference in the case of Plan B is that the OTC product is indicated for adults; the Rx product is indicated for patients 16 years of age and under. To me, that is the same as saying that meclizine is safe for use for motion sickness OTC but requires supervision for use for vertigo. Plan B is safe for use by adults but requires supervision when used in minors. The fact that the dose is the same for each population is immaterial. These are clearly different populations, thus justifying an OTC and Rx label.

</1: 3.8.4, 3.9.1>

1.

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<2: 4.1, 4.3.4>Apparently, there is confusion since the FDA chose not approve Plan B for OTC use for adults.</2: 4.1, 4.3.4>

C. If so, would a rulemaking on this issue help dispel that confusion?

<3: 5.3.2>Only if it codifies that intended population is a meaningful clinical difference that can be used to distinguish OTC and Rx status of a drug.</3: 5.3.2>

2

B. If it could, would it be able to do so as practical matter and, if so, how?

<4: 7.4.1, 7.4.4, 7.4.6>Pharmacies could be required to keep Plan B behind the counter. Women 17 years of age and older could approach the pharmacist for access to the drug. The pharmacist could check ID, create a permanent record of the transaction (similar to recording an oral prescription from a physician onto paper), and file the information with other pharmacy records. The only difference would be that no prescription would be required for adult patients. If the FDA wanted to monitor compliance, there would be a paper trail for every sale of Plan B.</4: 7.4.1, 7.4.4, 7.4.6>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<5: 8.1, 8.3.1>Yes, the standard warning that states that it is a violation of Federal Law to sell the item without a prescription could be modified to indicate the distinction between the two populations.</5: 8.1, 8.3.1>

GENERAL

GENERAL

<6: 3.8.2>Pharmacists are well-educated, competent healthcare professionals and there is no reason to believe that having a pharmacist control access to Plan B (allowing sale without a prescription for women 17 years of age and older, while requiring a prescription for younger women) would not work to protect the public's health. </6: 3.8.2><7: 6.6.3> If alcohol and cigarettes can be sold in this country based on age restrictions, then there is no valid reason to prohibit the OTC sale of Plan B to adult women.</7: 6.6.3> <8: 2.1>The stonewalling by the FDA needs to stop. As a woman and as a pharmacist, I am offended by the delay tactics surrounding a drug that actually prevents abortions, and has been used safely and effectively by thousands of women worldwide for many years. </8: 2.1>

COMMENT NUMBER - 2005N-0345-EC99

2005N-0345-EC99 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products

Commenter Organization Name: Stockton, Melissa

2005N-0345-EC99 - TEXT

Issue Areas/Comments

1

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both prescription drug product and an OTC drug product?

<1: 3.1>Yes.</1: 3.1> <2: 3.8.3>More emphasis needs to be placed on one's ability to make and be responsible for decisions regarding their own health. People usually become more mature with age and may not use an OTC wisely when younger. One should be able to make an informed decision with information contained or distributed with the medicine.</2: 3.8.3>

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC

drug product?

<3: 3.1>yes.</3: 3.1>

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

<4: 4.2>No.</4: 4.2>

2

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

<5: 6.7>I feel there should only be a limit if the product would become dangerous after (x) number of doses.</5: 6.7>

3

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

<6: 8.2>No</6: 8.2>,<7: 8.6.3> to discourage buying and redistributing, they should be in different packages.</7: 8.6.3>

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

<8: 9.1.2>I feel the best case scenario would be to have the packages differ. It would simply cause the fewest problems. </8: 9.1.2>

COMMENT NUMBER - 2005N-0345-EMC166

2005N-0345-EMC166 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Dalton, Mike

2005N-0345-EMC166 - TEXT

From: mike.dalton@nokia.com
Sent: Friday, September 16, 2005 1:35 AM
To: Dockets, FDA
Subject: 2005N-0345

<1: 3.2, 3.8.8>1. Should the FDA create and define a regulation to allow for a drug to be available both with a prescription and without?

No. I believe in practice it would be ineffective and easily circumvented. </1: 3.2, 3.8.8>

<2: 6.6.3>2. Does the FDA have the authority or ability to enforce restricting a drug from a subpopulation when it would be available to the larger population?

Two examples of this are alcohol and tobacco. The laws around restricting the sale of these two drugs are largely failing, so I would say the FDA has little ability to enforce this as a regulation.</2: 6.6.3>

<3: 1.2.3>3. Can a drug that is approved both with a prescription for some and without a prescription for others have the same packaging, or would it require different warning labels and instructions?

That is a minor point in a very serious discussion that, in my opinion, sets the tone for how our society views relationships and responsibility. The message this drug sends to our youth about the sanctity of life is extremely disheartening. The results I have seen from Europe make it quite clear we are a stronger country without this on store shelves where our school age children will essentially have easy access through their older friends or siblings. We need to make the decision that protects our youth, and giving this drug to them doesn't do that. </3: 1.2.3>

Thank you,
Mike Dalton

COMMENT NUMBER - 2005N-0345-EMC355

2005N-0345-EMC355 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Temple, Jennie

2005N-0345-EMC355 - TEXT

From: no-reply@erulemaking.net
Sent: Sunday, October 30, 2005 10:44 AM
To: Dockets, FDA
Subject: Public Submission

Please Do Not Reply This Email.

Public Comments on Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product:

Title: Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product FR Document
Number: 05-17390 Legacy Document ID:
RIN:
Publish Date: 09/01/2005 00:00:00
Submitter Info:

First Name: Jennie
Last Name: Temple
Category: Consumer Group - B0001
Organization Name:

Comment Info:

General Comment: Food and Drug Administration
Docket No. 2005N-0345

Response to Advanced Notice of Proposed Rulemaking

<1: 3.1, 3.3.1>The current definition of a prescription drug is found in the Federal Food, Drug, and Cosmetic Act. Prescription drugs, as explained in the act, are withheld from public consumption and regulated due to the implications that misuse of said drug might have. Failing to expressly define an over the counter drug can be viewed as an inherent flaw of the act, because making assumptions, like the understood definition of an over the counter drug, can be dangerous. Due to the language of section 503(b), the FDA is facing a dilemma of whether or not to initiate a rulemaking to possibly permit the sale of a substance both over the counter and by prescription. The FDA should definitely begin a rulemaking process to clearly define the circumstances under which identical drugs can be sold in different arenas.</1: 3.1, 3.3.1>

<2: 3.8.1, 3.8.3, 5.1, 5.3.2>The FDA should initiate the rulemaking process to determine whether or not a single substance can be marketed simultaneously as both a prescription drug and an over the counter one. Carrying out the rulemaking process for such a decision would not only clarify the provisions of the act, but it will also establish clear guidelines for drug vendors and manufacturers to follow when introducing a new product. The rulemaking process, by soliciting comments, would allow the decision to be based on public opinion rather than simply the will of the drug and pharmaceutical companies mentioned above. Initiating a rulemaking for this issue is necessary, because the language of the current rule does not expressly mention the conditions under which a substance can be simultaneously manufactured in two different markets.</2: 3.8.1, 3.8.3, 5.1, 5.3.2>

<3: 7.4.1>Requiring that the drug be only available by prescription to a particular subpopulation is a practical way to ensure a drug's safe usage and administration. Using age as a criterion is typically socially acceptable, as is the case with tobacco products, and the application and enforcement of such a law could be easily carried out. For example, a law requiring that recipients of the Plan B contraceptive if under the age of seventeen obtain a prescription could be easily enforced by placing the burden on the pharmacists themselves. The drug could be kept behind the counter, like many over the counter drugs commonly are, and all someone would have to do to obtain the drug is ask the pharmacists for it. </3: 7.4.1> <4: 7.4.4>A simple identification check, like ones done with tobacco products, would ensure that the recipient of the drug was the proper age to not need a prescription. Women under the age of seventeen would then only be able to receive the drug under the supervision of a licensed practitioner with little extra effort in the way of enforcement.</4: 7.4.4>

<5: 8.1, 8.4.1, 9.2.1, 9.3>If the potency and active ingredient are identical for both the over the counter and the prescription versions, then it is perfectly acceptable, if not essential, to market them in the same packaging. The fact that age stipulations are placed on the avenues through which a person can obtain the drug should have no effect on the final product that is received. The same drug, packaging included, should be available equally to all women regardless of the method used to obtain it. If the packaging were changed for the over the counter version, then there would be speculation that the drug is in some

way different from the one only available by prescription. It would be inappropriate, however, to market the same drug in identical packaging but the charge a considerably higher price for one version than is being charged for the other. For example, inflating the price of the prescription version of a drug would unfairly restrict its use by the subpopulation that is already required to pay for a doctor's visit in order to receive a prescription. On the other hand, it would be inappropriate to ask a considerably higher price for the over the counter version because it would deter women from choosing that avenue; instead, they would simply get a prescription and pay the lower price. Both versions of a drug, prescription and over the counter should be marketed in identical packages; however, with similar products and packaging should come a similar price as well. </5: 8.1, 8.4.1, 9.2.1, 9.3>

<6: 4.1, 7.4.4, 8.1>Initiating the rulemaking process to revise and clarify the Federal Food, Drug, and Cosmetic Act would be a beneficial move for the FDA. There is considerable confusion regarding the interpretation of whether a drug has to be only sold in one venue, or whether it is possible for circumstances to exist where marketing the drug as both over the counter and prescription is the most practical approach. Imposing age restrictions on the purchase drugs, such as Plan B, is the easiest way to ensure that the drug is safely administered. Requiring identification verification from women purchasing the drug over the counter limits underage sales, and shifts the burden of enforcement from the FDA and doctors to the pharmacist themselves. The packaging of both versions should be identical, as should the price of the drug. All of these topics should be addressed by the FDA by initiating a rulemaking to specifically clarify interpretation of section 503(b), and to establish specific guidelines when a drug can be simultaneously marketed as prescription and over the counter. </6: 4.1, 7.4.4, 8.1>

COMMENT NUMBER - 2005N-0345-EMC368

2005N-0345-EMC368 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Syed, Misbah

2005N-0345-EMC368 - TEXT

From: no-reply@erulemaking.net
Sent: Sunday, October 30, 2005 5:15 PM
To: Dockets, FDA
Subject: Public Submission

Please Do Not Reply This Email.

Public Comments on Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product:=====

Title: Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product FR Document
Number: 05-17390 Legacy Document ID:
RIN:
Publish Date: 09/01/2005 00:00:00

Submitter Info:

First Name: Misbah

Last Name: Syed

Category:

Organization Name:

Comment Info: =====

General Comment:To the Food and Drug Administration (FDA) in reference to Docket No. 2005N-0345, a dual approval is needed for both prescription and over-the-counter pharmaceuticals on the basis of circumstances under which an active ingredient maybe simultaneously marketed. <1: 3.1, 3.3.3, 3.9.1, 4.1, 5.1>My comment to this advance notice of proposed rulemaking is that the FDA should consider that in certain circumstances, a drug should be marketed both as prescription and over-the-counter. I will address this concern by answering the following questions provided by the Food and Drug Administration, to clarify that yes, a drug can be marketed for both prescription and over-the-counter use. I will also provide arguments for what position the FDA use in rulemaking and what the FDA should incorporate in any proposed rule.

The FDA should initiate a rulemaking code to clarify the interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug and over-the-counter drug form because this section only uses the Federal standard classifying drugs as either prescription or over-the-counter. It also defines what a prescription drug is, "a drug intended for use by man which because of its toxicity or other potential harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug?". This section does not define over-the-counter drugs. It explains that whatever drug does not meet the standards to make it a prescription drug, is classified as over-the-counter. This section only classifies a drug to be prescription or over-the-counter, but in certain circumstances, the FDA has interpreted certain drugs with the same active ingredients to be marketed as both prescription and over-the-counter. For example Meclizine, which is a prescription for vertigo, but for over-the-counter purposes? It handles nausea with motion sickness. Also Nicotine products like inhalers and nasal sprays, which are prescription drugs, but gums and patches are considered over-the-counter. It brings significant confusion regarding the FDA's interpretation of section 503(b) because other products like Plan B which is a morning-after pill is also over-the-counter, but to women 17 and older, otherwise it would be a prescription to those women younger than 17. The section clearly does not define rules about age limits and the agency has not figured out how to prevent younger teenagers from gaining access to the pill. It would then be necessary for the FDA to propose a rulemaking solution for this issue to help dispel the confusion.</1: 3.1, 3.3.3, 3.9.1, 4.1, 5.1>

<2: 6.1>If the FDA did limit the sale of an over-the-counter product to a particular population by making the product available to the people in prescription form only, the FDA would be able to enforce such a limitation because they can set standards to a targeted population. For instance, Plan B can be over-the-counter to women 17 and older, but prescription for women younger than 17. The practitioners can also take into consideration with the consent of parents of women younger than 17, if they should be allowed to use such product, even if some argue that it will make teenagers think that sex is appropriate. </2: 6.1>

<3: 8.9>If it was legal to market the same active ingredient as both a prescription and over-the-counter product, it should then also be able to be sold legally in the same package recognizing that one is over-the-counter and the other is prescription. However, it would be inappropriate to sell them in the same package, like Plan B or even H2 blockers, that contain over 300 mg to relieve ulcers. Some might

consider this inappropriate, but they could still be prescription or over-the-counter, just in separate packages.</3: 8.9>

<4: 2.2, 3.8.1>Considering all the options presented and explained, one might say that the key distinction in these examples is that there is some meaningful difference between the two products (indication, strength, route of administration, dosage form) that makes the prescription product safe only under the supervision of a licensed practitioner?. This just might be the case, but if one simultaneously marketed both prescription and over-the-counter with the same ingredient, he or she brings more options to some consumers. For example people who may not be able to afford prescription drugs and they either do not have insurance, or their insurance may not cover their product. This is why it is important for the FDA to setup an Advance Notice of Proposed Rulemaking to resolve the issue of circumstances under which an active ingredient may be simultaneously marketed, in both a prescription and over-the-counter form. </4: 2.2, 3.8.1>

COMMENT NUMBER - 2005N-0345-EMC373

2005N-0345-EMC373 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Tadeo, Peter

2005N-0345-EMC373 - TEXT

From: no-reply@erulemaking.net
Sent: Sunday, October 30, 2005 7:29 PM
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Subject: Public Submission

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Public Comments on Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product:

Title: Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product FR Document
Number: 05-17390 Legacy Document ID:
RIN:
Publish Date: 09/01/2005 00:00:00
Submitter Info:

First Name: peter
Last Name: tadeo
Category:
Organization Name:

Comment Info:

General Comment:comment for advance notice of proposed rulemaking (docket No. 2005-0345) attached

ATTACHMENT:

Peter A. Tadeo
2388-A Lawrenceville Hwy
Decatur, GA 30033
Docket No. 2005-0345

<1: 2.1>The Advanced Notice of Proposed Rulemaking (Docket No. 2005N-0345) by the FDA on whether an active ingredient may be simultaneously marketed in both a prescription drug and an over-the-counter drug should be looked at in many different perspectives. Rulemaking for this topic has been postponed and disregarded for far too long, and the necessity for rulemaking starts with comments from the American public. </1: 2.1>

<2: 3.3.3>Section 503(b) of the Durham-Humphrey Amendment does not simplify the confusion of what is considered an OTC drug and should be changed for drugs to be sold both in the OTC and in the prescription market.</2: 3.3.3> <3: 3.3.3>Regulations should be set in a practical manner, and many current drugs that are only available as prescription could be sold to the public without the supervision of a practitioner. When it comes down to this heavily debated topic the main question is: whether people can inform themselves on the product that they are consuming.</3: 3.3.3>

<4: 3.8.3>One of the risks of making more drugs over-the-counter is the threat of abuse of prescription drugs. Over history humans have always seen the beneficial and negative effects of decisions made by governments, whether it is war, laws, or policy. In some circumstance there are people who will constantly decide to abuse a great event, or in this case medicine, and exploit its contribution to many. Currently drugs containing the same active ingredient but with a smaller dosage are sold as OTC, and the more potent dosage is sold as a prescription product. Though, the smaller OTC dosages are still abused by addicts. For example, Ibuprofen is sold OTC at under 400mg, but one could consciously take more of the dosage prescribed on the label. The person taking this drug is knowledgeable about the side effects that this drug will have and making it only prescription should not be implemented because of that small population that chooses to misuse that medicine. Regulation is the option that one should look at when promulgating new policies for OTC drugs. </4: 3.8.3>

<5: 7.4.4, 7.4.5>The United States of America is known as the land of the free and of opportunity. In the early years of America our forefathers constructed the constitution to provide freedom from a centralized government. Though, without regulation and laws this country would be in shambles. Certain medicines with great potential for harm should always be monitored. For example, Hydrocodine should never be sold in high dosages to the public because of the possibility of abuse. Setting an age restriction for OTC drugs should be enforced more heavily. One way would be to force pharmacies to check ID for the purchase of the drug and if they broke this law, a certain number of times, they should be penalized in proportion to the transgression. </5: 7.4.4, 7.4.5>

<6: 1.2.2>One of the main drugs that will be affected by the creation of a policy toward dual approval for prescription and OTC pharmaceuticals would be the Plan B pill. This emergency contraception drug should be sold as over the counter to people over the age of 17 and as prescription to those under that age requirement. One of the arguments for not selling it as an OTC drug is that it would increase the possibility of premarital sex. Young people have been having sex since the times of Romeo and Juliet and making this drug more readily available will not increase what is naturally in the minds of

adolescents.</6: 1.2.2> <7: 7.4.6>Regulation for this drug could be used by creating a data base for any drug that has a high chance of abuse and have that person sign before they receive the pharmaceutical product. Drug stores could have this database on file to observe the number of times a person has used a particular drug so they could be aware of any type of misuse. </7: 7.4.6>

<8: 7.4.3>Section 503(b) should be changed to state that drugs that have shown or show a high possibility of abuse should be monitored more strictly than those drugs that have a lower threat of misuse. The drugs of high abuse rates can be seen by looking at past records. Regulating the purchase of pharmaceutical products can work if a system is well organized to do so</8: 7.4.3>.

<9: 3.8.3>Promulgating policy for prescription drugs should be viewed as a step forward in the right direction. Increasing the introduction of prescription drugs into the OTC market will boost competition and make pharmaceutical products more of a free market. This will in turn lower prices for those that can not afford to obtain drugs. Those with health insurance can still go to there doctor and receive the drug by prescription for only a co-payment or choose to buy it over-the counter. US citizens have the right to know what they are taking and informing the public about the drugs they are consuming would have to be increased. Accessible and affordable drugs are the answer to repairing the tarnished prescription drug system.</9: 3.8.3>

<10: 3.8.3>The FDA needs to approve rulemaking for the sell of an active ingredient in both in a prescription drug product and an over-the counter product so that all American citizens can receive medical help for any illness or problem they may have. A government's job is to keep order and to do what is best for the good of the people. </10: 3.8.3>

COMMENT NUMBER - 2005N-0345-EMC374

2005N-0345-EMC374 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Thames, Samuel

2005N-0345-EMC374 - TEXT

From: no-reply@erulemaking.net
Sent: Sunday, October 30, 2005 7:33 PM
To: Dockets, FDA
Subject: Public Submission

Please Do Not Reply This Email.

Public Comments on Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product:

Title: Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product FR Document
Number: 05-17390 Legacy Document ID:
RIN:

Publish Date: 09/01/2005 00:00:00

Submitter Info:

First Name: Samuel

Last Name: Thames

Category:

Organization Name:

Comment Info:

General Comment:<1: 3.1, 4.1, 6.1, 8.1>In regards to the FDA's request for comments on the advance notice of proposed rulemaking for the simultaneous marketing of drugs with identical active ingredients as both over the counter and prescription, I believe that the FDA should proceed with rulemaking to codify its interpretation of section 503 (b), that there is significant confusion in its current state, and that rulemaking would help dispel the confusion that is caused by the current rule. I also believe that the FDA would be able to legally enforce limitations on certain subpopulations and that those limitations could be practically enforced. Finally I believe that it would be legal to sell the products in the same packaging but that there would be some circumstances where selling identical items would be inappropriate.</1: 3.1, 4.1, 6.1, 8.1>

<2: 3.8.5>Codification of the FDA's interpretation of section 503 (b) would be greatly beneficial. The current wording of the rule is very broad and allows for very few exceptions. It seems to paint all drugs with the same brush when each drug should be looked at separately. The very fact that there is the question of a need for rulemaking illustrates the confusion on how the current rule should be interpreted and applied. Questions could be raised about what qualifies as a difference. Do they have to apply to the drug itself? Or can the circumstances of the some consumers count as a difference? There could also be widely varying interpretations of what is safe and for whom it applies. The current set of rules seems to group all drugs together and tries to separate over the counter from prescription with the same standards for every drug it looks at. But when it gets down to individual drugs, the method of dividing into prescription and over the counter may be totally inadequate. The FDA needs to address these questions in their rulemaking. They need to provide for a clearer way to separate drugs into prescription and over the counter. They also need to allow for exceptions when it comes to individual drugs. A large sweeping set of rules that use the same standards to separate prescription and over the counter is bound to break down along the way, as well as roll over some cases while letting other fall through the cracks. Codification of the FDA's interpretation of section 503 (b) would help to ensure that every drug gets looked at with the standards it needs to and would allow exceptions based on the unique circumstances of individual drugs.</2: 3.8.5>

<3: 6.1, 6.3.5, 7.1> If the FDA during the process of rulemaking was to place restrictions on certain subpopulations in regards to this rule, not only could it be legal but also vital to the rule affecting significant change. I will assume that the main subpopulation targeted by the restrictions would be those below a certain age. In this case, legally enforcing the rule will not only be legal, it will be practical as well. There are currently age restrictions of all kinds that spread across a broad range of products. These restrictions are enforced every day in a legal and practical manner. Putting similar restrictions on the over the counter sell to a subpopulation below a certain age should not produce many legal or practical problems and should also affect many of the same results that current restrictions do. Legal and practical problems aside, putting restrictions on a certain age subpopulation would produce some highly desirable effects. First off it would prevent irresponsible youths from acquiring drugs that they are either too young to fully grasp the implications of or that support behaviors that are not desirable. In putting an age restriction on over the counter sales of certain drugs and requiring a prescription for this subpopulation to

acquire the drug, it would allow a more responsible adult in on the decision. A doctor could more fully explain the consequences and uses of a drug than an underage consumer could learn from reading the side of a drug box. The effects of a drug alone are not the only concerns when dealing with the availability of drugs to underage consumers. There are damaging behaviors that a lack of an age restriction would help breed. In the case of the "morning after pill," the ability to get the drug over the counter would leave the potentially detrimental side effects of the behavior that led up to the pill's need unexplained. By going to a doctor to get a prescription for the pill, there would be an opportunity for the potentially damaging effects their behavior could have to be explained by a responsible and trained professional. At the very least, an age restriction on certain drugs would allow for an older, and hopefully more responsible, person in on the process. </3: 6.1, 6.3.5, 7.1>

<4: 8.1, 9.1.1>Finally, I do not see there being many legal problems arising from selling a product in the same packaging simultaneously in over the counter and prescription venues. Seeing as how the main reason for the separation of the two would be to allow someone more responsible in on an underage consumer's decision making, identical packaging would cause no great harm. But just because there are many circumstances where identical packaging for both prescription and over the counter drugs is appropriate, doesn't mean that there are not circumstances where the same packaging wouldn't be. In the case of a consumer going to the doctor to get the drug, there should be great leeway for the doctor in his/her decisions on things such as the number of doses that would require a different packaging. So while identical packaging for over the counter and prescription drugs should be allowed, there are definitely circumstances where it is in appropriate.</4: 8.1, 9.1.1>

<5: 3.1, 3.8.3, 5.3.2>The FDA should most definitely codify its interpretation of section 503 (b) to resolve confusion, it can and should place limits on certain subgroups, most notably those underage, and the FDA should also allow the identical packaging of over the counter and prescription drugs but also keep in mind that this is not always appropriate. The current state of the rules regarding prescription and over the counter drugs is inadequate and the FDA should proceed in the rulemaking process. </5: 3.1, 3.8.3, 5.3.2>

COMMENT NUMBER - 2005N-0345-EMC383

2005N-0345-EMC383 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Babalola, Abimbola

2005N-0345-EMC383 - TEXT

From: no-reply@erulemaking.net
Sent: Monday, October 31, 2005 6:35 AM
To: Dockets, FDA
Subject: Public Submission

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Public Comments on Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product:=====

Title: Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product FR Document Number: 05-17390 Legacy Document ID:

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Publish Date: 09/01/2005 00:00:00

Submitter Info:

First Name: Abimbola

Last Name: Babalola

Category: Consumer Group - B0001

Organization Name: Georgia State University

Comment Info: =====

General Comment:FDA's Advance Notice of Proposed Rulemaking

By: Abimbola Babalola (GA State Undergrad Student)

<1: 3.1, 3.8.1>In our ever-changing society, it is extremely important that the executive branch of the U.S. federal government fulfills its duties of faithfully executing laws that will benefit the lives of the people of our nation. By employing the law, U.S. federal agencies such as the Food and Drug Administration (FDA) officially announce vital rules on a daily basis to more thoroughly describe how U.S. statutes will be applied to specific circumstances. But, these rules are often politically controversial, requiring agencies to explain the reasons for their rules through the benefit of written public participation. Such is the present case with the FDA, as this agency is seeking public comments in response to their Advance Notice of Proposed Rulemaking (ANPRM) (Docket No. 2005N-0345) in dealing with the issue of what types of drugs may be sold simultaneously both by prescription and over-the-counter products. If the FDA initiates a plain-language rulemaking without using complicated and confusing speech in any proposed rule, and for this issue, then drugs that are marketed in both prescription and over-the-counter (OTC) drug products will provide easy access to consumers, will decrease the number of unintended pregnancies in women in the case of the Plan B pill, and will be more affordable to consumers nationwide.</1: 3.1, 3.8.1>

<2: 1.2.1>In order to have a better understanding as to why any drug should be simultaneously sold by prescription and over-the-counter products, we must explore the FDA's current issue of a particular Plan B pill, an emergency contraceptive that prevents pregnancies in women. According to an FDA statement released by FDA Commissioner Lester M. Crawford, the Plan B pill is currently available to all women only as a prescription drug, but FDA officials have recently begun debating whether or not to allow this drug to be marketed OTC to women who are 17 years of age and older, and remain prescription-only for those under the age of 17. By taking a pro stance on this issue, the FDA would ultimately create easy access of this, or any other drug, to consumers in at least a couple of ways. Useful and essential information about the drug will not only be known to women older than 17 who use the prescription, but women under 17 can read the drug labels on the OTC drug and educate themselves about what to expect while using the drug, such as what dosage is proper for their age group and what type of side effects, if any, are common. Also, easy accessibility of a drug, for example if the Plan B pill were to be sold both by prescription and OTC at the same time, would be especially beneficial to women under the age of 17 if an unfortunate case of rape were to occur to a particular individual. If a young woman under the age of 17 preferred to carefully prevent a pregnancy after being raped then she can easily purchase an OTC bottle of Plan B pills at her will. In the American culture today, it is practically inevitable that many teens will have premarital sex sometimes with or even without protection, therefore, greatly increasing their risk of producing unintended pregnancies. According to an ABC News online article, Susan Wood,

director of FDA's Office of Women's Health, claimed that complete access to the Plan B pill would significantly reduce unintended pregnancies and abortions. Basically, if the FDA proposes a rule allowing particularly the Plan B pill to be sold as a prescription as well as an OTC drug, then many unwanted and/or unintended pregnancies that can lead to abortions can be prevented. Susan Wood also supplies evidence for these circumstances by noting that the morning-after pill is a high dose of regular birth control that can lower the risk of pregnancy by up to 89 percent if it is taken within 72 hours of unprotected sex. </2: 1.2.1><3: 3.8.3>Another great reason why the FDA should propose a rule to allow drugs to be sold simultaneously both as prescription and OTC drug products is because the drugs could be more affordable to consumers. This can be the case in low-income families, or single-parent households that probably might not have insurance to cover certain drug costs along with paying for doctor visits. For example, if a single mother who is a diabetic needs to buy weekly supplies of insulin prescribed by her doctor and she has no insurance to pay for the drug costs, while also paying for other living expenses, then she can buy cheaper OTC pharmaceutical supplies versus the more expensive prescription. Taking into account some of the beneficial reasons of why certain drugs should be simultaneously marketed as both prescription and OTC drug products, the FDA should initiate a plain-language rulemaking to codify its interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act which provides the Federal standard used to classify drugs as prescription or OTC, and it describes when and how to switch a drug from prescription to OTC status. An FDA rulemaking would grant feasible accessibility of medications to consumers by educating them about a certain drug and would allow them to care for themselves given special circumstances.</3: 3.8.3> <4: 1.2.1>If the Plan B pill becomes available to women under the age of 17, eventually the number of teen pregnancies and abortions nation-wide will significantly decrease.</4: 1.2.1> <5: 3.8.3> In conclusion, a prescription and OTC drug product marketed together would be cost efficient because a consumer can purchase a pharmaceutical OTC drug even if his or her drug costs are not covered by insurance.</5: 3.8.3>

COMMENT NUMBER - 2005N-0345-EMC397

2005N-0345-EMC397 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: Vu, Tram

2005N-0345-EMC397 - TEXT

From: no-reply@erulemaking.net
Sent: Monday, October 31, 2005 9:54 AM
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Public Comments on Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product:

Title: Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product FR Document Number: 05-17390 Legacy Document ID:

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Publish Date: 09/01/2005 00:00:00
Submitter Info:

First Name: Tram
Last Name: Vu
Category: Consumer Group - B0001
Organization Name:

Comment Info:

General Comment:See Attachment.

ATTACHMENT:

Tram M. Vu
10540 Stonefield Landing
Duluth, GA 30097

Agency: Food and Drug Administration

Docket No. 2005N-0345

<1: 3.1, 3.8.3>In order to codify its interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an over the counter (OTC) drug product, the Food and Drug Administration should initiate a rulemaking. Codifying section 503(b) set specific standards that pharmaceutical companies can conform to so that there is no ambiguity in the ways drug companies can supply an active ingredient in both markets. Also made clear would be the conditions under which a drug is to be administered and sold. Established criterion and explanation protects consumers as well as eliminates carelessness of pharmaceutical companies on their pursuit to drop new drugs into the market.

For instance, if a new drug were put on the market with active ingredient 'n,' the drug companies would have to comply to more explicit standards and regulations enforced by the FDA in order to market the drug as a prescription and/or OTC product. Further, codified interpretations of section 503(b) would ensure standardized distribution under law. Providing concrete interpretation eliminates loopholes in which the drug companies may use to their commercial advantage. </1: 3.1, 3.8.3>

<2: 4.1, 4.3.3>The Federal Food, Drug, and Cosmetic Act's current language in section 503(b) is vague. Consequently, confusion regarding the FDA's interpretation is significant. </2: 4.1, 4.3.3><3: 5.1, 5.3.1, 5.3.2>Codifying the FDA's interpretation of section 503(b) makes the language more explicit and makes the federal administration more accountable to laws that were meant to protect consumers-as it is their function to serve the public health and not to submit to the lobbying tactics of profit-seeking pharmaceutical companies. In addition, clarification of the language protects consumers through means of education-providing legitimate and obtainable information. Any ambiguity on federal standards with regards to drugs should be accessible and in common language.</3: 5.1, 5.3.1, 5.3.2>

<4: 6.6.3, 7.4.5>Another issue raised in this advance notice of proposed rulemaking is whether or not the FDA would be able to enforce a limitation, as a matter of law, on the sale of OTC products to a particular subpopulation. Just as alcohol and tobacco are sold under the supervision of licensed sellers who confirm

identification, the prohibition of sale of any other OTC product to a subpopulation could be similarly enforced. If a seller were to violate restrictions on the sale of certain OTC products which require careful administration under law, it should be subject to penalty. </4: 6.6.3, 7.4.5>

<5: 7.4.6>The sale of an OTC product to a particular subpopulation could be enforced as a practical matter so long as proper implementation on the sale of such items is enacted. That is, sellers (and buyers) are well-informed of the lawful implications intended for transactions involving the specific products. What ever requirements may be established for the sale of a particular OTC product could be confirmed with adequate and proper identification by a licensed seller. </5: 7.4.6>

<6: 8.2, 8.6.4, 9.1.1>Assuming it is legal to market the same active ingredient in a prescription and OTC product, the different products should be sold in separate packages. The indications, side effects, directions for use, strength of dosage, age restrictions, and other implications for the drug may not be completely identical to its counter-part. Such differences in the drugs should be clarified through the packaging for the benefit of the consumer. Separate packaging, along with restrictions on dispersal of the prescription product, makes aware the distinction in the two products. </6: 8.2, 8.6.4, 9.1.1>

I hope not to undermine the FDA's concern for the general good of public health and the complexity of its rulemaking process. I trust that the administration will act in the interest of its people by initiating a rulemaking to make clear its interpretations of pre-established law. Establishing firm explanations of law legitimizes the legislative body as a whole.

COMMENT NUMBER - 2005N-0345-EMC446

2005N-0345-EMC446 - STRUCTURED DATA ELEMENTS

Initiative Name: Simultaneous Marketing of Rx and OTC Products
Commenter Organization Name: American Civil Liberties Union

2005N-0345-EMC446 - TEXT

From: Leaderman, Elizabeth [eleaderman@dcaclu.org]
Sent: Tuesday, November 01, 2005 4:54 PM
To: Dockets, FDA
Subject: Comment: 2005N-0345

<<FDA Comments Plan B.DOC>>

Elizabeth Leaderman
Assistant to the Associate Director/Chief Legislative Counsel ACLU Washington National Office 915
15th Street NW Washington, DC 20005 eleaderman@dcaclu.org 202-675-2323

November 1, 2005

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Advance Notice for Proposed Rulemaking, Docket Number 2005N-0345 Regarding Barr Laboratories' "Plan B" Petition

Dear Acting Commissioner von Eschenbach:

<1: 1.2.1>In response to the Advance Notice for Proposed Rulemaking, docket number 2005N-0345, the ACLU urges the Food and Drug Administration ("FDA") to suspend the proposed rulemaking process immediately and to approve without further delay Barr Laboratories' application to market Plan B, a form of emergency contraception, without a prescription. </1: 1.2.1>

<2: 3.2>A rulemaking proceeding is neither necessary nor legally required to approve Barr's petition for over-the-counter status for Plan B.</2: 3.2> <3: 1.2.1, 2.1>Increased access to Plan B would help prevent unintended pregnancies, reduce abortions, and promote women's reproductive health and rights. The FDA's continued delay in reaching a decision on this application permits politics to trump science and amounts to a failure to meet the agency's obligation to promote and protect women's health. Moreover, the agency's proposal for a two-tiered system of availability for Plan B would undermine the privacy rights of women of all ages who seek access to this critical drug. The ACLU urges the FDA to abandon this two-tiered approach and to permit women of all ages to purchase Plan B without a prescription.</3: 1.2.1, 2.1>

Background

<4: 1.2.1>Plan B was approved by the FDA in 1999 for use as a contraceptive. According to the approved labeling, Plan B decreases the risk of unintended pregnancy resulting from contraceptive failure or unprotected intercourse by 89%. [Footnote 1: FDA, Center for Drug Research and Evaluation, Medical Review, NDA 21045 (Plan B), available at http://www.fda.gov/cder/foi/nda/99/21-045_Plan%20B_medr.pdf.] In April 2003, Barr Laboratories, Plan B's manufacturer, filed an application with the FDA to make Plan B available over the counter.

In December 2003, two FDA advisory committees composed of medical experts voted overwhelmingly (23-4) in favor of granting Barr's petition. In reaching this conclusion, the advisory committees considered extensive scientific and social science evidence indicating that the drug is safe and effective and that over-the-counter access to it would serve the public health. Indeed, the FDA panel unanimously agreed both that Plan B was safe for use in a non-prescription setting and that there was no evidence that over-the-counter availability leads sexually active individuals to substitute emergency contraception for regular use of other contraceptive methods. See Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs 354-64 (Dec. 16, 2003). [Footnote 2: Available at www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.] FDA staff in the Center for Drug Evaluation and Research also recommended that Plan B be approved for over-the-counter use. See Gardiner Harris, Morning-After-Pill Ruling Defies Norm, New York Times, May 8, 2004, at A13.

Despite these views, in May 2004, the FDA rejected Barr's application, asserting that there was insufficient evidence that Plan B could be used safely without a prescription by women under sixteen. Based on the concerns expressed in the agency's non-approvable letter, Barr submitted a supplemental application proposing a two-tiered structure under which Plan B would be made available over-the-counter to women sixteen years of age or older, but only with a prescription to those under sixteen. The agency failed to act on this revised application for more than a year. On August 26, 2005, the FDA concluded, without warning, that Plan B should only be available over-the-counter to women seventeen and older. The agency also announced that it would not act on Barr's petition and instead would initiate a 60-day public comment and rulemaking process with no timetable for making a decision. </4: 1.2.1>

No Rulemaking Proceeding Is Required to Approve Barr's Petition.

<5: 3.5.2>A rulemaking proceeding is neither necessary nor legally required for the FDA to approve Barr's petition for over-the-counter status for Plan B. Although the FDA may change a drug's status from prescription to over-the-counter via a rulemaking process, as stated in the Advanced Notice of Proposed Rulemaking here, it may also change a drug's status by means of an agency order, in this case by approving a Supplemental New Drug Application by authority granted under the Food, Drug, and Cosmetic Act. [Footnote 3: See *SEC v. Chenery*, 332 U.S. 194, 202-203 (1947) (an administrative agency has the authority to use either rulemaking or other authority granted it by Congress to make decisions).] There is no compelling reason to require a rulemaking proceeding to evaluate Barr's petition. </5: 3.5.2>

<6: 1.2.1>The FDA already possesses sufficient information to conclude that Plan B is safe for use without a prescription. Plan B meets the FDA's criteria for determining that a drug is appropriate for over-the-counter use. It treats a condition that patients can diagnose themselves; it is safe and effective when used without direct prescriber supervision; and the drug's label adequately explains potential adverse effects and conditions of use. Plan B is easy to use, is not addictive, and has no known health hazards when self-administered. The drug has virtually no contraindications and few side effects. There is simply no compelling medical rationale for restricting Plan B to prescription-only use. The rulemaking process should therefore be suspended. </6: 1.2.1>

The FDA's Refusal to Approve Barr's Petition Cannot Be Justified By Medical Science.

<7: 1.2.1>The FDA's continued refusal to act on Barr's petition flies in the face of recommendations by two FDA Advisory Committees, FDA officials, and major medical groups. Two of the FDA's own advisory committees voted overwhelmingly to allow Plan B to be made available without a prescription. In concluding that emergency contraceptives are safe and effective, the FDA advisory panel considered a study showing that easy access to such contraceptives does not cause adolescents to have more unprotected sex or to stop using contraception.

The advisory committee's recommendation that Plan B be approved for non-prescription use was supported by the staff of the FDA. Indeed, memoranda from the FDA staff show the extent of disagreement with the agency's final decision to delay approval indefinitely: One senior FDA employee described the reasoning used to justify denying immediate approval for Plan B as "speculative and unbalanced." Marc Kaufman, *Staff Scientists Reject FDA's Plan B Reasoning*, *Washington Post*, June 18, 2004, at A02. Dr. Susan Wood, the former director of FDA's Office of Women's Health who resigned in protest over the agency's refusal to act on the petition, explained, "[S]cientific and clinical evidence, fully evaluated and recommended for approval by the professional staff [at the FDA], has been overruled." *F.D.A. Aide Quits in Protest of Morning-After Pill Decision*, *Associated Press*, August 31, 2005.

Moreover, major medical groups, including the American College of Obstetricians and Gynecologists, the American Medical Association, and the American Public Health Association, also supported making Plan B more readily accessible. </7: 1.2.1>

By refusing to act on Barr's application, the FDA ignored the scientific evidence and has turned what should be a science-based decision on a drug approval into a political game.

Over-the-Counter Availability Ensures Access to Emergency Contraception for the Many Women Who Need It.

<8: 1.2.1>Nearly half of all pregnancies in the United States are unintended. See Alan Guttmacher Institute, Questions About Pregnancy, Contraception and Abortion (2004). [Footnote 4: Available at <http://www.agi-usa.org/in-the-know/pregnancy.html>.] For the women who face a potential unintended pregnancy, widespread and timely access to emergency contraception is critical.

Emergency contraception must be taken within 72 to 120 hours after unprotected intercourse, but experts agree that it is more effective the sooner it is taken. See Charlotte Ellertson et al., Extending the Time Limit for Starting the Yuzpe Regimen of Emergency Contraception to 120 Hours, 101 *Obstet. Gynecol.* 1168, 1168 (2003). This narrow window makes ready access to emergency contraception critical. The current requirement that emergency contraception only be dispensed with a doctor's prescription acts as significant barrier to obtaining this safe and effective method of birth control. A woman who has just experienced unprotected sex, contraceptive failure, or sexual assault, must find an available physician who can and will fill a Plan B prescription; obtain the prescription; find a pharmacy and pharmacist that will dispense the drug; fill the prescription; and take the medication -- all "while the time window for efficacy is closing." Alastair Wood, et al., A Sad Day for Science at the FDA, 535 *N. Engl. J. Med.* 1197 (2005). For women who cannot afford a doctor's appointment, whose doctor's office is closed during the critical period, or who cannot obtain an appointment within the short window, the prescription requirement serves as a major impediment to obtaining the drug within the necessary time frame.

Denied access to emergency contraception, some women will face a choice of either continuing an unwanted pregnancy or having an abortion. See Rachel K. Jones et al., Contraceptive Use Among U.S. Women Having Abortions in 2000-2001, 34 *Persp. on Sex & Reprod. Health* 294, 300 (2002) (estimating 51,000 abortions were prevented in 2000 alone because of emergency contraceptive use). Emergency contraception prevents pregnancy, but does not disrupt an existing pregnancy. Moreover, emergency contraception is safe: to date, millions of women have used emergency contraception with no serious side effects or contraindications that would endanger their health. See World Health Organization, *Emergency Contraception: A Guide for Service Delivery* (1998).</8: 1.2.1>

Age-Based Restrictions Are Unnecessary, Will Infringe Women's Privacy Rights, and Will Impede Women of All Ages from Obtaining Plan B.

<9: 1.2.1>There is no scientific evidence that women under the age of seventeen are unable to use Plan B safely without a prescription. Data presented to the FDA in conjunction with Barr's original application demonstrated that Plan B is safe for young women and that more open access to Plan B does not increase risk-taking behavior, such as having unprotected sex, among teens. See Melanie Gold, Testimony at the Meeting of the FDA Nonprescription Drugs Advisory Committee in Joint Session with the Advisory Committee for Reproductive Health Drugs 155-57 (Dec. 16, 2003). [Footnote 5: Available at www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf.] Indeed, the FDA has not identified any data indicating that Plan B poses a health threat to younger women. See Alastair Wood, et al., A Sad Day for Science at the FDA, 535 *N. Engl. J. Med.* 1197, 1198 (2005).</9: 1.2.1>

<10: 1.2.1>And, significantly, imposing age-based restrictions on Plan B will breach the privacy rights of all women who seek access to this critical drug. A two-tiered, age-based structure will require pharmacies that sell Plan B over-the-counter to impose mandatory proof of age requirements on all women who purchase the drug. Such a requirement, which is not placed on other over-the-counter drugs, constitutes an unwarranted invasion of a woman's privacy. The prospect of being forced to produce public identification while purchasing a drug as personal and intimate as emergency contraception is likely to deter women of all ages from purchasing the drug. Given Plan B's demonstrated safety record, such an invasion serves no legitimate purpose, and indeed may only humiliate a woman who has just experienced contraceptive failure, unprotected sex, or sexual assault.</10: 1.2.1>

Improved Access to Emergency Contraception Is Particularly Critical for Sexual Assault Survivors.

<11: 1.2.1>Over-the-counter access to emergency contraception is especially important for sexual assault survivors. Every year, approximately 25,000 pregnancies occur because of sexual assault. See Felicia Stewart et al., Prevention of Pregnancy Resulting from Rape: A Neglected Preventive Health Measure, 19 Am. J. Preventive Med. 228, 228 (2000). Emergency contraception could prevent approximately 22,000 of these pregnancies. Id. at 229. Yet in many areas, more than half of hospital emergency rooms fail to provide emergency contraception to sexual assault patients routinely. See ACLU Reproductive Freedom Project Briefing Paper, Preventing Pregnancy after Rape: Emergency Care Facilities Put Women at Risk (2004). [Footnote 6: Available at <http://www.aclu.org/ReproductiveRights/ReproductiveRights.cfm?ID=17212&c=30>.] The prescription requirement serves as a major barrier to access to emergency contraception for sexual assault survivors in these areas. If a woman is denied access to emergency contraception in the emergency room to which she is initially brought, she must then somehow track down another doctor, answer more personal and painful questions, and find a pharmacy to fill her prescription, all within 72 to 120 hours of the assault. Ready availability of emergency contraception without a doctor's prescription would mean that at least one injury from the assault, the possibility of pregnancy, could be quickly and safely alleviated.</11: 1.2.1>

Conclusion

<12: 2.1>Approving over-the-counter access to Plan B will promote public health, prevent unintended pregnancies, and reduce abortions. Age-based restrictions, which are not medically warranted, will chill the ability of women of all ages to access Plan B. Given the strong support for the petition expressed by the FDA's independent committee of experts, FDA staff, and major medical groups, the ACLU urges you to suspend the rulemaking process and to act without further delay to approve over-the-counter status for Plan B emergency contraception.</12: 2.1>

Sincerely,

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