FDA Simultaneous Marketing ANPRM
Comment Excerpts Sorted By Issue

Issues 3 – 9 (Responses to ANPRM Questions)

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Final

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3 - Should FDA initiate a rulemaking regarding its interpretation of section 503(b)? [ANPRM Question 1.A.]

3.1 - Yes

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 24
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
Sure. Rules are great. Everyone knows the game plan when regulations exist, provided they are short, clear and to the point.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Black, Jerrold
Comment Number: 2005N-0345-EC111
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Mershon, Claire-Helene
Comment Number: 2005N-0345-EC12379
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 3.8.5 - Circumstances for OTC safety are case-specific
Excerpt Text:

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.

Commenter Organization Name: Dougherty, Anne
Comment Number: 2005N-0345-EC126
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
NEW - 5.1 - Yes
Excerpt Text:
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).

Commenter Organization Name: Rahl, Michael
Comment Number: 2005N-0345-EC13845
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
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.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Connors, Meaghan
Comment Number: 2005N-0345-EC141
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes. Doing so would move this prolonged, highly politicized process.

Commenter Organization Name: Soriano, Lauren
Comment Number: 2005N-0345-EC14388
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
Excerpt Text:
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.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
This too is not a difficult or complexed task. If an amendmentis - based on changing circumstances warrants - obvious and needed, than the change(s) should made based on procedural issues and not politics or ideological leanings.

Commenter Organization Name: Loomis, Shirley
Comment Number: 2005N-0345-EC147
Excerpt Number: 1

Excerpt Status: NEW
Excerpt Text:
Yes, provided the drug is safe for distribution.

Commenter Organization Name: Marshall, Laura
Comment Number: 2005N-0345-EC15
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes, I believe a rulemaking is in order.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.4 - Administrative Procedures Act (APA) arguments
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 3.4 - Administrative Procedures Act (APA) arguments
Excerpt Text:
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.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription

only

NEW - 4.2 - No

NEW - 4.4.1 - Legal arguments that little or no confusion exists

Excerpt Text:

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.

Commenter Organization Name: Smart, Stephanie
Comment Number: 2005N-0345-EC16
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
Excerpt Text:

A drug is not only its active ingrediant. 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 ingrediant.

Commenter Organization Name: Hutson, Paul
Comment Number: 2005N-0345-EC162
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
Excerpt Text:

The FDA should allow for the dispensing of selected drugs without a prescription by a licensed pharmacist, physician's assistant, or nurse practitioner.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:

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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:

Yes

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 12

Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Wilson, Rhianna
Comment Number: 2005N-0345-EC186
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Moon, Kristin
Comment Number: 2005N-0345-EC1927
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Tuchinsky, Marla
Comment Number: 2005N-0345-EC201
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
To the extent that your interpretation is preventing women from getting access to a perfectly safe and effective drug, yes.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107

Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 2.1 - Comments on time, manner, and nature of rulemaking process
Excerpt Text:
Yes- and in a realistic way, not as outlawing disguised as regulation.

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
yes

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Levinson, R. Saul
Comment Number: 2005N-0345-EC297
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.2 - Approve simultaneous marketing approach (market both OTC and Rx)
NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Wu, Jackie
Comment Number: 2005N-0345-EC307
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Waychoff, W. Aaron

Comment Number: 2005N-0345-EC311
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.5 - Circumstances for OTC safety are case-specific
Excerpt Text:
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.

Commenter Organization Name: Collum, Mark
Comment Number: 2005N-0345-EC33
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
Excerpt Text:
Yes. This should either be fully OTC or it should be classified into a category where RPh can prescribe and dispense it.

Commenter Organization Name: McLeod, Doug
Comment Number: 2005N-0345-EC364
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes it should and the decision should be made to allow this action. Especially if the scientific evidence supports that decision.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Kulshrestha, Vikram V
Comment Number: 2005N-0345-EC405
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Labbe, Carl
Comment Number: 2005N-0345-EC408
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third

class of "behind-the-counter" drugs (pharmacist distributed)
Excerpt Text:
I believe that there are very sound arguements 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 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.

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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

Commenter Organization Name: Duchon, Kathleen
Comment Number: 2005N-0345-EC426
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Duchon, Kathleen
Comment Number: 2005N-0345-EC426
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes, times are we a consumer can get a product in illegal ways. Why not make it a safe consumer choice?

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
YES

Commenter Organization Name: Zahn, Steven
Comment Number: 2005N-0345-EC52
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Ramirez, Robert
Comment Number: 2005N-0345-EC527
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
Yes, if clarification is needed iniate 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.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
Yes, this would seem to be a required point considering the amount of drug therapies available and the numders will only increase. In addition, when ever there are regulatory vagaries groups seems to always take advantage and promote unintended agendas.

Commenter Organization Name: Leonard, Ruth Tehila
Comment Number: 2005N-0345-EC59
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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 engredient can be sold on and off the counter simultaneously I think the answer is yes.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:

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 ideaology instead of science should be made available by any truly scientific health organization.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
I think that the FDA should make rules about when a drug can be sold as both prescription and OTC

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
I think that actually codifying this would be good.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Peer, Gerald
Comment Number: 2005N-0345-EC626
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
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.

Commenter Organization Name: Ray, Amy
Comment Number: 2005N-0345-EC65
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:

Yes, if the benefit is clearly defined to those who would benefit from such an interpretation.

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Ricci, Stephen
Comment Number: 2005N-0345-EC73
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Carlson, Brent
Comment Number: 2005N-0345-EC77
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Macdonell, Megan
Comment Number: 2005N-0345-EC779
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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).

Commenter Organization Name: Kuskey, Garvan
Comment Number: 2005N-0345-EC793
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.10 - Examples of FDA actions disallowing simultaneous marketing
Excerpt Text:
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.

Commenter Organization Name: Camron, Kiera
Comment Number: 2005N-0345-EC811
Excerpt Number: 2
Excerpt Status: NEW

Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Wagner, Patricia
Comment Number: 2005N-0345-EC813
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
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 dissimular that the ordinary customer will identify them as two different products.

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes it should.

Commenter Organization Name: Oyola, Sandra
Comment Number: 2005N-0345-EC85
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
Yes. This would clarify the regulations for any future products that may be sold either as prescription or OTC.

Commenter Organization Name: Holden, Karen
Comment Number: 2005N-0345-EC895
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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 partcular subgroup is beyond the legitimate interest of the FDA.

Commenter Organization Name: Aengst, Jennifer
Comment Number: 2005N-0345-EC921
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
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.

Commenter Organization Name: Wurtz, Richard
Comment Number: 2005N-0345-EC94
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
YES

Commenter Organization Name: Trubow, Marshall
Comment Number: 2005N-0345-EC95
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Trubow, Marshall
Comment Number: 2005N-0345-EC95
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Stockton, Melissa
Comment Number: 2005N-0345-EC99
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Stockton, Melissa
Comment Number: 2005N-0345-EC99
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
yes.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.1 - FD&C Act requires rulemaking
Excerpt Text:
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 form 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.

Commenter Organization Name: Syed, Misbah
Comment Number: 2005N-0345-EMC368
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
NEW - 3.9.1 - Drug approval examples
NEW - 4.1 - Yes
NEW - 5.1 - Yes
Excerpt Text:
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 nausia 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 mourning-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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
NEW - 6.1 - Yes
NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

Commenter Organization Name: Babalola, Abimbola
Comment Number: 2005N-0345-EMC383
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
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 nation-

wide.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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.

3.2 - No

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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).

Commenter Organization Name: University of California, San Franscisco
Comment Number: 2005N-0345-C320
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.

Comment Number: 2005N-0345-C414
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
NEW - 3.6.2 - Court case arguments opposing a rulemaking
Excerpt Text:
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.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-l 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)(l)(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.

Commenter Organization Name: Family Planning Advocates of New York State
Comment Number: 2005N-0345-C61
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
NEW - 5.2 - No
Excerpt Text:
In response to the questions posed in RIN 0910-AF72, FPA believes the first three questions (lA, 1B and lC) 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.

Commenter Organization Name: Family Planning Advocates of New York State
Comment Number: 2005N-0345-C61
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Alterton, Faith
Comment Number: 2005N-0345-C83
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
NO.

Commenter Organization Name: Ladd, Judy
Comment Number: 2005N-0345-EC1032
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Shaffer, Kathleen
Comment Number: 2005N-0345-EC106
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
It is a contradiciton 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.

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
It makes very little sense, if the drug is nessisary 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.

Commenter Organization Name: Roye, Carol
Comment Number: 2005N-0345-EC110
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 10 - Studies/data provided in comment
Excerpt Text:
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.

Commenter Organization Name: Slee, April
Comment Number: 2005N-0345-EC121
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Severance, Peter
Comment Number: 2005N-0345-EC135
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
No. Why are you complicating this? The FDA is supposed to regulate drugs based on clinical evidence, not make social policy.

Commenter Organization Name: Jones, Kim
Comment Number: 2005N-0345-EC16543
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.5 - Circumstances for OTC safety are case-specific
Excerpt Text:
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.

Commenter Organization Name: Hein, Rachel
Comment Number: 2005N-0345-EC168
Excerpt Number: 1
Excerpt Status: NEW

Other Sections: NEW - 3.8.5 - Circumstances for OTC safety are case-specific
Excerpt Text:
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.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.5 - Circumstances for OTC safety are case-specific
Excerpt Text:
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.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
No. The interpretation is too restrictive

Commenter Organization Name: Murphy, Cynthia
Comment Number: 2005N-0345-EC176
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Murphy, Cynthia
Comment Number: 2005N-0345-EC176
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
n/a The last thing we need in this country is MORE rules!

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
no. It should be one or the other,not both.

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
no.

Commenter Organization Name: Dowell, Duane
Comment Number: 2005N-0345-EC195
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
there is no compelling reason to initiate the process at this time

Commenter Organization Name: Crousey, Joshua
Comment Number: 2005N-0345-EC1970
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Munro, Margaret
Comment Number: 2005N-0345-EC2022
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No - the FDA should not initiate rulemaking.

Commenter Organization Name: Munro, Margaret
Comment Number: 2005N-0345-EC2022
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No - the FDA should not initiate a rulemaking to codify its interpretation.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
This same situation has worked for Claritin. It is now available OTC and by prescription. No other law making is necessary.

Commenter Organization Name: Richman, Bobbi
Comment Number: 2005N-0345-EC21
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
DEFINATELY NOT.

Commenter Organization Name: Young, Stan
Comment Number: 2005N-0345-EC211
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
No, I believe your previous guidelines are adequate. If it is safe without a practitioner's prescription then it should be available OTC.

Commenter Organization Name: Rankis, A
Comment Number: 2005N-0345-EC22
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No, Current situation is fine

Commenter Organization Name: Cepeda, Baudi
Comment Number: 2005N-0345-EC226
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No, a rulemaking on Section 503(b) is unnecessary.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 14
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 7.6 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Myers, Micah
Comment Number: 2005N-0345-EC319
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Dolinski, Elizabeth
Comment Number: 2005N-0345-EC522
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.2 - Approve simultaneous marketing approach (market both OTC and Rx)
NEW - 3.8.8 - Other policy arguments opposing a rulemaking

Excerpt Text:
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.

Commenter Organization Name: Della Paolera, Mark
Comment Number: 2005N-0345-EC555
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Porter, Rebecca
Comment Number: 2005N-0345-EC56
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
I feel strongly that the FDA should not initiate a rulemaking to codify their interpretation of section 503(b), about duel-marketing both a prescription drug product and simultaneously an OTC product.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
I believe the rulemaking should stay as it is. And not go change policy, allowing duel-marketing of both a prescription drug product and simultaneously an OTC product. The FDA should remain firm on this issue in this regard.

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Vrankar, Anna
Comment Number: 2005N-0345-EC668
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
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"

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
No, the policy in effect now is adequate.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Hager, Joseph R
Comment Number: 2005N-0345-EC716
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
NO!

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762

Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 2.1 - Comments on time, manner, and nature of rulemaking process
Excerpt Text:
Denying the approval of Plan B as an over the counter drug, especially after being so overwhelming 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).

Commenter Organization Name: Phlips, Thomas
Comment Number: 2005N-0345-EC788
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
no

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Smith, Rodney
Comment Number: 2005N-0345-EC83
Excerpt Number: 1
Excerpt Status: NEW

Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
No. How can a drug be both, especially when the Rx form is of a HIGHER concentration?

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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.

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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.

Commenter Organization Name: Vander Bleek, Luke
Comment Number: 2005N-0345-EC870
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: Kopp, Margaret
Comment Number: 2005N-0345-EC903
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Hawkins, Susan
Comment Number: 2005N-0345-EC91
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Dalton, Mike
Comment Number: 2005N-0345-EMC166
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
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.

Commenter Organization Name: American Civil Liberties Union
Comment Number: 2005N-0345-EMC446
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
A rulemaking proceeding is neither necessary nor legally required to approve Barr's petition for over-the-counter status for Plan B.

3.3 - FD&C Act and amendments

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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 au 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.

Commenter Organization Name: Richman, Bobbi
Comment Number: 2005N-0345-EC21
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
Excerpt Text:
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.

3.3.1 - FD&C Act requires rulemaking

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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 form 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.

3.3.2 - FD&C Act is clear regarding when a drug should be prescription only

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 3.6.2 - Court case arguments opposing a rulemaking
NEW - 6.3.2 - No laws prevent the policy
Excerpt Text:
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).]

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.5 - Circumstances for OTC safety are case-specific
Excerpt Text:
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.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:

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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 3.6.2 - Court case arguments opposing a rulemaking
Excerpt Text:
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.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-l 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)(l)(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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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 2l U.S.C. § 353(b)(l)). 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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.5.1 - FD&C Act - Legal differences between statutory requirements for Rx and OTC
Excerpt Text:
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, 2457 (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).

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
Excerpt Text:
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).

Commenter Organization Name: Shaffer, Kathleen
Comment Number: 2005N-0345-EC106
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
It is a contradiciton 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.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes. The only time this should be allowed is when the active ingredients harmful properties are made unharmful in the drug that is over the counter. If it can not be made unharmful for public consumption, then it should be prescriptive.

Commenter Organization Name: Academy of Managed Care Pharmacy
Comment Number: 2005N-0345-EC15687
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Academy of Managed Care Pharmacy
Comment Number: 2005N-0345-EC15687
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Academy of Managed Care Pharmacy
Comment Number: 2005N-0345-EC15687
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
Excerpt Text:
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.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931

Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 4.2 - No
NEW - 4.4.1 - Legal arguments that little or no confusion exists
Excerpt Text:
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.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
No, I believe your previous guidelines are adequate. If it is safe without a practitioner's prescription then it should be available OTC.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.3.4 - Age limitations are in line with other meaningful differences
Excerpt Text:
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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 1.2.2 - Approve simultaneous marketing approach (market both OTC and Rx)
NEW - 7.3.1 - Regulate product sponsor
Excerpt Text:
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.

Commenter Organization Name: Ramirez, Robert
Comment Number: 2005N-0345-EC527
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Leonard, Ruth Tehila
Comment Number: 2005N-0345-EC59
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
I can see no reason why an identical product will have to be given by perscription for one person and free for purchase to another. I suggest you allow certain people to carry open perscriptions for products they need regularly for a particular medical condition, but otherwise substances with the same active engredients 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 perscription.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:

Only pharmaceutical products with the potential for minimal health hazard should be offered as Over The Counter formulations.

Commenter Organization Name: Vrankar, Anna
Comment Number: 2005N-0345-EC668
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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"

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
Any product which has been judged sufficiently dangerous to warrant professional supervision via prescription -- should not be presented to the public without such protection.

Commenter Organization Name: Smith, Rodney
Comment Number: 2005N-0345-EC83
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
No. How can a drug be both, especially when the Rx form is of a HIGHER concentration?

3.3.3 - Other arguments related to FD&C Act

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
Excerpt Text:
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.

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 6.3.4 - Age limitations are in line with other meaningful differences
Excerpt Text:
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 that 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.

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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-l 15, § 126, 111 Stat. 2296, 2327-2328 (1997).]

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 8.5.1 - FD&C Act - Legal differences between statutory requirements for Rx and OTC
Excerpt Text:
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 2 1 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.]

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 3.8.7 - Cost-benefit concerns regarding rulemaking
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
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).

Commenter Organization Name: Garden, Nicole
Comment Number: 2005N-0345-EC14598
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
Excerpt Text:
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.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Smart, Stephanie
Comment Number: 2005N-0345-EC16
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
A drug is not only its active ingrediant. 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 ingrediant.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 18
Excerpt Status: NEW
Other Sections: NEW - 6.3.1 - FD&C Act
MODIFIED - 7.3.1.3 - Require risk management program
Excerpt Text:
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 postmarking 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.

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
Excerpt Text:
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.

Commenter Organization Name: Hagan, Jane
Comment Number: 2005N-0345-EC32
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
I believe the importance of making this drug available to the public is substantial emough that the FDA should do whatever is necessary to accomplish that.

Commenter Organization Name: McLeod, Doug
Comment Number: 2005N-0345-EC364
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Anspach, Kurt
Comment Number: 2005N-0345-EC447
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
If it were safe to take theses pills without a prescription in one form then how can it not be for another use?Thats 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.

Commenter Organization Name: Porter, Rebecca
Comment Number: 2005N-0345-EC56
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Billingsley, Daniel
Comment Number: 2005N-0345-EC609
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
I just believe if a product is safe enough to OTC then a prescription should not be required.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610

Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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, the 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.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 16
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Burns, Ben
Comment Number: 2005N-0345-EC93
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Syed, Misbah
Comment Number: 2005N-0345-EMC368
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 3.9.1 - Drug approval examples
NEW - 4.1 - Yes
NEW - 5.1 - Yes
Excerpt Text:
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 nausia 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 mourning-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.

Commenter Organization Name: Tadeo, Peter
Comment Number: 2005N-0345-EMC373
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Tadeo, Peter
Comment Number: 2005N-0345-EMC373
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

3.4 - Administrative Procedures Act (APA) arguments

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 25
Excerpt Status: NEW
Excerpt Text:

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 tri 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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 29
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:

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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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).]

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Dowell, Duane
Comment Number: 2005N-0345-EC195
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 9.2.2 - All circumstances (i.e., it's always appropriate, there are no inappropriate circumstances)
Excerpt Text:
None

3.5 - Supplemental New Drug Application (SNDA) and New Drug Application (NDA) regulations

3.5.1 - SNDA/NDA regulatory arguments supporting rulemaking

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 41
Excerpt Status: NEW
Other Sections: NEW - 1.2 - Specific comments on drug approval process for Morning-after Pill/Plan B
NEW - 1.2.3 - Maintain Rx only
NEW - 3.11 - Miscellaneous arguments/discussions
Excerpt Text:
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.]

3.5.2 - SNDA/NDA regulatory arguments opposing rulemaking

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Specifically, the regulatory framework governing drug approvals and prescription-to-OTC "switches" are clear and should lead to swift approval of Barr's sNDA.

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Family Planning Advocates of New York State
Comment Number: 2005N-0345-C61
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: American Civil Liberties Union
Comment Number: 2005N-0345-EMC446
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

3.6 - Court opinion legal arguments

3.6.1 - Court case arguments supporting a rulemaking

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 26
Excerpt Status: NEW
Excerpt Text:
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 , l974). 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.

3.6.2 - Court case arguments opposing a rulemaking

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
NEW - 6.3.2 - No laws prevent the policy
Excerpt Text:
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).]

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only

Excerpt Text:
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.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-l 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)(l)(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.

3.7 - Other legal arguments

3.7.1 - Other legal arguments supporting rulemaking

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 27
Excerpt Status: NEW
Other Sections: NEW - 8.5.4 - Other legal arguments opposing one package
Excerpt Text:
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 l4: 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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 28
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes
NEW - 5.3.1 - Legal arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

Commenter Organization Name: Hein, Rachel
Comment Number: 2005N-0345-EC168
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
It is illegal to withhold OTC suitable active ingregients based on discrimination by age, gender or race. All packaging should contain full information.

Commenter Organization Name: Padden, Phillip
Comment Number: 2005N-0345-EC505
Excerpt Number: 1
Excerpt Status: NEW

Excerpt Text:
Check your congressional mandate. If it requires that interpretations be justified then yes, codifying your interpretation would be an extension of justification.

3.7.2 - Other legal arguments opposing rulemaking

Commenter Organization Name: Ahmed , Stephanie
Comment Number: 2005N-0345-EC1117
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Parks, C
Comment Number: 2005N-0345-EC23
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

3.8 - Policy arguments

3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)

Commenter Organization Name: Speight, Thomas
Comment Number: 2005N-0345-EC1041
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
The FDA should clarify all regulations so that they can be understood by the layman, and possibilties for abuse may be minimized.

Commenter Organization Name: Speight, Thomas
Comment Number: 2005N-0345-EC1041
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
Sure. Rules are great. Everyone knows the game plan when regulations exist, provided they are short, clear and to the point.

Commenter Organization Name: Reynolds, Charles
Comment Number: 2005N-0345-EC12
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes, this is an important decision for the future of health care in the US.

Commenter Organization Name: Reynolds, Charles
Comment Number: 2005N-0345-EC12
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.5 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Rahl, Michael
Comment Number: 2005N-0345-EC13845

Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Rahl, Michael
Comment Number: 2005N-0345-EC13845
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rahl, Michael
Comment Number: 2005N-0345-EC13845
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
The FDA should initiate a rulemaking to codify it 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.

Commenter Organization Name: Marshall, Laura
Comment Number: 2005N-0345-EC15
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Reusch, Elizabeth
Comment Number: 2005N-0345-EC165
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 2

Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Pechacek, Deborah
Comment Number: 2005N-0345-EC27
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes I think the FDA needs to clarify this rule to eliminate any future issues.

Commenter Organization Name: Pechacek, Deborah
Comment Number: 2005N-0345-EC27
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
This is purely dependent on whether this case represents an anomoly, 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.

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
YES!!! We need to make this process much more simple and bring these medications to the American public sooner.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 14
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.11 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Clarity is necessary.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
Yes, this would seem to be a required point considering the amount of drug therapies available and the numders will only increase. In addition, when ever there are regulatory vagaries groups seems to always take advantage and promote unintended agendas.

Commenter Organization Name: Peer, Gerald
Comment Number: 2005N-0345-EC626
Excerpt Number: 1
Excerpt Status: NEW

Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Oyola, Sandra
Comment Number: 2005N-0345-EC85
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
Yes. This would clarify the regulations for any future products that may be sold either as prescription or OTC.

Commenter Organization Name: Aengst, Jennifer
Comment Number: 2005N-0345-EC921
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
NEW - 5.1 - Yes
NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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 manufactures 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.

Commenter Organization Name: Syed, Misbah
Comment Number: 2005N-0345-EMC368
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 2.2 - Support ANPRM request for comments
Excerpt Text:
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 Propose rulemaking to resolve the issue of circumstances under which an active ingredient maybe simultaneously marketed, in both a prescription and over-the-counter form.

Commenter Organization Name: Babalola, Abimbola
Comment Number: 2005N-0345-EMC383
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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 nation-wide.

3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.5 - Circumstances for OTC safety are case-specific
NEW - 3.8.6 - Develop/update guidance as alternative for rulemaking
Excerpt Text:
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.

Commenter Organization Name: National Association of Boards of Pharmacy
Comment Number: 2005N-0345-C443
Excerpt Number: 1

Excerpt Status: NEW
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
NEW - 7.4.2 - Involve other authorities (e.g., states, state boards of pharmacies)
Excerpt Text:
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

Commenter Organization Name: National Association of Boards of Pharmacy
Comment Number: 2005N-0345-C443
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: National Association of Boards of Pharmacy
Comment Number: 2005N-0345-C443
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Women's Bar Associaion of the State of New York
Comment Number: 2005N-0345-C489
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes, by a creating a third class of drugs, those sold by a pharmacist without requiring a prescription.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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 br held accountable to enforce the limitation on the sale of the product.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 1.1 - General comments on drug approval process
Excerpt Text:
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.

Commenter Organization Name: Corlette, Chauncey
Comment Number: 2005N-0345-EC14491

Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Hutson, Paul
Comment Number: 2005N-0345-EC162
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
The FDA should allow for the dispensing of selected drugs without a prescription by a licensed pharmacist, physician's assistant, or nurse practitioner.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Collum, Mark
Comment Number: 2005N-0345-EC33
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
Yes. This should either be fully OTC or it should be classified into a category where RPh can prescribe and dispense it.

Commenter Organization Name: Scarpace, Sarah
Comment Number: 2005N-0345-EC38
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
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.

Commenter Organization Name: Labbe, Carl
Comment Number: 2005N-0345-EC408
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
I believe that there are very sound arguements 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 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.

Commenter Organization Name: Labbe, Carl
Comment Number: 2005N-0345-EC408
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Pharmacists are well-educated, compentent 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.

3.8.3 - Other policy arguments for initiating a rulemaking

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 23
Excerpt Status: NEW
Other Sections: NEW - 6.6.2 - Congress
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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-l 7, 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 he 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.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.5 - Circumstances for OTC safety are case-specific
Excerpt Text:
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.

Commenter Organization Name: Kwak, Eugene
Comment Number: 2005N-0345-EC13643
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kwak, Eugene
Comment Number: 2005N-0345-EC13643
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kwak, Eugene
Comment Number: 2005N-0345-EC13643

Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Soriano, Lauren
Comment Number: 2005N-0345-EC14388
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Moon, Kristin
Comment Number: 2005N-0345-EC1927
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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

Commenter Organization Name: Witherwax, Carol
Comment Number: 2005N-0345-EC193
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
When the product would help to benefit the majority of the people (in this case women) and assist in aleviating the unneccessary medical, social, and psycological impact on society if the drug was not dispensed.

Commenter Organization Name: Tuchinsky, Marla
Comment Number: 2005N-0345-EC201
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
To the extent that your interpretation is preventing women from getting access to a perfectly safe and effective drug, yes.

Commenter Organization Name: Levinson, R. Saul

Comment Number: 2005N-0345-EC297
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.2 - Approve simultaneous marketing approach (market both OTC and Rx)
NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 1.2 - Specific comments on drug approval process for Morning-after Pill/Plan B
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
As a medical provider, I believe that it is safe to have two products be legally market to the general public.

Commenter Organization Name: Duchon, Kathleen
Comment Number: 2005N-0345-EC426
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Katrib, Elise
Comment Number: 2005N-0345-EC516
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Ramirez, Robert
Comment Number: 2005N-0345-EC527
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
Yes, if clarification is needed iniate 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.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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 ideaology instead of science should be made available by any truly scientific health organization.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Camron, Kiera
Comment Number: 2005N-0345-EC811
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
FDA rules are much more readily available as meaningful information to typical consumers.

Commenter Organization Name: Holden, Karen
Comment Number: 2005N-0345-EC895
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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 partcular subgroup is beyond the legitimate interest of the FDA.

Commenter Organization Name: Mock, Suzanne
Comment Number: 2005N-0345-EC940
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Stockton, Melissa
Comment Number: 2005N-0345-EC99
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
More emphasis needs to be placed on one's ability to make and be responsible for decisions reguarding 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 a informed decision with information contained or distributed with the medicine.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
NEW - 5.1 - Yes
NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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 manufactures 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.

Commenter Organization Name: Tadeo, Peter
Comment Number: 2005N-0345-EMC373
Excerpt Number: 4
Excerpt Status: MODIFIED
Excerpt Text:
One of the risks of making more dugs 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.

Commenter Organization Name: Tadeo, Peter
Comment Number: 2005N-0345-EMC373
Excerpt Number: 9
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Tadeo, Peter
Comment Number: 2005N-0345-EMC373
Excerpt Number: 10
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Thames, Samuel

Comment Number: 2005N-0345-EMC374
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

Commenter Organization Name: Babalola, Abimbola
Comment Number: 2005N-0345-EMC383
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Babalola, Abimbola
Comment Number: 2005N-0345-EMC383
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

3.8.4 - Interpretation is clear in present form

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
In addition to 21 CRF 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).

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
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.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 13
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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).

Commenter Organization Name: Dorn, Kellie
Comment Number: 2005N-0345-EC117
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
I agree that if a medication is unsafe for some, it should remain as prescription only.

Commenter Organization Name: Thomas, Tiffany
Comment Number: 2005N-0345-EC13026
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Severance, Peter
Comment Number: 2005N-0345-EC135
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 3.8.7 - Cost-benefit concerns regarding rulemaking
Excerpt Text:
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.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 1
Excerpt Status: NEW

Excerpt Text:
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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kisly, Anne
Comment Number: 2005N-0345-EC212
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
No, I believe your previous guidelines are adequate. If it is safe without a practitioner's prescription then it should be available OTC.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
Excerpt Text:
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.

Commenter Organization Name: Llewellyn, Heather
Comment Number: 2005N-0345-EC325
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 1.2 - Specific comments on drug approval process for Morning-after Pill/Plan B
NEW - 4.4.1 - Legal arguments that little or no confusion exists
Excerpt Text:
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.

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 3.1 - Yes
Excerpt Text:
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

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 2

Excerpt Status: NEW
Excerpt Text:
There is no need to initiate any further rulemaking for codification of the action. It is quite clear in its present form.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
The current usage - where the molecule/drug is used for different purposes/doses it is either prescription or OTC - seems intelligent enough.

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
No, the policy in effect now is adequate.

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking
Excerpt Text:
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. It 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.

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839

Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 2.1 - Comments on time, manner, and nature of rulemaking process
Excerpt Text:
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.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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 adminstration). 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.

3.8.5 - Circumstances for OTC safety are case-specific

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403

Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
NEW - 3.8.6 - Develop/update guidance as alternative for rulemaking
Excerpt Text:
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.

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
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.

Commenter Organization Name: Paslawsky, JoAnn
Comment Number: 2005N-0345-EC1129
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Mershon, Claire-Helene
Comment Number: 2005N-0345-EC12379
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Hein, Rachel
Comment Number: 2005N-0345-EC168
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Kisly, Anne
Comment Number: 2005N-0345-EC212
Excerpt Number: 2
Excerpt Status: NEW

Excerpt Text:
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.

Commenter Organization Name: Kisly, Anne
Comment Number: 2005N-0345-EC212
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Decisions can be made on a case by case level.

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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 duel-marketing drugs' in this manner.

What if other drugs arise in the future and likewise the drug companies suppling 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.

Commenter Organization Name: Rosati, Lucia
Comment Number: 2005N-0345-EC76
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
I believe it is acceptable to consider drugs on a case-by-case basis.

Commenter Organization Name: Rosati, Lucia
Comment Number: 2005N-0345-EC76
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

3.8.6 - Develop/update guidance as alternative for rulemaking

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
NEW - 3.8.5 - Circumstances for OTC safety are case-specific
Excerpt Text:
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.

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Aventis Pharmaceuticals, Inc and Sanofi- Synthelabo, Inc.
Comment Number: 2005N-0345-C453
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
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,

Commenter Organization Name: Aventis Pharmaceuticals, Inc and Sanofi- Synthelabo, Inc.
Comment Number: 2005N-0345-C453
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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 (I) 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.

3.8.7 - Cost-benefit concerns regarding rulemaking

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
NEW - 5.4.3 - There is no confusion, therefore rulemaking unnecessary
Excerpt Text:
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.

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
Excerpt Text:
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.

Commenter Organization Name: Severance, Peter
Comment Number: 2005N-0345-EC135
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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.

Commenter Organization Name: Young, Stan
Comment Number: 2005N-0345-EC211
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 2.1 - Comments on time, manner, and nature of rulemaking process
Excerpt Text:
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.

Commenter Organization Name: Rommel, Scott

Comment Number: 2005N-0345-EC54
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
NO, This seems to be a problem waiting for a whole lot of money to be waisted on. Either a drug is over the counter or it is not.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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!

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments
Excerpt Text:
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.

3.8.8 - Other policy arguments opposing a rulemaking

Commenter Organization Name: University of California, San Franscisco
Comment Number: 2005N-0345-C320
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 3.2 - No

Excerpt Text:
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.

Commenter Organization Name: Ruckdeschel, Diana
Comment Number: 2005N-0345-C71
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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 0TC use or not?...It either is or it isn't!" "'Can't they make up their minds?"

Commenter Organization Name: Ladd, Judy
Comment Number: 2005N-0345-EC1032
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
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.

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:

It makes very little sense, if the drug is nessisary 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.

Commenter Organization Name: Slee, April
Comment Number: 2005N-0345-EC121
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Severance, Peter
Comment Number: 2005N-0345-EC135
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
No. Why are you complicating this? The FDA is supposed to regulate drugs based on clinical evidence, not make social policy.

Commenter Organization Name: Smith, Jennifer
Comment Number: 2005N-0345-EC157
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
Excerpt Text:
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?

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
No. The interpretation is too restrictive

Commenter Organization Name: Myers, Micah
Comment Number: 2005N-0345-EC319
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Bilz, Michael
Comment Number: 2005N-0345-EC4
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Has it done so for Ibuprofen? It is sold both ways today.

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Dolinski, Elizabeth
Comment Number: 2005N-0345-EC522
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.2 - Approve simultaneous marketing approach (market both OTC and Rx)
NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Porter, Rebecca
Comment Number: 2005N-0345-EC56
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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 controversay, difficulty, and perhaps even future lawsuits from consumers at the extreme.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 6
Excerpt Status: NEW

Other Sections: NEW - 3.2 - No
Excerpt Text:
I believe the rulemaking should stay as it is. And not go change policy, allowing duel-marketing of both a prescription drug product and simultaneously an OTC product. The FDA should remain firm on this issue in this regard.

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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. It 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.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Devine, Naomi
Comment Number: 2005N-0345-EC710
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
If the products are identical and for identical uses, all should be regulated.

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 2.1 - Comments on time, manner, and nature of rulemaking process
Excerpt Text:
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.

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Vander Bleek, Luke
Comment Number: 2005N-0345-EC870
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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.

Commenter Organization Name: Vander Bleek, Peter
Comment Number: 2005N-0345-EC882
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kopp, Margaret
Comment Number: 2005N-0345-EC903

Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Dalton, Mike
Comment Number: 2005N-0345-EMC166
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

3.9 - Examples of previous FDA actions in allowing simultaneous marketing of Rx and OTC products

3.9.1 - Drug approval examples

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 5
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 6.3.4 - Age limitations are in line with other meaningful differences
Excerpt Text:
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.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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 dysmenorrheal are prescription indications. These indications are closely related to the OTC indications.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
(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.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
(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 relive gas symptoms and indications tied to a particular subpopulation's state: gas pain in postoperative or endoscopic exam settings. See 21 CRF 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, brouchodilator, 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 this 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 CRF 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.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
(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 lopcramide, 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.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
(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.

Commenter Organization Name: Micro ICU Project
Comment Number: 2005N-0345-C5
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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!

Commenter Organization Name: White, Alan
Comment Number: 2005N-0345-EC1121
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: White, Alan
Comment Number: 2005N-0345-EC1121
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Clague, Alexander
Comment Number: 2005N-0345-EC13
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
NEW - 8.7 - Examples of Rx and OTC labeling that is similar but with one or two differences - e.g., dosage/age distinction
Excerpt Text:
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.

Commenter Organization Name: Kwak, Eugene
Comment Number: 2005N-0345-EC13643
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rahl, Michael
Comment Number: 2005N-0345-EC13845
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Soriano, Lauren
Comment Number: 2005N-0345-EC14388

Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.3.4 - Age limitations are in line with other meaningful differences
Excerpt Text:
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.

Commenter Organization Name: Corlette, Chauncey
Comment Number: 2005N-0345-EC14491
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.3.4 - Age limitations are in line with other meaningful differences
Excerpt Text:
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.

Commenter Organization Name: Scott, Cindy
Comment Number: 2005N-0345-EC148
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.8 - Examples of similar labeling of Rx and OTC products that are the same drug and dose, in the market place or previously marketed
Excerpt Text:
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.

Commenter Organization Name: Marshall, Laura
Comment Number: 2005N-0345-EC15
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155

Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Academy of Managed Care Pharmacy
Comment Number: 2005N-0345-EC15687
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
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.

Commenter Organization Name: Marcelli, Christian
Comment Number: 2005N-0345-EC16427
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Saling, Elle
Comment Number: 2005N-0345-EC16546
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Pepcid AC is sold as both prescription and over the counter as is Motrin.

Commenter Organization Name: Wilson, Rhianna
Comment Number: 2005N-0345-EC186
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Morrisroe, Julia
Comment Number: 2005N-0345-EC194
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
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.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
This same situation has worked for Claritin. It is now available OTC and by prescription. No other law making is necessary.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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)

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
It is legal. For example, I currently have OTC Prilosec in my pharmacy AND a prescription-only omeprazole.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 3

Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
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.

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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 Ibuprofin 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.

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
Excerpt Text:
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).

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Socha, Kathleen
Comment Number: 2005N-0345-EC678
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
I take a drug sold both ways. I buy by prescription because my insurance pays for it that way.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: Macdonell, Megan
Comment Number: 2005N-0345-EC779
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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).

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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.

Commenter Organization Name: Burns, Ben
Comment Number: 2005N-0345-EC93
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
Excerpt Text:
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.

Commenter Organization Name: Trubow, Marshall
Comment Number: 2005N-0345-EC95
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 17
Excerpt Status: NEW
Other Sections: NEW - 8.8 - Examples of similar labeling of Rx and OTC products that are the same drug and dose, in the market place or previously marketed

Excerpt Text:
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.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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 adminstration). 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.

Commenter Organization Name: Syed, Misbah
Comment Number: 2005N-0345-EMC368
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 3.3.3 - Other arguments related to FD&C Act
NEW - 4.1 - Yes
NEW - 5.1 - Yes
Excerpt Text:
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 nausia 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 mourning-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.

3.9.2 - FDA guidance or other documents (e.g., FDA 1999 Manual of Policy and Procedures (MAPP) statements, testimony, letters to industry, Q&As)

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
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 o-f 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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 14
Excerpt Status: NEW
Excerpt Text:
"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).

3.9.3 - Veterinary drug policy

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 15
Excerpt Status: NEW
Excerpt Text:
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.

3.9.4 - Other examples

3.10 - Examples of FDA actions disallowing simultaneous marketing

Commenter Organization Name: Aventis Pharmaceuticals, Inc and Sanofi- Synthelabo, Inc.
Comment Number: 2005N-0345-C453
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
FDA has consistently interpreted section 503(b)(l) 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.

Commenter Organization Name: Kuskey, Garvan
Comment Number: 2005N-0345-EC793
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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.

3.11 - Miscellaneous arguments/discussions

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 41
Excerpt Status: NEW

Other Sections: NEW - 1.2 - Specific comments on drug approval process for Morning-after Pill/Plan B

NEW - 1.2.3 - Maintain Rx only

NEW - 3.5.1 - SNDA/NDA regulatory arguments supporting rulemaking

Excerpt Text:

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.]

Commenter Organization Name: Thomas, Tiffany
Comment Number: 2005N-0345-EC13026
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Thomas, Tiffany
Comment Number: 2005N-0345-EC13026
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Thomas, Tiffany
Comment Number: 2005N-0345-EC13026
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Hibberd, Rachel
Comment Number: 2005N-0345-EC196
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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 justfified, 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.

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
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.

Commenter Organization Name: Zahn, Steven
Comment Number: 2005N-0345-EC52
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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 cirucmstances 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.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
And I think that the studies for this should be conducted by someone other than the drug comapny 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.

4 - Is there significant confusion regarding interpretation of section 503(b) of the act? [ANPRM Q 1.B.]

4.1 - Yes

Commenter Organization Name: Aventis Pharmaceuticals, Inc and Sanofi- Synthelabo, Inc.
Comment Number: 2005N-0345-C453
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.6 - Develop/update guidance as alternative for rulemaking
Excerpt Text:
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,

Commenter Organization Name: Ladd, Judy
Comment Number: 2005N-0345-EC1032
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
This is unclear and opens a pandora's box of abuses by the pharmaceutical companies.

Commenter Organization Name: Ladd, Judy
Comment Number: 2005N-0345-EC1032
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Completely.

Commenter Organization Name: Speight, Thomas
Comment Number: 2005N-0345-EC1041
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
Yes, if the FDA has finally gotten around to realizing that it needs to be rulemaking.

Commenter Organization Name: Shaffer, Kathleen
Comment Number: 2005N-0345-EC106
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
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 clarfication as to when you are discussing the ingredient drug versus the medicine drug

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Definitly, because I am certianly confused.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Dougherty, Anne
Comment Number: 2005N-0345-EC126
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Most consumers do not understand section 503(b)

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 5.1 - Yes
Excerpt Text:
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).

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
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.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
Significant confusion exists, especially in light on concerns that section 503(b)'s criteria may unfairly and negatively impact accessibility to legal and scientifically-validated medications.

Commenter Organization Name: Severance, Peter
Comment Number: 2005N-0345-EC135
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
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.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
There is significant confusion in regarding the FDA?s interpretation of section 503[b].

Commenter Organization Name: Connors, Meaghan
Comment Number: 2005N-0345-EC141
Excerpt Number: 2
Excerpt Status: NEW

Excerpt Text:
Confusion at best, disillusionment at worst.

Commenter Organization Name: Loomis, Shirley
Comment Number: 2005N-0345-EC147
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
There's significant confusion regarding all regulations. It's what keeps your lawyers working.

Commenter Organization Name: Marshall, Laura
Comment Number: 2005N-0345-EC15
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
I would say so; confusion and rumor, not to mention bad PR for the FDA.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
There is some confusion regarding the Agency's interpretation of the statute.

Commenter Organization Name: Hein, Rachel
Comment Number: 2005N-0345-EC168
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
yes...why are you holding up the release of a scientifically approved drug for prescription requirements that would lend the drug ineffective?

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.4.2 - Policy arguments that little or no confusion exists
Excerpt Text:
Affirmitive, you seem quite confused between your role in approving drugs on scientific merit and benefit (vs social engineering and backdoor legisalated morality).

Commenter Organization Name: Moon, Kristin
Comment Number: 2005N-0345-EC1927
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Dowell, Duane
Comment Number: 2005N-0345-EC195
Excerpt Number: 2

Excerpt Status: NEW
Excerpt Text:
There seems to be confusion at the FDA.

Commenter Organization Name: Hibberd, Rachel
Comment Number: 2005N-0345-EC196
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
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.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
It would seem so.

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Apparently there is, since this question came up.

Commenter Organization Name: Endris, Kelle
Comment Number: 2005N-0345-EC278
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
YES

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
In the particular case of emergency contraception - Plan B, yes. It is not clear why the FDA believes this section falls short.

Commenter Organization Name: McLeod, Doug
Comment Number: 2005N-0345-EC364
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 1.2.2 - Approve simultaneous marketing approach (market both OTC and Rx)
Excerpt Text:

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.

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.3.2 - Diverse industry and public opinion/reaction to ANPRM and statements re: FDA's authority
Excerpt Text:
YES! I think the public and providers are very confused about the process and the length of time it takes to make a decision.

Commenter Organization Name: Labbe, Carl
Comment Number: 2005N-0345-EC408
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes, the section is open to various interpretations.

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 2.2 - Support ANPRM request for comments
Excerpt Text:
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 alterior 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.

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes - to a degree.

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
YES

Commenter Organization Name: Katrib, Elise
Comment Number: 2005N-0345-EC516

Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.5 - Miscellaneous arguments/discussions
Excerpt Text:
Yes, it seems that given enough pressure or money, a drug will be able to overcome FDA interpretation of any act.

Commenter Organization Name: Kowalczyk, Brigid
Comment Number: 2005N-0345-EC518
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
there is significan confusion.

Commenter Organization Name: Zahn, Steven
Comment Number: 2005N-0345-EC52
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: McGhee, Tim
Comment Number: 2005N-0345-EC53
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes, the FDA's interpretation would create legal confusion.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Billingsley, Daniel
Comment Number: 2005N-0345-EC609
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
I believe there is a lot of confusion.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 4.3.3 - Other legal arguments/conclusions supporting confusion re: FDA's interpretation
NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:

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 sp,e 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.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.2 - Diverse industry and public opinion/reaction to ANPRM and statements re: FDA's authority
Excerpt Text:
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.

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
Yes, when applied to the particular application concerning "Plan B".

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Carter, Thomas
Comment Number: 2005N-0345-EC691
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes - I am not even sure what it is!!

Commenter Organization Name: Devine, Naomi
Comment Number: 2005N-0345-EC710
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
Yes, there is confusion. It is hard to understand why a drug should be prescription for some and over the counter for others.

Commenter Organization Name: Gorini, Joseph
Comment Number: 2005N-0345-EC717
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
If the FDA applies section 503(b) it would ceate confusion by seeming to accept Plan B as falling under FDA's concern for 'health and safety.' See General Comment.

Commenter Organization Name: Ricci, Stephen
Comment Number: 2005N-0345-EC73
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Rosati, Lucia
Comment Number: 2005N-0345-EC76
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Phlips, Thomas
Comment Number: 2005N-0345-EC788
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Kuskey, Garvan
Comment Number: 2005N-0345-EC793
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
yes

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Information regarding this interpretation is not well understood by the general public today.

Commenter Organization Name: Aengst, Jennifer
Comment Number: 2005N-0345-EC921
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Burns, Ben

Comment Number: 2005N-0345-EC93
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
yes there is a lot of confusion over it.

Commenter Organization Name: Trubow, Marshall
Comment Number: 2005N-0345-EC95
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
Apparently, there is confusion since the FDA chose not approve Plan B for OTC use for adults.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
NEW - 8.1 - Yes
Excerpt Text:
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 were marketing the drug as both over the counter and prescription is the most practical approach. Imposing age restrictions on the purchase drugs, such a 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.

Commenter Organization Name: Syed, Misbah
Comment Number: 2005N-0345-EMC368
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 3.3.3 - Other arguments related to FD&C Act
NEW - 3.9.1 - Drug approval examples
NEW - 5.1 - Yes
Excerpt Text:
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 nausia 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 mourning-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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 6.1 - Yes
NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.3 - Other legal arguments/conclusions supporting confusion re: FDA's interpretation
Excerpt Text:
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.

4.2 - No

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.7 - Cost-benefit concerns regarding rulemaking
NEW - 5.4.3 - There is no confusion, therefore rulemaking unnecessary
Excerpt Text:
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.

Commenter Organization Name: Family Planning Advocates of New York State
Comment Number: 2005N-0345-C61
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 5.2 - No
Excerpt Text:
In response to the questions posed in RIN 0910-AF72, FPA believes the first three questions (lA, 1B and lC) 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.

Commenter Organization Name: Black, Jerrold
Comment Number: 2005N-0345-EC111
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
no

Commenter Organization Name: Paslawsky, JoAnn
Comment Number: 2005N-0345-EC1129
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.3.2 - Diverse industry and public opinion/reaction to ANPRM and statements re: FDA's authority
Excerpt Text:
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.

Commenter Organization Name: Slee, April
Comment Number: 2005N-0345-EC121
Excerpt Number: 2
Excerpt Status: MODIFIED
Excerpt Text:
No, I think the interpretation is reasonable and correct.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
NEW - 4.4.1 - Legal arguments that little or no confusion exists
Excerpt Text:
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.

Commenter Organization Name: Smart, Stephanie
Comment Number: 2005N-0345-EC16
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No, but I do not agree with the interpretation.

Commenter Organization Name: Jones, Kim
Comment Number: 2005N-0345-EC16543
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.4.2 - Policy arguments that little or no confusion exists
Excerpt Text:
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.

Commenter Organization Name: Jones, Kim
Comment Number: 2005N-0345-EC16543
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
There is no confusion.

Commenter Organization Name: Murphy, Cynthia
Comment Number: 2005N-0345-EC176
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 3

Excerpt Status: NEW
Excerpt Text:
no.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
I disagree that there is confusion over this issue.

Commenter Organization Name: Young, Stan
Comment Number: 2005N-0345-EC211
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.4.2 - Policy arguments that little or no confusion exists
Excerpt Text:
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.

Commenter Organization Name: Rankis, A
Comment Number: 2005N-0345-EC22
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No,

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
only by the FDA who are more politically bound!

Commenter Organization Name: Cepeda, Baudi
Comment Number: 2005N-0345-EC226
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 4

Excerpt Status: NEW
Excerpt Text:
No, there should be no confusion regarding the FDA?s interpretation of Section 503(b)(1).

Commenter Organization Name: Levinson, R. Saul
Comment Number: 2005N-0345-EC297
Excerpt Number: 2
Excerpt Status: MODIFIED
Excerpt Text:
No confusion.... just old fashioned politics are entering into FDAs interpretation of section 503(b) of the act.

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
The confusion is imagined on the part of the FDA. I belive 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.

Commenter Organization Name: Hagan, Jane
Comment Number: 2005N-0345-EC32
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.4.2 - Policy arguments that little or no confusion exists
Excerpt Text:
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.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418

Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: Duchon, Kathleen
Comment Number: 2005N-0345-EC426
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No, but it does need to be update as the world issues broaden and expand

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
NO.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Della Paolera, Mark
Comment Number: 2005N-0345-EC555
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
I myself, am not confused by 503(b) as explained on your web site here.

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 3
Excerpt Status: NEW

Excerpt Text:
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.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.4.2 - Policy arguments that little or no confusion exists
Excerpt Text:
No. If there were, it would have come up long before now

Commenter Organization Name: Peer, Gerald
Comment Number: 2005N-0345-EC626
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.4.2 - Policy arguments that little or no confusion exists
Excerpt Text:
Not in the past. Confusion is building due to special interest pressure.

Commenter Organization Name: Vrankar, Anna
Comment Number: 2005N-0345-EC668
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
no

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
no

Commenter Organization Name: Socha, Kathleen
Comment Number: 2005N-0345-EC678
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:

No.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No, there is not significant confusion.

Commenter Organization Name: Carlson, Brent
Comment Number: 2005N-0345-EC77
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Smith, Rodney
Comment Number: 2005N-0345-EC83
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Oyola, Sandra
Comment Number: 2005N-0345-EC85
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
I do not feel there is.

Commenter Organization Name: Vander Bleek, Luke
Comment Number: 2005N-0345-EC870
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: Kopp, Margaret
Comment Number: 2005N-0345-EC903
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.4.2 - Policy arguments that little or no confusion exists
Excerpt Text:
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.

Commenter Organization Name: Hawkins, Susan
Comment Number: 2005N-0345-EC91
Excerpt Number: 2
Excerpt Status: NEW

Excerpt Text:
I do not believe so.

Commenter Organization Name: Wurtz, Richard
Comment Number: 2005N-0345-EC94
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: Wurtz, Richard
Comment Number: 2005N-0345-EC94
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: Brakman, Anita
Comment Number: 2005N-0345-EC97
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Stockton, Melissa
Comment Number: 2005N-0345-EC99
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No.

4.3 - Arguments supporting significant confusion regarding FDA's interpretation

4.3.1 - FDA's interpretation of FD&C Act 505(b)(2) conflicts with interpretation of 503(b)

Commenter Organization Name: Aventis Pharmaceuticals, Inc and Sanofi- Synthelabo, Inc.
Comment Number: 2005N-0345-C453
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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 QTC 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.

Commenter Organization Name: Aventis Pharmaceuticals, Inc and Sanofi- Synthelabo, Inc.
Comment Number: 2005N-0345-C453
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

4.3.2 - Diverse industry and public opinion/reaction to ANPRM and statements re: FDA's authority

Commenter Organization Name: Paslawsky, JoAnn
Comment Number: 2005N-0345-EC1129
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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).

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 21
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Pechacek, Deborah
Comment Number: 2005N-0345-EC27
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Obviously there is since the Drug company is asking you to do something that I thought was not legal.

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
YES! I think the public and providers are very confused about the process and the length of time it takes to make a decision.

Commenter Organization Name: Dolinski, Elizabeth
Comment Number: 2005N-0345-EC522
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
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.

4.3.3 - Other legal arguments/conclusions supporting confusion re: FDA's

interpretation

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Owens, B
Comment Number: 2005N-0345-EC14261
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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).

Commenter Organization Name: Collum, Mark
Comment Number: 2005N-0345-EC33
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 6

Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
NEW - 4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation
Excerpt Text:
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 sp,e 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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
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.

4.3.4 - Other policy arguments/statements supporting confusion re: FDA's interpretation

Commenter Organization Name: Speight, Thomas
Comment Number: 2005N-0345-EC1041
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
Yes, if the FDA has finally gotten around to realizing that it needs to be rulemaking.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
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 clarfication as to when you are discussing the ingredient drug versus the medicine drug

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
Significant confusion exists, especially in light on concerns that section 503(b)'s criteria may unfairly and

negatively impact accessibility to legal and scientifically-validated medications.

Commenter Organization Name: Severance, Peter
Comment Number: 2005N-0345-EC135
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Morrisroe, Julia
Comment Number: 2005N-0345-EC194
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Hibberd, Rachel
Comment Number: 2005N-0345-EC196
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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 interepretion for political gains.

Commenter Organization Name: Richman, Bobbi
Comment Number: 2005N-0345-EC21
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: McGhee, Tim
Comment Number: 2005N-0345-EC53
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Leonard, Ruth Tehila
Comment Number: 2005N-0345-EC59
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
I can see no reason why an identical product will have to be given by perscription for one person and free for purchase to another. I suggest you allow certain people to carry open perscriptions for products they need regularly for a particular medical condition, but otherwise substances with the same active engredients 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 perscription.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
NEW - 4.3.3 - Other legal arguments/conclusions supporting confusion re: FDA's interpretation
Excerpt Text:
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 sp,e 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.

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
Yes, when applied to the particular application concerning "Plan B".

Commenter Organization Name: Devine, Naomi
Comment Number: 2005N-0345-EC710
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
Yes, there is confusion. It is hard to understand why a drug should be prescription for some and over the counter for others.

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Holden, Karen
Comment Number: 2005N-0345-EC895
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
Apparently, there is confusion since the FDA chose not approve Plan B for OTC use for adults.

4.4 - Arguments indicating that little or no confusion exists

4.4.1 - Legal arguments that little or no confusion exists

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.

Comment Number: 2005N-0345-C414
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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).

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 16
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
NEW - 4.2 - No

Excerpt Text:
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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 1.2 - Specific comments on drug approval process for Morning-after Pill/Plan B
NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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.

4.4.2 - Policy arguments that little or no confusion exists

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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.

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

Comment Number: 2005N-0345-C415
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Jones, Kim
Comment Number: 2005N-0345-EC16543
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
Excerpt Text:
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.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
Affirmitive, you seem quite confused between your role in approving drugs on scientific merit and benefit (vs social engineering and backdoor legisalated morality).

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
Excerpt Text:
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.

Commenter Organization Name: Hagan, Jane
Comment Number: 2005N-0345-EC32
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
Excerpt Text:
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.

Commenter Organization Name: Lamermayer, Richard J

Comment Number: 2005N-0345-EC43
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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).

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
Excerpt Text:
No. If there were, it would have come up long before now

Commenter Organization Name: Peer, Gerald
Comment Number: 2005N-0345-EC626
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
Excerpt Text:
Not in the past. Confusion is building due to special interest pressure.

Commenter Organization Name: Socha, Kathleen
Comment Number: 2005N-0345-EC678
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
I think the problem lies in trying to limit the age to purchase the OTC drug.

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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 presidence for a number of OTC formulations and similar drugs only availble 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.

Commenter Organization Name: Kopp, Margaret
Comment Number: 2005N-0345-EC903
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 4.2 - No
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

4.5 - Miscellaneous arguments/discussions

Commenter Organization Name: Reynolds, Charles
Comment Number: 2005N-0345-EC12
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
Excerpt Text:
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.

Commenter Organization Name: Llewellyn, Heather
Comment Number: 2005N-0345-EC325
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Anspach, Kurt
Comment Number: 2005N-0345-EC447
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Parts of the statement is 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 throught the media.

Commenter Organization Name: Katrib, Elise
Comment Number: 2005N-0345-EC516
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
Excerpt Text:
Yes, it seems that given enough pressure or money, a drug will be able to overcome FDA interpretation of any act.

Commenter Organization Name: Kowalczyk, Brigid
Comment Number: 2005N-0345-EC518
Excerpt Number: 4
Excerpt Status: NEW

Excerpt Text:
No drug should be sold both by prescription and OTC.

Commenter Organization Name: Zahn, Steven
Comment Number: 2005N-0345-EC52
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 19
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No confusion regarding present practice; plenty of confusion over what may happen in the future.

Commenter Organization Name: Townsend, Elisha
Comment Number: 2005N-0345-EC90
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
There are other drugs that have age limits such a tobacco and alcohol. However both of those have proven negative side effects, and are not also prescription.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 1.2 - Specific comments on drug approval process for Morning-after Pill/Plan B
Excerpt Text:
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.

Commenter Organization Name: Etter, Eleanor
Comment Number: 2005N-0345-EC96
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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 FDAs scientists recommend one course of action and the agency acts against that recommendation, the public's trust of the agency is understandably undermined.

5 - Would rulemaking for clarification dispel confusion? [ANPRM Q 1.C.]

5.1 - Yes

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes, a rule would clarify the confusion by stating what actions are to be taken.

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 4.1 - Yes
Excerpt Text:
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).

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.7.1 - Other legal arguments supporting rulemaking
NEW - 5.3.1 - Legal arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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 constituents a prescription drug or an OTC drug.

Commenter Organization Name: Connors, Meaghan
Comment Number: 2005N-0345-EC141
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Hopefully.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 5.5 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Marshall, Laura
Comment Number: 2005N-0345-EC15
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes, just give us the rulemakeing.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
Yes, a well developed regulation that codifies the Agency's interpretation of Section 503(b) should reduce confusion.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 22
Excerpt Status: NEW
Excerpt Text:
Codifying the Agency's interpretation of Section 503(b) would be a step towards dispelling that confusion.

Commenter Organization Name: Dowell, Duane
Comment Number: 2005N-0345-EC195

Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
That is not likely

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Pechacek, Deborah
Comment Number: 2005N-0345-EC27
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
YES!

Commenter Organization Name: Hudson, Ralph
Comment Number: 2005N-0345-EC34
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
It may dispel that confusion, if done correctly, but it will not "dispet" that confusion, as is written on your webpage.

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
I would think so.

Commenter Organization Name: Labbe, Carl
Comment Number: 2005N-0345-EC408
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 5

Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
YES

Commenter Organization Name: Kowalczyk, Brigid
Comment Number: 2005N-0345-EC518
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
If there is confusion on any issue, wouldn't making a rule to dispell the confusion take it away. I don't believe this question is even worth asking.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
I think that a more defined set of rules would help alleviate the confusion.

Commenter Organization Name: Peer, Gerald
Comment Number: 2005N-0345-EC626
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 3

Excerpt Status: NEW
Other Sections: NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Carter, Thomas
Comment Number: 2005N-0345-EC691
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
It would seem so, although I do not know what the ramifications of such a rulemaking would be.

Commenter Organization Name: Ricci, Stephen
Comment Number: 2005N-0345-EC73
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
It is more likely

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 5.3.1 - Legal arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

Commenter Organization Name: Aengst, Jennifer
Comment Number: 2005N-0345-EC921
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

Commenter Organization Name: Burns, Ben
Comment Number: 2005N-0345-EC93
Excerpt Number: 3

Excerpt Status: NEW
Excerpt Text:
it probably would.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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 manufactures 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.

Commenter Organization Name: Syed, Misbah
Comment Number: 2005N-0345-EMC368
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 3.3.3 - Other arguments related to FD&C Act
NEW - 3.9.1 - Drug approval examples
NEW - 4.1 - Yes
Excerpt Text:
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 nausia 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 mourning-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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 5.3.1 - Legal arguments supporting rulemaking to dispel confusion
NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

5.2 - No

Commenter Organization Name: Family Planning Advocates of New York State
Comment Number: 2005N-0345-C61
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.2 - No
NEW - 4.2 - No
Excerpt Text:
In response to the questions posed in RIN 0910-AF72, FPA believes the first three questions (lA, 1B and lC) 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.

Commenter Organization Name: Shaffer, Kathleen
Comment Number: 2005N-0345-EC106
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: White, Alan
Comment Number: 2005N-0345-EC1121
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 1.2.2 - Approve simultaneous marketing approach (market both OTC and Rx)
NEW - 2.1 - Comments on time, manner, and nature of rulemaking process
Excerpt Text:

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).

Commenter Organization Name: Paslawsky, JoAnn
Comment Number: 2005N-0345-EC1129
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No, I believe a rulemaking would simply provide additional opportunities for clouding the issue when it is conveyed to the public.

Commenter Organization Name: Severance, Peter
Comment Number: 2005N-0345-EC135
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: Loomis, Shirley
Comment Number: 2005N-0345-EC147
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No. You will not dispel confusion. You may just simply be better able to serve the American public.

Commenter Organization Name: Hein, Rachel
Comment Number: 2005N-0345-EC168
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
no...please follow previous rulemaking precedents and release the drug for use.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
Excerpt Text:
No. A reminder to the FDA that its role is to approve or dissapprove drugs for use based on potential harm and validity of claims is needed.

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 4
Excerpt Status: NEW

Excerpt Text:
no.

Commenter Organization Name: Hibberd, Rachel
Comment Number: 2005N-0345-EC196
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No. No amount of rulemaking (barring the overturn of Roe v. Wade) will change the politics involved.

Commenter Organization Name: Young, Stan
Comment Number: 2005N-0345-EC211
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Rankis, A
Comment Number: 2005N-0345-EC22
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: Cepeda, Baudi
Comment Number: 2005N-0345-EC226
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No, the FDA can simply make transparent and concrete the basis for its decision.

Commenter Organization Name: Collum, Mark
Comment Number: 2005N-0345-EC33
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
NO! More rules only add to the confusion. Medicine & Pharmacy are too highly regulated as it is. More

rules = more confusion.

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 5.4.2.2 - Other policy arguments
Excerpt Text:
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.

Commenter Organization Name: Anspach, Kurt
Comment Number: 2005N-0345-EC447
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
no!

Commenter Organization Name: McGhee, Tim
Comment Number: 2005N-0345-EC53
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
I find this to be unlikely.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Billingsley, Daniel
Comment Number: 2005N-0345-EC609
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
I don't believe a new rulemaking on confusing rule would help.

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
no

Commenter Organization Name: Socha, Kathleen
Comment Number: 2005N-0345-EC678
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:

Only to you.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Gorini, Joseph
Comment Number: 2005N-0345-EC717
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 5.4.2.2 - Other policy arguments
Excerpt Text:
I fear that rulemaking on this issue would only further codify the opinion driven barriers which prevent scientific recommendation from being heeded.

Commenter Organization Name: Phlips, Thomas
Comment Number: 2005N-0345-EC788
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Vander Bleek, Luke
Comment Number: 2005N-0345-EC870
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: Trubow, Marshall
Comment Number: 2005N-0345-EC95
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Doubtful. We don't need more rules- we need some basic common sense to prevail, and have the politicians stay out of this.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951

Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 5.4.1 - Legal arguments that rulemaking would not clarify
Excerpt Text:
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.

Commenter Organization Name: Etter, Eleanor
Comment Number: 2005N-0345-EC96
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 2.1 - Comments on time, manner, and nature of rulemaking process
Excerpt Text:
No. Using "rulemaking" to delay approval would not help

Commenter Organization Name: Brakman, Anita
Comment Number: 2005N-0345-EC97
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No

5.3 - Arguments that support concept that a rulemaking would provide clarification

5.3.1 - Legal arguments supporting rulemaking to dispel confusion

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.7.1 - Other legal arguments supporting rulemaking
NEW - 5.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: McLeod, Doug
Comment Number: 2005N-0345-EC364
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes

Excerpt Text:
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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes
NEW - 5.3.2 - Policy arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

5.3.2 - Policy arguments supporting rulemaking to dispel confusion

Commenter Organization Name: Dougherty, Anne
Comment Number: 2005N-0345-EC126
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes
Excerpt Text:
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 constituents a prescription drug or an OTC drug.

Commenter Organization Name: Soriano, Lauren
Comment Number: 2005N-0345-EC14388
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Marshall, Laura
Comment Number: 2005N-0345-EC15
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Levinson, R. Saul
Comment Number: 2005N-0345-EC297
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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*

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes
Excerpt Text:
If there is confusion on any issue, wouldn't making a rule to dispell the confusion take it away. I don't believe this question is even worth asking.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Oyola, Sandra
Comment Number: 2005N-0345-EC85
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes, because consumers and manufacturers will have a better understanding of the regulations.

Commenter Organization Name: Aengst, Jennifer
Comment Number: 2005N-0345-EC921
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.1 - Rulemaking will improve future FDA decisions (clarity, consistency, efficiency)
NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
NEW - 5.1 - Yes
Excerpt Text:
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 manufactures 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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
Excerpt Text:
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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes
NEW - 5.3.1 - Legal arguments supporting rulemaking to dispel confusion
Excerpt Text:
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.

5.4 - Arguments that a rulemaking would not provide clarification

5.4.1 - Legal arguments that rulemaking would not clarify

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 17
Excerpt Status: NEW
Excerpt Text:
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 2l-04S/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 2l-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).

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 5.2 - No
Excerpt Text:
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.

5.4.2 - Policy arguments that rulemaking would not clarify

Commenter Organization Name: Brakman, Anita
Comment Number: 2005N-0345-EC97
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:

There is no confusion, only politically motivated delay.

5.4.2.1 - Guidance instead of rulemaking

5.4.2.2 - Other policy arguments

Commenter Organization Name: Hibberd, Rachel
Comment Number: 2005N-0345-EC196
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Richman, Bobbi
Comment Number: 2005N-0345-EC21
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 1.3 - Specific comments about other drug product
Excerpt Text:
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 CORRUPTI0N 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.

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 5.2 - No
Excerpt Text:
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.

Commenter Organization Name: Anspach, Kurt
Comment Number: 2005N-0345-EC447
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
If there was a rulemaking how would the people know were to look for it?How many people know to go on the FDA website?

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 5.2 - No
Excerpt Text:
I fear that rulemaking on this issue would only further codify the opinion driven barriers which prevent scientific recommendation from being heeded.

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

5.4.3 - There is no confusion, therefore rulemaking unnecessary

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.7 - Cost-benefit concerns regarding rulemaking
NEW - 4.2 - No
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: White, Alan
Comment Number: 2005N-0345-EC1121
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:

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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
No, because there is no confusion.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 1.2.2 - Approve simultaneous marketing approach (market both OTC and Rx)
Excerpt Text:
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.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
There is no significant confusion to be dispelled.

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
I am unaware of the definition for the word "dispet" 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 it's job, and do not have a problem with their interpretation of what has been entered into the code of law governing FDA.

5.5 - Miscellaneous arguments/discussions

Commenter Organization Name: Ladd, Judy
Comment Number: 2005N-0345-EC1032
Excerpt Number: 4
Excerpt Status: NEW

Excerpt Text:
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.

Commenter Organization Name: Speight, Thomas
Comment Number: 2005N-0345-EC1041
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
If such a rulemaking would not in any way change the intent or action of the section's language, yes.

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Rules can alleviate confusion or they can make it worse. The nice thing about rules is they provide grounds for further action.

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Maybe so, but more than likely it will restrict the process of issuing drugs even further.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 5.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Morrisroe, Julia
Comment Number: 2005N-0345-EC194
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
If you rule that access is a right for all women.

Commenter Organization Name: Gay, Sarah
Comment Number: 2005N-0345-EC199
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Llewellyn, Heather
Comment Number: 2005N-0345-EC325
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Bilz, Michael
Comment Number: 2005N-0345-EC4
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Dolinski, Elizabeth
Comment Number: 2005N-0345-EC522
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Vrankar, Anna
Comment Number: 2005N-0345-EC668
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
only if the rule made it clear that if a prescription is required, it is universally required.

Commenter Organization Name: Holden, Karen
Comment Number: 2005N-0345-EC895

Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Townsend, Elisha
Comment Number: 2005N-0345-EC90
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
I'm not so sure. We are trying to change the rules so that our descrimination 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.

6 - If FDA limited sale of OTC product to sub-population, would FDA be able to enforce limitation as a matter of law? [ANPRM Q 2.A.]

6.1 - Yes

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 6.3.1 - FD&C Act
NEW - 7.1 - Yes
Excerpt Text:
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.. ." (FFDCA, 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.

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.3.5 - Other legal/policy arguments
Excerpt Text:
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.

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
Sure. In California, the sale of over the counter sinus medication (used in the production of methanphetimines) is restricted to people with an ID stating that they are over 18 years of age. This seems to be working.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
Excerpt Text:

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 br held accountable to enforce the limitation on the sale of the product.

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
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 where 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.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
The FDA would be able to enforce the limitation as a matter of law to the sale of OTC product to a subpopulation.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
I believe that the FDA can enforce whatever it wants or needs to.

Commenter Organization Name: Yao, Yvonne
Comment Number: 2005N-0345-EC1565
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160

Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Hutson, Paul
Comment Number: 2005N-0345-EC162
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
Yes, if the non-prescription sale was made through a licensed pharmacy and by a licensed pharmacist, PA, or NP.

Commenter Organization Name: Reusch, Elizabeth
Comment Number: 2005N-0345-EC165
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
Yes, as a matter of law, the FDA can enforce a subpopulation limitation on the sale of an OTC product.

Commenter Organization Name: Ross, Angela
Comment Number: 2005N-0345-EC172
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Murphy, Cynthia
Comment Number: 2005N-0345-EC176
Excerpt Number: 4
Excerpt Status: NEW

Excerpt Text:
Yes, but why would it want to.

Commenter Organization Name: Murphy, Cynthia
Comment Number: 2005N-0345-EC176
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.3.5 - Other legal/policy arguments
NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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)

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.3.5 - Other legal/policy arguments
Excerpt Text:
yes. Laws would be made to make sure of that.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
Absolutely.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Dietz, Ken
Comment Number: 2005N-0345-EC217
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 6.6.4 - Other entities
Excerpt Text:
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?

Commenter Organization Name: Cepeda, Baudi
Comment Number: 2005N-0345-EC226
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
YES

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
The FDA has the legal authority to restrict an OTC product in this manner

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 6.3.1 - FD&C Act
NEW - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
Excerpt Text:
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.

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement

Excerpt Text:
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.

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes. Other items have been regulated in a similar fashion.

Commenter Organization Name: Endris, Kelle
Comment Number: 2005N-0345-EC278
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Possibly.

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.3.5 - Other legal/policy arguments
Excerpt Text:
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.

Commenter Organization Name: Wu, Jackie
Comment Number: 2005N-0345-EC307
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418

Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Duchon, Kathleen
Comment Number: 2005N-0345-EC426
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
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?

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Legally, FDA would probably be able to enforce such a limitation.

Commenter Organization Name: Clason, Dennis
Comment Number: 2005N-0345-EC47
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Katrib, Elise
Comment Number: 2005N-0345-EC516
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Yes it is possible to sell to a subpopulation.

Commenter Organization Name: Zahn, Steven
Comment Number: 2005N-0345-EC52
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.3.2 - No laws prevent the policy
Excerpt Text:
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.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
Regulations based on age have existed in this country since it's onset. Voting was the first restriction, tobacco and alcohol have legal ages for purchase at stores across the country.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Carter, Thomas
Comment Number: 2005N-0345-EC691
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes, I believe so.

Commenter Organization Name: Dawson, Jennifer

Comment Number: 2005N-0345-EC7
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes, the limitation would be easily enforceable.

Commenter Organization Name: Rosati, Lucia
Comment Number: 2005N-0345-EC76
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
The FDA through the pharmacy chains would be able to enforce it just as they enforce any other prescription medication.

Commenter Organization Name: Carlson, Brent
Comment Number: 2005N-0345-EC77
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Phlips, Thomas
Comment Number: 2005N-0345-EC788
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Probably.

Commenter Organization Name: Smith, Rodney
Comment Number: 2005N-0345-EC83
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Oberst, Sara
Comment Number: 2005N-0345-EC860
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
Yes, the FDA should be able to sanction pharmacists or pharmacies that are not in compliance.

Commenter Organization Name: Townsend, Elisha
Comment Number: 2005N-0345-EC90
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
They could, but they should not.

Commenter Organization Name: Mock, Suzanne
Comment Number: 2005N-0345-EC940

Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
I believe this could occur.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
As mentioned above, such limitations on alcohol and tobacco are widespread and enforceable.

Commenter Organization Name: Brakman, Anita
Comment Number: 2005N-0345-EC97
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Syed, Misbah
Comment Number: 2005N-0345-EMC368
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 4.1 - Yes
NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374

Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.3.5 - Other legal/policy arguments
NEW - 7.1 - Yes
Excerpt Text:
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.

6.2 - No

Commenter Organization Name: Alterton, Faith
Comment Number: 2005N-0345-C83
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
NO.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Black, Jerrold

Comment Number: 2005N-0345-EC111
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
no

Commenter Organization Name: Slee, April
Comment Number: 2005N-0345-EC121
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.3.4 - Age limitations are in line with other meaningful differences
Excerpt Text:
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.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
Excerpt Text:
"Enforcement" should not be the FDA's primary responsibilty in these cases - rulemaking is.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
Excerpt Text:
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.

Commenter Organization Name: Loomis, Shirley
Comment Number: 2005N-0345-EC147
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.7 - Miscellaneous arguments/discussions
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Academy of Managed Care Pharmacy
Comment Number: 2005N-0345-EC15687
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:

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.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments
Excerpt Text:
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.

Commenter Organization Name: Jones, Kim
Comment Number: 2005N-0345-EC16543
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments
Excerpt Text:
No. It would implicate equal protection rights, among other problems.

Commenter Organization Name: Hein, Rachel
Comment Number: 2005N-0345-EC168
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
The FDA should not limit the sale of an OTC product to a particular subpopulation.

Commenter Organization Name: Wilson, Rhianna
Comment Number: 2005N-0345-EC186
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments
Excerpt Text:
No, the gaurdians and parents of that subpopulation should be able to purchase the medication for the subpopulation.

Commenter Organization Name: Crousey, Joshua
Comment Number: 2005N-0345-EC1970
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments
Excerpt Text:
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.

Commenter Organization Name: Young, Stan
Comment Number: 2005N-0345-EC211

Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.5.3 - Court cases
Excerpt Text:
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.

Commenter Organization Name: Rankis, A
Comment Number: 2005N-0345-EC22
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: Labbe, Carl
Comment Number: 2005N-0345-EC408
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Not under current rules.

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.7 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Landauer, Christopher
Comment Number: 2005N-0345-EC49
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
NEW - 7.2 - No
NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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.

Commenter Organization Name: Padden, Phillip
Comment Number: 2005N-0345-EC505
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments

Excerpt Text:
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.

Commenter Organization Name: Zahn, Steven
Comment Number: 2005N-0345-EC52
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
No, not under the current regulations and its interpretations.

Commenter Organization Name: Thompson, Sharon
Comment Number: 2005N-0345-EC526
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
It would not be possible to regulate having "prescription" status for a particular subpopulation because it would be too easy to circumvent this.

Commenter Organization Name: Ramirez, Robert
Comment Number: 2005N-0345-EC527
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No. One this would be a enforcement nightmare.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 3.8.7 - Cost-benefit concerns regarding rulemaking
Excerpt Text:
NO, This seems to be a problem waiting for a whole lot of money to be waisted on. Either a drug is over the counter or it is not.

Commenter Organization Name: Della Paolera, Mark
Comment Number: 2005N-0345-EC555
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
NO, the FDA cannot guarantee that such age restrictions would be satisfied.

Commenter Organization Name: Porter, Rebecca
Comment Number: 2005N-0345-EC56
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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 impossibilty to enforce such a regulation.

This is a bad idea for the FDA to pursue.

Commenter Organization Name: Doran, Gregory
Comment Number: 2005N-0345-EC586
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Billingsley, Daniel
Comment Number: 2005N-0345-EC609
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments
Excerpt Text:
The enforcement would not fall to the FDA, it would fall on the entity selling the product.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Ray, Amy
Comment Number: 2005N-0345-EC65
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: Vrankar, Anna
Comment Number: 2005N-0345-EC668
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Without any real knowledge of law, I believe that a law must be reasonably enforceable to be real law.

Commenter Organization Name: Socha, Kathleen
Comment Number: 2005N-0345-EC678
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
You can't even prevent kids from buying cigarettes or alcohol. What are you thinking?

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments
Excerpt Text:
Probably not. It would result in lawsuits challenging the right to restrict sales; challenging the appropriateness of the cutoff age, alleging age discrimination.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Jago, Laura

Comment Number: 2005N-0345-EC839
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Oyola, Sandra
Comment Number: 2005N-0345-EC85
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
I do not believe so. I do not agree with limiting sales to a subpopulation.

Commenter Organization Name: Hawkins, Susan
Comment Number: 2005N-0345-EC91
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Aengst, Jennifer
Comment Number: 2005N-0345-EC921
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.5.4 - Other arguments
Excerpt Text:
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 questionnable 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.

Commenter Organization Name: Wurtz, Richard
Comment Number: 2005N-0345-EC94
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
NO

6.3 - Legal/policy arguments that support/detail FDA's authority to enforce limitation on availability of OTC products by sub-population

6.3.1 - FD&C Act

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307

Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 7.1 - Yes
Excerpt Text:
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.. ." (FFDCA, 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.

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:
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 medica1 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.]

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 19
Excerpt Status: NEW
Excerpt Text:
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 2l-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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 18
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
MODIFIED - 7.3.1.3 - Require risk management program
Excerpt Text:
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 postmarking 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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
Excerpt Text:
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.

6.3.2 - No laws prevent the policy

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
NEW - 3.6.2 - Court case arguments opposing a rulemaking
Excerpt Text:
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).]

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
Excerpt Text:
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.

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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.

6.3.3 - Court cases

6.3.4 - Age limitations are in line with other meaningful differences

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
Excerpt Text:
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 that 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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 18
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Black, Jerrold
Comment Number: 2005N-0345-EC111
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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".

Commenter Organization Name: Slee, April
Comment Number: 2005N-0345-EC121
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Soriano, Lauren
Comment Number: 2005N-0345-EC14388
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Corlette, Chauncey
Comment Number: 2005N-0345-EC14491
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

Commenter Organization Name: Corlette, Chauncey
Comment Number: 2005N-0345-EC14491
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Gay, Sarah
Comment Number: 2005N-0345-EC199
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription

only
Excerpt Text:
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.

6.3.5 - Other legal/policy arguments

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 10
Excerpt Status: MODIFIED
Excerpt Text:
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 issues 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 provide 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 chose to use the product and do the inappropriate people deselect, or chose 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, omerprazole, 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.

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes

Excerpt Text:
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.

Commenter Organization Name: Paslawsky, JoAnn
Comment Number: 2005N-0345-EC1129
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
Excerpt Text:
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.

Commenter Organization Name: Dorn, Kellie
Comment Number: 2005N-0345-EC117
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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 dificult 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.

Commenter Organization Name: Murphy, Cynthia
Comment Number: 2005N-0345-EC176
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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)

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
yes. Laws would be made to make sure of that.

Commenter Organization Name: Gay, Sarah
Comment Number: 2005N-0345-EC199
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: McLeod, Doug

Comment Number: 2005N-0345-EC364
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
The answer would clearly depend on how the subpopulation was classified. Age restrictions, for example, could be enforced as a matter of law.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 7.1 - Yes
Excerpt Text:
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.

6.4 - Examples/precedents that support/detail FDA's authority to enforce limitation on availability of OTC products by sub-population

6.4.1 - Nicotine replacement therapy (e.g., Nicorette)

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
Excerpt Text:
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.

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
Excerpt Text:
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.

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: White, Alan
Comment Number: 2005N-0345-EC1121
Excerpt Number: 4
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Nicotine replacement products available OTC are "restricted" to persons 18 and older.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.3.5 - Other legal/policy arguments
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 11
Excerpt Status: MODIFIED
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
Excerpt Text:
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 of 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.]

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 12
Excerpt Status: MODIFIED
Excerpt Text:
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.]

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
The FDA already only allows nictoine 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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 6.3.1 - FD&C Act
Excerpt Text:
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.

Commenter Organization Name: Dawson, Jennifer
Comment Number: 2005N-0345-EC7
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
Such limitations already exist for medicines like nicotine-replacement therapy, as well as for other controlled substances such as tobacco and alcohol.

6.4.2 - Other examples

6.5 - Legal/policy arguments that FDA does not have authority to enforce the limitation (or permit dual marketing or implement "behind-the-counter" (pharmacist distribution) system)

6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
FDA has no relevant regulatory authority over consumers or resellers and is not responsible for the elimination of intentional abuse.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 9
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
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).

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
"Enforcement" should not be the FDA's primary responsibilty in these cases - rulemaking is.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 6
Excerpt Status: NEW

Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Academy of Managed Care Pharmacy
Comment Number: 2005N-0345-EC15687
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
NEW - 6.6.2 - Congress
Excerpt Text:
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.

Commenter Organization Name: Saling, Elle
Comment Number: 2005N-0345-EC16546
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
Excerpt Text:
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.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 5.2 - No
Excerpt Text:
No. A reminder to the FDA that its role is to approve or dissapprove drugs for use based on potential harm and validity of claims is needed.

Commenter Organization Name: Munro, Margaret
Comment Number: 2005N-0345-EC2022
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.6.2 - Congress
Excerpt Text:
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.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Hagan, Jane
Comment Number: 2005N-0345-EC32
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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).

Commenter Organization Name: Landauer, Christopher
Comment Number: 2005N-0345-EC49
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
NEW - 7.2 - No
NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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.

Commenter Organization Name: Peer, Gerald
Comment Number: 2005N-0345-EC626
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Extension of law enforcement by FDA on the general population complicates its mission and enlarges the obtrusive arm of government into private lives.

Commenter Organization Name: Aengst, Jennifer
Comment Number: 2005N-0345-EC921
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

6.5.2 - Other FD&C Act arguments

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.CA.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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:

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 195.l. 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 cheek 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.]

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 21
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Owens, B
Comment Number: 2005N-0345-EC14261
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Owens, B
Comment Number: 2005N-0345-EC14261
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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 meaning 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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
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.

6.5.3 - Court cases

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 14
Excerpt Status: NEW
Excerpt Text:
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 l6.]

Commenter Organization Name: Speight, Thomas
Comment Number: 2005N-0345-EC1041
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Young, Stan
Comment Number: 2005N-0345-EC211
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839

Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 7.6 - Miscellaneous arguments/discussions
Excerpt Text:
Another issue is that many pharmacist currently have the option NOT to dispense emergency contraception (the case in Maryland),due to relgious 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 obliverate this right of mine to refuse to dispense, since I object to its use in those over the age of 17 as well.

6.5.4 - Other arguments

Commenter Organization Name: Ruckdeschel, Diana
Comment Number: 2005N-0345-C71
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Shaffer, Kathleen
Comment Number: 2005N-0345-EC106
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
The FDA would risk profuse litigation by angry parents, such as myself!

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Condoms are available OTC; there is no age verification.

Commenter Organization Name: Severance, Peter
Comment Number: 2005N-0345-EC135
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Irrelevant. The FDA would be creating an overly-complicated system of enforcement.

Commenter Organization Name: Marshall, Laura

Comment Number: 2005N-0345-EC15
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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 angencies and entities enter into the process.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Smart, Stephanie
Comment Number: 2005N-0345-EC16
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
I think this is a poor policy consideration. By limiting drug availabilty you open the door for discrtimiation 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.

Commenter Organization Name: Jones, Kim
Comment Number: 2005N-0345-EC16543
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
No. It would implicate equal protection rights, among other problems.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
Excerpt Text:
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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 14
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Wilson, Rhianna
Comment Number: 2005N-0345-EC186
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:

No, the gaurdians and parents of that subpopulation should be able to purchase the medication for the subpopulation.

Commenter Organization Name: Crousey, Joshua
Comment Number: 2005N-0345-EC1970
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
Excerpt Text:
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!

Commenter Organization Name: Llewellyn, Heather
Comment Number: 2005N-0345-EC325
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
It is not the FDA's role to enforce it's rulings - that is the responsibility of distributors, guardians and the police.

Commenter Organization Name: Hudson, Ralph
Comment Number: 2005N-0345-EC34
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Scarpace, Sarah
Comment Number: 2005N-0345-EC38
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:

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 mentstrual periods/ heavy flow. Does a 15 year-old rape victim not have the same rights as a 16 year-old?

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: Padden, Phillip
Comment Number: 2005N-0345-EC505
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
Excerpt Text:
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 invansion of family privacy.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
To change the interpretation might bring legal consequences upon the FDA or the stores selling this drug if a wrongful death suit were initiated.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
What would be legal consequences in a wrongful death suit to the FDA and the stores who carry this OTC medication?

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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 impossibilty to enforce such a regulation.

This is a bad idea for the FDA to pursue.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Billingsley, Daniel
Comment Number: 2005N-0345-EC609
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Billingsley, Daniel
Comment Number: 2005N-0345-EC609
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
The enforcement would not fall to the FDA, it would fall on the entity selling the product.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
Probably not. It would result in lawsuits challenging the right to restrict sales; challenging the appropriateness of the cutoff age, alleging age discrimination.

Commenter Organization Name: Hager, Joseph R

Comment Number: 2005N-0345-EC716
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
I say that the pharmicist/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.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 3.8.7 - Cost-benefit concerns regarding rulemaking
Excerpt Text:
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.

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
Excerpt Text:
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 sancioned product available that is deamed safe and effective for OTC use.

Commenter Organization Name: Fogelgren, Katharine
Comment Number: 2005N-0345-EC82
Excerpt Number: 1

Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
Excerpt Text:
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 sufficiant 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.

Commenter Organization Name: Corder, Traci
Comment Number: 2005N-0345-EC9
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Aengst, Jennifer
Comment Number: 2005N-0345-EC921
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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 questionnable 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.

Commenter Organization Name: Burns, Ben
Comment Number: 2005N-0345-EC93
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

6.6 - Authority of other entities to enforce the limitation

6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 16
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 17
Excerpt Status: NEW
Excerpt Text:
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.]

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 18
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 38
Excerpt Status: NEW
Other Sections: NEW - 6.6.4 - Other entities
Excerpt Text:
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.]

Commenter Organization Name: Micro ICU Project
Comment Number: 2005N-0345-C5
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
Sure. In California, the sale of over the counter sinus medication (used in the production of methanphetimines) is restricted to people with an ID stating that they are over 18 years of age. This seems to be working.

Commenter Organization Name: White, Alan
Comment Number: 2005N-0345-EC1121
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
NEW - 6.6.2 - Congress
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.5.2 - Other FD&C Act arguments
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
Not relevant. Other such enforcement is already performed: alcohol, tobacco, pseudopherine, spray paints and other inhalable solvents, ...

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
yes. The states would regulate it.

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Tuchinsky, Marla
Comment Number: 2005N-0345-EC201
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
Excerpt Text:
State Departments of Health will inspect the process as it does all other processes.

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 10
Excerpt Status: NEW
Other Sections: NEW - 2.1 - Comments on time, manner, and nature of rulemaking process
Excerpt Text:
This is no reason for a delay to market. Incidently, 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.

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
Recently, however, certain states have take action to put certain OTC cold medications behind the phramacy 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.

Commenter Organization Name: Levinson, R. Saul
Comment Number: 2005N-0345-EC297
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
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.

Commenter Organization Name: Duchon, Kathleen
Comment Number: 2005N-0345-EC426
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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?

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:
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.

6.6.2 - Congress

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 23
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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-l 7, 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 he 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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
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.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Munro, Margaret
Comment Number: 2005N-0345-EC2022
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
Excerpt Text:
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.

6.6.3 - Alcohol and tobacco enforcement

Commenter Organization Name: Rucker, Gwendolyn

Comment Number: 2005N-0345-EC1080
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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 overseee 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.

Commenter Organization Name: Mershon, Claire-Helene
Comment Number: 2005N-0345-EC12379
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes. If the age of a person buying cigarettes or alcohol is subject to legal enforcement, why would this limitation not be enforceable?

Commenter Organization Name: Dougherty, Anne
Comment Number: 2005N-0345-EC126
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Dougherty, Anne
Comment Number: 2005N-0345-EC126
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Analogously to the ATF and tobacco/alcohol regulations, a limitation on availability to a subpopulation could be enforced.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 5

Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
NEW - 7.4.6 - Other actions
Excerpt Text:
Insomuch 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, consumers 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.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 7
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Connors, Meaghan
Comment Number: 2005N-0345-EC141
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Soriano, Lauren
Comment Number: 2005N-0345-EC14388
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Corlette, Chauncey
Comment Number: 2005N-0345-EC14491
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.3.4 - Age limitations are in line with other meaningful differences
Excerpt Text:
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.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Yao, Yvonne
Comment Number: 2005N-0345-EC1565
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Akin to alcohol and tobacco, Plan B can be regulated.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.6 - Other actions
Excerpt Text:
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.

Commenter Organization Name: Reusch, Elizabeth
Comment Number: 2005N-0345-EC165
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
Not relevant. Other such enforcement is already performed: alcohol, tobacco, pseudopherine, spray paints and other inhalable solvents, ...

Commenter Organization Name: Ross, Angela
Comment Number: 2005N-0345-EC172
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Murphy, Cynthia
Comment Number: 2005N-0345-EC176
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 6.3.5 - Other legal/policy arguments
Excerpt Text:
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)

Commenter Organization Name: Hibberd, Rachel
Comment Number: 2005N-0345-EC196
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Asking this question makes the FDA look rediculous 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.

Commenter Organization Name: Gay, Sarah
Comment Number: 2005N-0345-EC199
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.3.2 - Other FDA enforcement practices that it has the legal authority to put in place

Excerpt Text:
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?

Commenter Organization Name: Tuchinsky, Marla
Comment Number: 2005N-0345-EC201
Excerpt Number: 2
Excerpt Status: MODIFIED
Excerpt Text:
1. You already do limit the use of certain drugs by age -- alcohol and tobacco are both age-regulated drugs.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.4 - Require identification for age
Excerpt Text:
Certainly by prescriptions for minors and "carding" everyone else, just like alcohol or cigarettes

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 6
Excerpt Status: NEW

Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
ID's will be checked for OTC product as with nicotine patches, alcohol, cigarettes, etc

Commenter Organization Name: Dietz, Ken
Comment Number: 2005N-0345-EC217
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 6.6.4 - Other entities
Excerpt Text:
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?

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
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.

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 4
Excerpt Status: NEW

Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
Recently, however, certain states have take action to put certain OTC cold medications behind the phramacy 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.

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
It would be possible, just follow the examples set forth in how cigarettes and alcohol are regulated.

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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 belive 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 acquision of the product just as today the vendor or proxy is punished in underage cigarette and alcohol acquisition.

Commenter Organization Name: Hagan, Jane
Comment Number: 2005N-0345-EC32
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 5
Excerpt Status: MODIFIED
Other Sections: MODIFIED - 2.1 - Comments on time, manner, and nature of rulemaking process
Excerpt Text:
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.

Commenter Organization Name: Llewellyn, Heather
Comment Number: 2005N-0345-EC325
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 5.5 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Llewellyn, Heather
Comment Number: 2005N-0345-EC325
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
Of course - but the package should have warnings, just like alcohol and tobacco do.

Commenter Organization Name: Llewellyn, Heather
Comment Number: 2005N-0345-EC325
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
The package should have warnings, just like alcohol and tobacco do, preventing any circumstance that would be inappropriate.

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Scarpace, Sarah
Comment Number: 2005N-0345-EC38
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
Such enforcement would likely require that the drug be stored 'behind the counter', like cigerettes, and many women who would benefit from the intended use of the drug would not ask for it.

Commenter Organization Name: Bilz, Michael
Comment Number: 2005N-0345-EC4
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Clason, Dennis
Comment Number: 2005N-0345-EC47
Excerpt Number: 1

Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Katrib, Elise
Comment Number: 2005N-0345-EC516
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
How do we enforce the sale of tobacco and alcohol? Just check ID.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
This is already done, for instance, with tobacco and alcohol.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
Yes, in the same manner as sales of tobacco and alcohol are controlled.

Commenter Organization Name: Porter, Rebecca
Comment Number: 2005N-0345-EC56
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
Look at the amount of alcohol that is sold to minors. There will always be a way for the underaged to get this medications.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:

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.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
Regulations based on age have existed in this country since it's onset. Voting was the first restriction, tobacco and alcohol have legal ages for purchase at stores across the country.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Similar methods to alcohol and tobacco could easily be used to regulate the sale of drugs.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.2 - Involve other authorities (e.g., states, state boards of pharmacies)
Excerpt Text:
Absolutely. I would recommend the wholesale borrowing of state statutes regulating tobacco sales as the basis for regulation and enforcement.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 4

Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Peer, Gerald
Comment Number: 2005N-0345-EC626
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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."

Commenter Organization Name: Vrankar, Anna
Comment Number: 2005N-0345-EC668
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
Is the ban on tobacco sales to minors enforeceable? Absolutely not.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Socha, Kathleen
Comment Number: 2005N-0345-EC678
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
You can't even prevent kids from buying cigarettes or alcohol. What are you thinking?

Commenter Organization Name: Dawson, Jennifer
Comment Number: 2005N-0345-EC7
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
Excerpt Text:
Such limitations already exist for medicines like nicotine-replacement therapy, as well as for other controlled substances such as tobacco and alcohol.

Commenter Organization Name: Dawson, Jennifer
Comment Number: 2005N-0345-EC7
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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.

Commenter Organization Name: Macdonell, Megan
Comment Number: 2005N-0345-EC779
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Wagner, Patricia
Comment Number: 2005N-0345-EC813
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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?

Commenter Organization Name: Oberst, Sara
Comment Number: 2005N-0345-EC860
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
As mentioned above, such limitations on alcohol and tobacco are widespread and enforceable.

Commenter Organization Name: Etter, Eleanor
Comment Number: 2005N-0345-EC96
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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 that there would be in a drug store.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 7
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Dalton, Mike
Comment Number: 2005N-0345-EMC166
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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.

6.6.4 - Other entities

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 38
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
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.]

Commenter Organization Name: Dowell, Duane
Comment Number: 2005N-0345-EC195
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
There is some precedent in control of firearms and of narcotics.

Commenter Organization Name: Dietz, Ken
Comment Number: 2005N-0345-EC217
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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?

6.7 - Miscellaneous arguments/discussions

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:

Either science dictates an age cutoff, or it doesn't.

Commenter Organization Name: Reynolds, Charles
Comment Number: 2005N-0345-EC12
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Unknown if the FDA has the ability to regulate this under its jurisdiction.

Commenter Organization Name: Loomis, Shirley
Comment Number: 2005N-0345-EC147
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Reusch, Elizabeth
Comment Number: 2005N-0345-EC165
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
Excerpt Text:
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.

Commenter Organization Name: Bilz, Michael
Comment Number: 2005N-0345-EC4
Excerpt Number: 3

Excerpt Status: NEW
Excerpt Text:
Do they have a vehicle for enforcing it now? If so, what is it? Is it effective?

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Dolinski, Elizabeth
Comment Number: 2005N-0345-EC522
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Ricci, Stephen
Comment Number: 2005N-0345-EC73
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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

Commenter Organization Name: Trubow, Marshall
Comment Number: 2005N-0345-EC95
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Would it really need to?

Commenter Organization Name: Stockton, Melissa
Comment Number: 2005N-0345-EC99
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
I feel there should only be a limit if the product would become dangerous after (x) number of doses.

7 - Would FDA be able to enforce limitation to sub-population as a practical matter? [ANPRM Q 2.B.]

7.1 - Yes

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 6.3.1 - FD&C Act
Excerpt Text:
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.. ." (FFDCA, 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.

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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!

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
By restricting access based on IDs and age, or the presence of an adult, unless prescribed by a doctor.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
Yes, Pharmacies and pharmacists are required to abide with multiple other rules and regulations pertaining to the dispensing of drugs.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
The enforcement can be a practical matter.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 4.3.2 - Diverse industry and public opinion/reaction to ANPRM and statements re: FDA's authority
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
Whatever you decide will be what is complied with.

Commenter Organization Name: Yao, Yvonne
Comment Number: 2005N-0345-EC1565
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.)

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:

Yes.

Commenter Organization Name: Hutson, Paul
Comment Number: 2005N-0345-EC162
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Reusch, Elizabeth
Comment Number: 2005N-0345-EC165
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
By requiring an identification card be presented at the time of purchase.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 13
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
yes. The states would regulate it.

Commenter Organization Name: Hibberd, Rachel
Comment Number: 2005N-0345-EC196
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
YES, this again is a rediculous 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.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 7
Excerpt Status: NEW

Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.4 - Require identification for age
Excerpt Text:
Certainly by prescriptions for minors and "carding" everyone else, just like alcohol or cigarettes

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes.

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
The practicality of enforcement would be difficult, but no more than existing products available in both forms.

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
It would be possible, just follow the examples set forth in how cigarettes and alcohol are regulated.

Commenter Organization Name: Wu, Jackie
Comment Number: 2005N-0345-EC307
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.6 - Other actions
Excerpt Text:
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 supervison of the pharmacist. An electronic pharmacy record will be helpful to track the number of drugs a subject takes.

Commenter Organization Name: Hudson, Ralph
Comment Number: 2005N-0345-EC34

Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.3.2 - Other FDA enforcement practices that it has the legal authority to put in place
Excerpt Text:
By the same methods currently used to enforce the separation of over-the-counter from prescriptions.

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
YES!!! This would not increase the amount of time or money in asking for ID.

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.6 - Other actions
Excerpt Text:
Such a requirement is commonly done with cigarettes sold in Pharmacies. Enforcement is left to the local merchant.

Commenter Organization Name: Clason, Dennis
Comment Number: 2005N-0345-EC47
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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.

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
Yes. Minors are not permitted to buy alcohol without proper ID showing proof of age.

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Padden, Phillip
Comment Number: 2005N-0345-EC505
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
Yes, follow the example of alchol and tobacco age restrictions.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
Yes, in the same manner as sales of tobacco and alcohol are controlled.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.2 - Involve other authorities (e.g., states, state boards of pharmacies)
Excerpt Text:
Absolutely. I would recommend the wholesale borrowing of state statutes regulating tobacco sales as the basis for regulation and enforcement.

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
No, it would not be able to monitor the use of such drugs adequately as a practical matter.

Commenter Organization Name: Carter, Thomas
Comment Number: 2005N-0345-EC691
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Dawson, Jennifer

Comment Number: 2005N-0345-EC7
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Rosati, Lucia
Comment Number: 2005N-0345-EC76
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
How does it normally enforce the sale of prescription drugs? However, the drug would have to merit regulation.

Commenter Organization Name: Carlson, Brent
Comment Number: 2005N-0345-EC77
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.4 - Require identification for age
Excerpt Text:
You could either require identification at the point-of-sale or require dispensing by a pharmacist (with ID).

Commenter Organization Name: Macdonell, Megan
Comment Number: 2005N-0345-EC779
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Oberst, Sara
Comment Number: 2005N-0345-EC860
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 6.3.5 - Other legal/policy arguments
Excerpt Text:
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.

7.2 - No

Commenter Organization Name: Alterton, Faith
Comment Number: 2005N-0345-C83
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
NO.

Commenter Organization Name: Ladd, Judy
Comment Number: 2005N-0345-EC1032
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
It would be impossible to regulate something that is readily available to every other person OTC.

Commenter Organization Name: Marshall, Laura
Comment Number: 2005N-0345-EC15

Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
As a matter of law, perhaps, but fake IDs and passing on of a prescription legally purchased would make the reality different.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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.

Commenter Organization Name: Jones, Kim
Comment Number: 2005N-0345-EC16543
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.4 - Other arguments
Excerpt Text:
No. Looking, for example, at minors, if minors can obtain cigarettes and alcohol, they will be able to obtain OTC medications as well.

Commenter Organization Name: Hein, Rachel
Comment Number: 2005N-0345-EC168
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
Excerpt Text:
It should NOT. Clear instructions and warnings should instead be required of the drug distributor.

Commenter Organization Name: Morrisroe, Julia
Comment Number: 2005N-0345-EC194
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
No, keep you hands off. Your talking about individual rights here, the agency is stepping out of bounds.

Commenter Organization Name: Felty, Amy
Comment Number: 2005N-0345-EC210
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:

Therefore, no I do not think it could be enforced in a practical manner.

Commenter Organization Name: Young, Stan
Comment Number: 2005N-0345-EC211
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Rankis, A
Comment Number: 2005N-0345-EC22
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
No, the use of the product would be abused

Commenter Organization Name: Myers, Micah
Comment Number: 2005N-0345-EC319
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Fisher, Julie
Comment Number: 2005N-0345-EC343
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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?

Commenter Organization Name: McLeod, Doug
Comment Number: 2005N-0345-EC364
Excerpt Number: 6

Excerpt Status: NEW
Other Sections: NEW - 7.6 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Kulshrestha, Vikram V
Comment Number: 2005N-0345-EC405
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
NEW - 7.5.4 - Other arguments
Excerpt Text:
In practice, this would raise the cost of prescription services and would probably not result in equitable and accurate enforcement.

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
Probably not, as mentioned above

Commenter Organization Name: Landauer, Christopher
Comment Number: 2005N-0345-EC49
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and

labeling
NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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.

Commenter Organization Name: McGhee, Tim
Comment Number: 2005N-0345-EC53
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
I do not believe it could.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.4 - Require identification for age
Excerpt Text:
Most likly not, the only practicle 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 despensing.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
It couldn't.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
No. I cannot see this happening.

Commenter Organization Name: Naughton, John
Comment Number: 2005N-0345-EC572
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Absolutely not.

Commenter Organization Name: Leonard, Ruth Tehila
Comment Number: 2005N-0345-EC59
Excerpt Number: 7
Excerpt Status: NEW

Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Billingsley, Daniel
Comment Number: 2005N-0345-EC609
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
The FDA could not enforce this limitation.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 10
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
It is ludicrous, insane, unresponsible to think that this would even be practical.

Commenter Organization Name: Ray, Amy
Comment Number: 2005N-0345-EC65
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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

Commenter Organization Name: Vrankar, Anna
Comment Number: 2005N-0345-EC668
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 4

Excerpt Status: NEW
Excerpt Text:
Absolutely not.

Commenter Organization Name: Socha, Kathleen
Comment Number: 2005N-0345-EC678
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Not possible.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Devine, Naomi
Comment Number: 2005N-0345-EC710
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
No. In practicality, this type of restiction would be nearly impossible to enforce.

Commenter Organization Name: Hager, Joseph R
Comment Number: 2005N-0345-EC716
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
No!

Commenter Organization Name: Gorini, Joseph
Comment Number: 2005N-0345-EC717
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No!

Commenter Organization Name: Ricci, Stephen
Comment Number: 2005N-0345-EC73
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
I do not believe it is likely even as a practical matter.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 8

Excerpt Status: NEW
Excerpt Text:
It would not be able to do so as a practical matter.

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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.

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Clearly not.

Commenter Organization Name: Smith, Rodney
Comment Number: 2005N-0345-EC83
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Wurtz, Richard
Comment Number: 2005N-0345-EC94
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
NO

7.3 - Actions FDA could take in order to enforce limitation of an OTC product to a sub-population

7.3.1 - Regulate product sponsor

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 1.2.2 - Approve simultaneous marketing approach (market both OTC and Rx)
NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:

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.

7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
Excerpt Text:
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.

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 13
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.4 - Other product approval conditions
Excerpt Text:
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).

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415

Excerpt Number: 28
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
Excerpt Text:
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.

Commenter Organization Name: National Association of Boards of Pharmacy
Comment Number: 2005N-0345-C443
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
NEW - 7.4.2 - Involve other authorities (e.g., states, state boards of pharmacies)
Excerpt Text:
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

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
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 where 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.

Commenter Organization Name: Soriano, Lauren
Comment Number: 2005N-0345-EC14388
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Hutson, Paul
Comment Number: 2005N-0345-EC162
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
Excerpt Text:
Yes, if the non-prescription sale was made through a licensed pharmacy and by a licensed pharmacist, PA, or NP.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: MODIFIED - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
Excerpt Text:
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 of 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.]

Commenter Organization Name: American Pharmacists Association

Comment Number: 2005N-0345-EC16675
Excerpt Number: 14
Excerpt Status: MODIFIED
Other Sections: MODIFIED - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
Excerpt Text:
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.

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Levinson, R. Saul
Comment Number: 2005N-0345-EC297
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
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.

Commenter Organization Name: Collum, Mark
Comment Number: 2005N-0345-EC33
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Scarpace, Sarah
Comment Number: 2005N-0345-EC38
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third

class of "behind-the-counter" drugs (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Vander Bleek, Luke
Comment Number: 2005N-0345-EC870
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

7.3.1.2 - Require retailer, pharmacist, and consumer education programs

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.3.4 - Age limitations are in line with other meaningful differences

Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 25
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 28
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
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.

Commenter Organization Name: National Association of Boards of Pharmacy
Comment Number: 2005N-0345-C443
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association

Comment Number: 2005N-0345-EC16675
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: MODIFIED - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
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 of 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.]

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 14
Excerpt Status: MODIFIED
Other Sections: MODIFIED - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
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.

Commenter Organization Name: Hein, Rachel
Comment Number: 2005N-0345-EC168
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
It should NOT. Clear instructions and warnings should instead be required of the drug distributor.

Commenter Organization Name: Macdonell, Megan
Comment Number: 2005N-0345-EC779
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.4 - Require identification for age

Excerpt Text:
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.

7.3.1.3 - Require risk management program

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 12
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.4 - Other product approval conditions
Excerpt Text:
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."]

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 18
Excerpt Status: MODIFIED
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
NEW - 6.3.1 - FD&C Act
Excerpt Text:
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 postmarking 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.

7.3.1.4 - Other product approval conditions

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 12
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.3 - Require risk management program
Excerpt Text:
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."]

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 13
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
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).

Commenter Organization Name: National Association of Boards of Pharmacy
Comment Number: 2005N-0345-C443
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:

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

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
Rules governing the OTC and precription 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.

7.3.2 - Other FDA enforcement practices that it has the legal authority to put in place

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 26
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rahl, Michael
Comment Number: 2005N-0345-EC13845
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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."

Commenter Organization Name: Gay, Sarah
Comment Number: 2005N-0345-EC199
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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?

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Hudson, Ralph
Comment Number: 2005N-0345-EC34
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
By the same methods currently used to enforce the separation of over-the-counter from prescriptions.

Commenter Organization Name: Vander Bleek, Luke
Comment Number: 2005N-0345-EC870
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Practicality would be dependent on the structure of the business entity allowed to offer these items for sale.

7.4 - Other point-of-sale enforcement suggestions

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 19
Excerpt Status: MODIFIED
Other Sections: MODIFIED - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 23
Excerpt Status: NEW
Excerpt Text:
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.

7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 20
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: National Association of Boards of Pharmacy
Comment Number: 2005N-0345-C443
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
Additionally, this classification would provide a mechanism for the verification of the patient's age, if necessary, or any other subpopulation requirements.

Commenter Organization Name: Women's Bar Associaion of the State of New York
Comment Number: 2005N-0345-C489
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Pruis, Trisha
Comment Number: 2005N-0345-EC1044
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
I think if a law were created, it would have to be enforced at the level of the pharmacy or doctor.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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 overseee 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.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
Yes, Pharmacies and pharmacists are required to abide with multiple other rules and regulations pertaining to the dispensing of drugs.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Leaving the product behind the pharmacy counter would ensure only certain persons get the product, but it would also pose a barrier.

Commenter Organization Name: Reynolds, Charles
Comment Number: 2005N-0345-EC12
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Mershon, Claire-Helene
Comment Number: 2005N-0345-EC12379
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Corlette, Chauncey
Comment Number: 2005N-0345-EC14491
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.3.1.4 - Other product approval conditions
Excerpt Text:
Rules governing the OTC and precription 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.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Yao, Yvonne
Comment Number: 2005N-0345-EC1565
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.4 - Require identification for age
Excerpt Text:

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.)

Commenter Organization Name: Hutson, Paul
Comment Number: 2005N-0345-EC162
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 15
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 16
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675

Excerpt Number: 17
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Morrisroe, Julia
Comment Number: 2005N-0345-EC194
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Tuchinsky, Marla
Comment Number: 2005N-0345-EC201
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
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.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.4.5 - Pursue criminal actions against violators
NEW - 7.4.6 - Other actions
Excerpt Text:
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 significnat penalty of legal sanctions, including possible jail time.

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
Recently, however, certain states have take action to put certain OTC cold medications behind the phramacy 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.

Commenter Organization Name: Levinson, R. Saul
Comment Number: 2005N-0345-EC297
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Wu, Jackie
Comment Number: 2005N-0345-EC307
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.6 - Other actions
Excerpt Text:
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 supervison of the pharmacist. An electronic pharmacy record will be helpful to track the number of drugs a subject takes.

Commenter Organization Name: Collum, Mark
Comment Number: 2005N-0345-EC33
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
Such enforcement would likely require that the drug be stored 'behind the counter', like cigerettes, and

many women who would benefit from the intended use of the drug would not ask for it.

Commenter Organization Name: Labbe, Carl
Comment Number: 2005N-0345-EC408
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Labbe, Carl
Comment Number: 2005N-0345-EC408
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Thompson, Sharon
Comment Number: 2005N-0345-EC526

Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
NEW - 7.4.4 - Require identification for age
Excerpt Text:
Most likly not, the only practicle 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 despensing.

Commenter Organization Name: Della Paolera, Mark
Comment Number: 2005N-0345-EC555
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 9.2.2 - All circumstances (i.e., it's always appropriate, there are no inappropriate circumstances)
Excerpt Text:
There is none. It needs to remain behind the counter.

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
NEW - 7.4.6 - Other actions
Excerpt Text:
Allow pharacists to card those purchasing the drugs and the purchaser must sign a form stating "met age requirements".

Commenter Organization Name: Dawson, Jennifer
Comment Number: 2005N-0345-EC7
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Carlson, Brent
Comment Number: 2005N-0345-EC77

Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.4 - Require identification for age
Excerpt Text:
You could either require identification at the point-of-sale or require dispensing by a pharmacist (with ID).

Commenter Organization Name: Macdonell, Megan
Comment Number: 2005N-0345-EC779
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
NEW - 7.5.4 - Other arguments
Excerpt Text:
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 pseudoephidrine-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 phamacy personnel having access to patient information (and interference with a request for an OTC drug) that can guide this train of thought?

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
In this case, pharmacists would have to control the sale, maybe including the OTC product behing the counter although still OTC.

Commenter Organization Name: Mock, Suzanne
Comment Number: 2005N-0345-EC940
Excerpt Number: 3

Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
NEW - 7.4.6 - Other actions
Excerpt Text:
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.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

7.4.2 - Involve other authorities (e.g., states, state boards of pharmacies)

Commenter Organization Name: American Society for Reproductive Medicine
Comment Number: 2005N-0345-C350
Excerpt Number: 14
Excerpt Status: NEW
Excerpt Text:
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/330partl.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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 21
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 24
Excerpt Status: NEW
Excerpt Text:
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 awn 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.]

Commenter Organization Name: National Association of Boards of Pharmacy
Comment Number: 2005N-0345-C443
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.2 - Two-class system (OTC and Rx) not sufficient - need a third class of "behind-the-counter" drugs (pharmacist distributed)
NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
Excerpt Text:
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

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 10
Excerpt Status: NEW
Other Sections: NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
Excerpt Text:
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.

Commenter Organization Name: Endris, Kelle
Comment Number: 2005N-0345-EC278
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Through Public Health Clinics.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.1 - Yes
Excerpt Text:
Absolutely. I would recommend the wholesale borrowing of state statutes regulating tobacco sales as the basis for regulation and enforcement.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
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 pharmceuticals 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.

7.4.3 - Monitor compliance and enforcement / conduct random inspections

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)

NEW - 7.3.1.1 - Require sales restrictions as condition for approval (e.g., restrict sales to entities that are licensed pharmacies)
NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 22
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
State Departments of Health will inspect the process as it does all other processes.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 10
Excerpt Status: NEW
Other Sections: NEW - 7.4.2 - Involve other authorities (e.g., states, state boards of pharmacies)
Excerpt Text:

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.

Commenter Organization Name: Carter, Thomas
Comment Number: 2005N-0345-EC691
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Dawson, Jennifer
Comment Number: 2005N-0345-EC7
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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.

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 8.5.3 - Need separate National Drug Code (NDC) numbers for billing
Excerpt Text:
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.

Commenter Organization Name: Oberst, Sara
Comment Number: 2005N-0345-EC860
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 14
Excerpt Status: NEW
Excerpt Text:
Periodic ?stings? with underage-looking consumers (similar to those performed in bars and convenience

stores) would provide sufficient deterrent for selling to ?minors.?

Commenter Organization Name: Tadeo, Peter
Comment Number: 2005N-0345-EMC373
Excerpt Number: 8
Excerpt Status: MODIFIED
Excerpt Text:
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

7.4.4 - Require identification for age

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 20
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: National Association of Boards of Pharmacy
Comment Number: 2005N-0345-C443
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
Additionally, this classification would provide a mechanism for the verification of the patient's age, if necessary, or any other subpopulation requirements.

Commenter Organization Name: Women's Bar Associaion of the State of New York
Comment Number: 2005N-0345-C489
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 10 - Studies/data provided in comment
Excerpt Text:
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."]

Commenter Organization Name: Pruis, Trisha
Comment Number: 2005N-0345-EC1044
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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 procduct 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.

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
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!

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
By restricting access based on IDs and age, or the presence of an adult, unless prescribed by a doctor.

Commenter Organization Name: Paslawsky, JoAnn
Comment Number: 2005N-0345-EC1129
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: Clague, Alexander

Comment Number: 2005N-0345-EC13
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.6 - Other actions
Excerpt Text:
Insomuch 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, consumers 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.

Commenter Organization Name: Rahl, Michael
Comment Number: 2005N-0345-EC13845
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
How about checking ID like for alcohol purchasing

Commenter Organization Name: Yao, Yvonne
Comment Number: 2005N-0345-EC1565
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.)

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Pharmacists and store cashiers should be allowed to require photo identification in order to purchase Plan B over-the- counter

Commenter Organization Name: Reusch, Elizabeth
Comment Number: 2005N-0345-EC165
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
By requiring an identification card be presented at the time of purchase.

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
Yes, depending upon the subpopulation, With age, identifications could be checked or in my comments below I also have a possible alternative solution.

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.4.6 - Other actions
Excerpt Text:
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.

Commenter Organization Name: Babb, Beverly
Comment Number: 2005N-0345-EC170
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 7.4.6 - Other actions
Excerpt Text:
On the front of the package thelabel 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.

Commenter Organization Name: Ross, Angela
Comment Number: 2005N-0345-EC172
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 6.1 - Yes
NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Ross, Angela
Comment Number: 2005N-0345-EC172
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.4.6 - Other actions
Excerpt Text:
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 cabnets 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.

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
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.

Commenter Organization Name: Witherwax, Carol
Comment Number: 2005N-0345-EC193
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
Probably not 100%. Pharmacies can be mandated by law to request thatcustomers 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.

Commenter Organization Name: Hibberd, Rachel
Comment Number: 2005N-0345-EC196
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
YES, this again is a rediculous 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.

Commenter Organization Name: Gay, Sarah
Comment Number: 2005N-0345-EC199
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 6.4.1 - Nicotine replacement therapy (e.g., Nicorette)
Excerpt Text:
The FDA already only allows nictoine 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.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Kisly, Anne
Comment Number: 2005N-0345-EC212
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.1 - Yes
Excerpt Text:
Certainly by prescriptions for minors and "carding" everyone else, just like alcohol or cigarettes

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
ID's will be checked for OTC product as with nicotine patches, alcohol, cigarettes, etc

Commenter Organization Name: Cepeda, Baudi
Comment Number: 2005N-0345-EC226
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.6 - Other actions

Excerpt Text:
Last resort would be to ask those who look young to provide ID and to limit the sale to just one package.

Commenter Organization Name: Hagan, Jane
Comment Number: 2005N-0345-EC32
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Llewellyn, Heather
Comment Number: 2005N-0345-EC325
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.8.4 - Interpretation is clear in present form
Excerpt Text:
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.

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
YES!!! This would not increase the amount of time or money in asking for ID.

Commenter Organization Name: Bilz, Michael
Comment Number: 2005N-0345-EC4
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:

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.

Commenter Organization Name: Clason, Dennis
Comment Number: 2005N-0345-EC47
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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.

Commenter Organization Name: Stier, Christopher
Comment Number: 2005N-0345-EC495
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
Yes. Minors are not permitted to buy alcohol without proper ID showing proof of age.

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
BY MAKING CASH REGISTERS CHECK DATE OF BIRTH

Commenter Organization Name: Padden, Phillip
Comment Number: 2005N-0345-EC505
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
Yes, follow the example of alchol and tobacco age restrictions.

Commenter Organization Name: Katrib, Elise
Comment Number: 2005N-0345-EC516
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
How do we enforce the sale of tobacco and alcohol? Just check ID.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
Most likly not, the only practicle 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 despensing.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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 impliment 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.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.6 - Other actions
Excerpt Text:
Allow pharacists to card those purchasing the drugs and the purchaser must sign a form stating "met age requirements".

Commenter Organization Name: Carter, Thomas
Comment Number: 2005N-0345-EC691
Excerpt Number: 5
Excerpt Status: NEW

Other Sections: NEW - 7.1 - Yes
NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
Excerpt Text:
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.

Commenter Organization Name: Dawson, Jennifer
Comment Number: 2005N-0345-EC7
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Rosati, Lucia
Comment Number: 2005N-0345-EC76
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Carlson, Brent
Comment Number: 2005N-0345-EC77
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
You could either require identification at the point-of-sale or require dispensing by a pharmacist (with ID).

Commenter Organization Name: Macdonell, Megan
Comment Number: 2005N-0345-EC779
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Macdonell, Megan

Comment Number: 2005N-0345-EC779
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.3.1.2 - Require retailer, pharmacist, and consumer education programs
Excerpt Text:
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.

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.5.4 - Other arguments
Excerpt Text:
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 pseudoephidrine-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 phamacy personnel having access to patient information (and interference with a request for an OTC drug) that can guide this train of thought?

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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).

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
Requiring photo ID from consumers for sale of such products would be an obvious first step.

Commenter Organization Name: Etter, Eleanor
Comment Number: 2005N-0345-EC96
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Brakman, Anita
Comment Number: 2005N-0345-EC97
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Such age limitations are already in place for purchasing cigarettes and alcohol. Similar age limits exist for everything from renting a car to voting.

Commenter Organization Name: Brakman, Anita
Comment Number: 2005N-0345-EC97
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
This could be simply enforced by asking consumers for proof of age and identification.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.6 - Other actions
Excerpt Text:
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.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
NEW - 8.1 - Yes
Excerpt Text:

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 were marketing the drug as both over the counter and prescription is the most practical approach. Imposing age restrictions on the purchase drugs, such a 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.

Commenter Organization Name: Tadeo, Peter
Comment Number: 2005N-0345-EMC373
Excerpt Number: 5
Excerpt Status: MODIFIED
Other Sections: MODIFIED - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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.

7.4.5 - Pursue criminal actions against violators

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 23
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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 overseee 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.

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
Other enforcement would be setting heavy fines or penalties to deter purchasers to purchase OTC drugs if they do not meet those limitations.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.7 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.6 - Other actions
Excerpt Text:
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 significnat penalty of legal sanctions, including possible jail time.

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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 belive 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 acquision of the product just as today the vendor or proxy is punished in underage cigarette and alcohol acquisition.

Commenter Organization Name: Clason, Dennis
Comment Number: 2005N-0345-EC47
Excerpt Number: 2

Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Recourse for illegal purchase can be turned over to the local authorities for processecution

Commenter Organization Name: Dawson, Jennifer
Comment Number: 2005N-0345-EC7
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
Excerpt Text:
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.

Commenter Organization Name: Oberst, Sara
Comment Number: 2005N-0345-EC860
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Tadeo, Peter
Comment Number: 2005N-0345-EMC373
Excerpt Number: 5
Excerpt Status: MODIFIED
Other Sections: MODIFIED - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

7.4.6 - Other actions

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 27
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to

achieve
Excerpt Text:
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.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
NEW - 7.4.4 - Require identification for age
Excerpt Text:
Insomuch 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, consumers 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.

Commenter Organization Name: Soriano, Lauren
Comment Number: 2005N-0345-EC14388
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
or accepting implied truth of asking for the patient's birthday and believing them.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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.

Commenter Organization Name: Babb, Beverly
Comment Number: 2005N-0345-EC170
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 7.4.4 - Require identification for age
Excerpt Text:
On the front of the package thelabel 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.

Commenter Organization Name: Ross, Angela
Comment Number: 2005N-0345-EC172
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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 cabnets 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.

Commenter Organization Name: Oyen, Duane

Comment Number: 2005N-0345-EC2107
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.6 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.5 - Pursue criminal actions against violators
Excerpt Text:
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 significnat penalty of legal sanctions, including possible jail time.

Commenter Organization Name: Cepeda, Baudi
Comment Number: 2005N-0345-EC226
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
Last resort would be to ask those who look young to provide ID and to limit the sale to just one package.

Commenter Organization Name: Wu, Jackie
Comment Number: 2005N-0345-EC307
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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 supervison of the pharmacist. An electronic pharmacy record will be helpful to track the number of drugs a subject takes.

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
Such a requirement is commonly done with cigarettes sold in Pharmacies. Enforcement is left to the local merchant.

Commenter Organization Name: Thompson, Sharon
Comment Number: 2005N-0345-EC526
Excerpt Number: 3

Excerpt Status: NEW
Excerpt Text:
For any subpopulation that is a minor, I would think a signature of a legal guardian would be necessary.

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
The box could have obvious differences such as labelling and shape to make sure the cashier realizes that he has to check ID.

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.4 - Require identification for age
Excerpt Text:
Allow pharacists to card those purchasing the drugs and the purchaser must sign a form stating "met age requirements".

Commenter Organization Name: Mock, Suzanne
Comment Number: 2005N-0345-EC940
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.4 - Require identification for age

Excerpt Text:
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.

Commenter Organization Name: Tadeo, Peter
Comment Number: 2005N-0345-EMC373
Excerpt Number: 7
Excerpt Status: MODIFIED
Excerpt Text:
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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

7.5 - FDA will be unable or it will be difficult to enforce as a practical matter

7.5.1 - FDA does not have authority to enforce limitation, and it cannot enforce as a practical matter

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 15
Excerpt Status: NEW
Other Sections: NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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 thee 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 ho regulations to instruct third parties in appropriate enforcement activities, nor is there any mechanism for FDA to ensure that enforcement is carried out.

Commenter Organization Name: Speight, Thomas
Comment Number: 2005N-0345-EC1041
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Landauer, Christopher
Comment Number: 2005N-0345-EC49
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No the agency does not have the authority to comply w/ this.

7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 15
Excerpt Status: NEW
Other Sections: NEW - 7.5.1 - FDA does not have authority to enforce limitation, and it cannot enforce as a practical matter
Excerpt Text:
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 thee 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 ho regulations to instruct third parties in appropriate enforcement activities, nor is there any mechanism for FDA to ensure that enforcement is carried out.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 5
Excerpt Status: NEW

Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
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.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
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.

Commenter Organization Name: Felty, Amy
Comment Number: 2005N-0345-EC210
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
As a quality assurance professional I would be concerned that it would not be practically feasable to have the appropriate controls in place to prevent abuse of some drugs if they were sold as both presciptions 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 ingedients if not used exactly per the label indications.

Commenter Organization Name: Fisher, Julie
Comment Number: 2005N-0345-EC343
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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?

Commenter Organization Name: Landauer, Christopher
Comment Number: 2005N-0345-EC49
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
NEW - 6.5.1 - FDA's authority limited to drug safety, effectiveness/efficacy, and labeling
NEW - 7.2 - No
Excerpt Text:
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.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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.

Commenter Organization Name: Ray, Amy
Comment Number: 2005N-0345-EC65
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
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.

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839

Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
there would have to be extensive regulations as to its access. many pharmacists are crunched for time as is. see below.

7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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; (I) 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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 19
Excerpt Status: NEW
Excerpt Text:
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 must 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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 20
Excerpt Status: NEW
Excerpt Text:
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 .]

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 22
Excerpt Status: NEW
Excerpt Text:
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.]

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 23
Excerpt Status: NEW
Other Sections: NEW - 3.8.3 - Other policy arguments for initiating a rulemaking
NEW - 6.6.2 - Congress
Excerpt Text:
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-l 7, 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 he 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.

Commenter Organization Name: LaChance, Robin
Comment Number: 2005N-0345-C54
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Ruckdeschel, Diana
Comment Number: 2005N-0345-C71
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
b. How can we be sure en 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.

Commenter Organization Name: Alterton, Faith
Comment Number: 2005N-0345-C83
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
Excerpt Text:
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.

Commenter Organization Name: Alterton, Faith
Comment Number: 2005N-0345-C83
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rose, Demian
Comment Number: 2005N-0345-EC1009
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
not without severely restricting access to the "legal" population.

Commenter Organization Name: Ladd, Judy
Comment Number: 2005N-0345-EC1032
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
It would be impossible to regulate something that is readily available to every other person OTC.

Commenter Organization Name: Pruis, Trisha
Comment Number: 2005N-0345-EC1044
Excerpt Number: 4
Excerpt Status: NEW

Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
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 procduct 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.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Roye, Carol
Comment Number: 2005N-0345-EC110
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
It is difficult. Think about how many teens buy alcohol and cigarettes.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 7.4.6 - Other actions
Excerpt Text:
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.

Commenter Organization Name: Dorn, Kellie
Comment Number: 2005N-0345-EC117
Excerpt Number: 1

Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 6.3.5 - Other legal/policy arguments
Excerpt Text:
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 dificult 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.

Commenter Organization Name: Thomas, Tiffany
Comment Number: 2005N-0345-EC13026
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Thomas, Tiffany
Comment Number: 2005N-0345-EC13026
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rahl, Michael
Comment Number: 2005N-0345-EC13845
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.3.2 - Other FDA enforcement practices that it has the legal authority to put in place
Excerpt Text:
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."

Commenter Organization Name: Loomis, Shirley
Comment Number: 2005N-0345-EC147
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
NEW - 6.7 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Marshall, Laura
Comment Number: 2005N-0345-EC15
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
As a matter of law, perhaps, but fake IDs and passing on of a prescription legally purchased would make the reality different.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
Obvoiusly, 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.

Commenter Organization Name: Association of American Physicians & Surgeons
Comment Number: 2005N-0345-EC15690
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
Excerpt Text:
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.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 6.5.4 - Other arguments
Excerpt Text:
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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 9
Excerpt Status: MODIFIED
Excerpt Text:
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 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?

Commenter Organization Name: Moon, Kristin
Comment Number: 2005N-0345-EC1927
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Witherwax, Carol
Comment Number: 2005N-0345-EC193
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age
Excerpt Text:
Probably not 100%. Pharmacies can be mandated by law to request thatcustomers 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.

Commenter Organization Name: Crousey, Joshua
Comment Number: 2005N-0345-EC1970
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: Richman, Bobbi
Comment Number: 2005N-0345-EC21
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
Excerpt Text:
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.

Commenter Organization Name: Felty, Amy
Comment Number: 2005N-0345-EC210
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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 presciption 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 contolling who buys what unless an entire system is set up as we do for the purchasing of alcohol.

Commenter Organization Name: Felty, Amy
Comment Number: 2005N-0345-EC210
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
As a quality assurance professional I would be concerned that it would not be practically feasable to have the appropriate controls in place to prevent abuse of some drugs if they were sold as both presciptions 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 ingedients if not used exactly per the label indications.

Commenter Organization Name: Young, Stan
Comment Number: 2005N-0345-EC211
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kisly, Anne
Comment Number: 2005N-0345-EC212
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rankis, A
Comment Number: 2005N-0345-EC22
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
No, the use of the product would be abused

Commenter Organization Name: Rankis, A
Comment Number: 2005N-0345-EC22
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
If a drug is indeed for "emergency contraception", there appears no way to control or enforce it's use in emergencies only

Commenter Organization Name: Pechacek, Deborah
Comment Number: 2005N-0345-EC27
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Pechacek, Deborah
Comment Number: 2005N-0345-EC27
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Again - I am at a loss as to how you will control and monitor where the product goes, once it is sold.

Commenter Organization Name: Myers, Micah
Comment Number: 2005N-0345-EC319
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 7.2 - No
Excerpt Text:
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.

Commenter Organization Name: Fisher, Julie
Comment Number: 2005N-0345-EC343
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: Fisher, Julie
Comment Number: 2005N-0345-EC343

Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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?

Commenter Organization Name: Scarpace, Sarah
Comment Number: 2005N-0345-EC38
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kulshrestha, Vikram V
Comment Number: 2005N-0345-EC405
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
In my opinion, it will not be possible to ensure the misuse.

Commenter Organization Name: Kulshrestha, Vikram V
Comment Number: 2005N-0345-EC405
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
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.

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
NEW - 7.5.4 - Other arguments
Excerpt Text:
In practice, this would raise the cost of prescription services and would probably not result in equitable and accurate enforcement.

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
Any violation of the prescription product's sales would be virtually unenforceable from a practical standpoint.

Commenter Organization Name: Anspach, Kurt
Comment Number: 2005N-0345-EC447
Excerpt Number: 2

Excerpt Status: NEW
Excerpt Text:
There wouldn't be any control over who buys these pills.Why fool ourselves saying lets put a age limit on them.After all is possible to purchased anything at any time.

Commenter Organization Name: Thompson, Sharon
Comment Number: 2005N-0345-EC526
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
It would not be possible to regulate having "prescription" status for a particular subpopulation because it would be too easy to circumvent this.

Commenter Organization Name: Thompson, Sharon
Comment Number: 2005N-0345-EC526
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
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.

Commenter Organization Name: McGhee, Tim
Comment Number: 2005N-0345-EC53
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: McGhee, Tim
Comment Number: 2005N-0345-EC53
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Della Paolera, Mark
Comment Number: 2005N-0345-EC555
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Della Paolera, Mark
Comment Number: 2005N-0345-EC555
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Porter, Rebecca
Comment Number: 2005N-0345-EC56
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
Excerpt Text:
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.

Commenter Organization Name: Porter, Rebecca
Comment Number: 2005N-0345-EC56
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
Look at the amount of alcohol that is sold to minors. There will always be a way for the underaged to get this medications.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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.

Commenter Organization Name: Tansley, Kathleen
Comment Number: 2005N-0345-EC569
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
NEW - 6.5.4 - Other arguments
Excerpt Text:
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 impossibilty to enforce such a regulation.

This is a bad idea for the FDA to pursue.

Commenter Organization Name: Naughton, John
Comment Number: 2005N-0345-EC572
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Older teens will buy the pills for younger teens.

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.6 - Other actions
Excerpt Text:
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.

Commenter Organization Name: Doran, Gregory
Comment Number: 2005N-0345-EC586
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
You would NOT be able to inforce 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 physiscian to properly educate the patient on its safe usage if it is safe for that patient.

Commenter Organization Name: Leonard, Ruth Tehila
Comment Number: 2005N-0345-EC59
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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 perscription or parental consent to purchase it. A quick cursery jaunt into chat rooms specific to teen issues in Israel shows this is a rather popular view of the new solution to free sex.

Commenter Organization Name: Leonard, Ruth Tehila
Comment Number: 2005N-0345-EC59
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Leonard, Ruth Tehila
Comment Number: 2005N-0345-EC59
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
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.

Commenter Organization Name: Leonard, Ruth Tehila
Comment Number: 2005N-0345-EC59
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
NEW - 4.2 - No
Excerpt Text:
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.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
Excerpt Text:
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, the 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.

Commenter Organization Name: Koch, Frances

Comment Number: 2005N-0345-EC610
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
The ability to enforce the law would be basically non-existant, and therefore, the hoped for protections for any subpopulation that would come through requiring a prescription would not, for practical purposes, be in place.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 10
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
It is ludicrous, insane, unresponsible to think that this would even be practical.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 15
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 17
Excerpt Status: NEW
Excerpt Text:
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).

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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 ineffecitve except as "political cover" for craven and unethical governmental

administrators.

Commenter Organization Name: Ray, Amy
Comment Number: 2005N-0345-EC65
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
The front line for such inforcement is pharmacists and they would not be able to adequately recommend, dispense and monitor subpopulations without significant work environment changes.

Commenter Organization Name: Ray, Amy
Comment Number: 2005N-0345-EC65
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
NEW - 7.5.2 - Infrastructure for FDA enforcement (e.g., resources, personnel, training, monitoring, third-party regulations) not in place
Excerpt Text:
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

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.1 - Yes
Excerpt Text:
No, it would not be able to monitor the use of such drugs adequately as a practical matter.

Commenter Organization Name: Vrankar, Anna
Comment Number: 2005N-0345-EC668
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
Is the ban on tobacco sales to minors enforeceable? Absolutely not.

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 5
Excerpt Status: NEW

Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Devine, Naomi
Comment Number: 2005N-0345-EC710
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
No. In practicality, this type of restiction would be nearly impossible to enforce.

Commenter Organization Name: Hager, Joseph R
Comment Number: 2005N-0345-EC716
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Phlips, Thomas
Comment Number: 2005N-0345-EC788
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Very difficultly.

Commenter Organization Name: Wagner, Patricia
Comment Number: 2005N-0345-EC813
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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?

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
Excerpt Text:
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.

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Look at methamphetamines and alcohol as examples!

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 7.4.4 - Require identification for age

Excerpt Text:
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).

Commenter Organization Name: Guy, Katie
Comment Number: 2005N-0345-EC896
Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
If a drug has a limitation for one group of individuals and not another, being simutaneously 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.

Commenter Organization Name: Guy, Katie
Comment Number: 2005N-0345-EC896
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
This would be extremely hard to enforce by law. Any GIRL 16 years or younger can easily have a friend or relative purchase the drugh OTC for them. If, as a result of this act, the child fell ill the FDA would be responsible.

Commenter Organization Name: Kopp, Margaret
Comment Number: 2005N-0345-EC903
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
No. The subpopulation in question would simply find a person who meets the preferred criteria to obtain the OTC product for them.

Commenter Organization Name: Hawkins, Susan
Comment Number: 2005N-0345-EC91
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 6.2 - No
Excerpt Text:
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.

7.5.4 - Other arguments

Commenter Organization Name: Dorn, Kellie
Comment Number: 2005N-0345-EC117
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Severance, Peter
Comment Number: 2005N-0345-EC135
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Irrelevant. The FDA would be creating an overly-complicated system of enforcement.

Commenter Organization Name: Jones, Kim
Comment Number: 2005N-0345-EC16543
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
No. Looking, for example, at minors, if minors can obtain cigarettes and alcohol, they will be able to obtain OTC medications as well.

Commenter Organization Name: Dowell, Duane
Comment Number: 2005N-0345-EC195
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
It seems that it would be overly cumbersome for the pharmacist.

Commenter Organization Name: Pechacek, Deborah
Comment Number: 2005N-0345-EC27
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
My other comment is about monitoring. How do you think you will prevent consumers in the NON-EXEMPT catagory from purchasing and either giving or selling the medication to people in the EXEMPT catagory? 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

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
In practice, this would raise the cost of prescription services and would probably not result in equitable and accurate enforcement.

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
NEW - 7.4.4 - Require identification for age

Excerpt Text:
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 pseudoephidrine-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 phamacy personnel having access to patient information (and interference with a request for an OTC drug) that can guide this train of thought?

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 15
Excerpt Status: NEW
Excerpt Text:
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.

7.6 - Miscellaneous arguments/discussions

Commenter Organization Name: Thomas, Tiffany
Comment Number: 2005N-0345-EC13026
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.4.6 - Other actions
Excerpt Text:
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.

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 14
Excerpt Status: NEW
Other Sections: NEW - 1.2.1 - Approve for OTC for all
NEW - 3.2 - No
Excerpt Text:
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.

Commenter Organization Name: McLeod, Doug
Comment Number: 2005N-0345-EC364
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 7.2 - No
Excerpt Text:
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.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 6.5.3 - Court cases
Excerpt Text:
Another issue is that many pharmacist currently have the option NOT to dispense emergency contraception (the case in Maryland),due to relgious 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 obliverate this right of mine to refuse to

dispense, since I object to its use in those over the age of 17 as well.

8 - Assuming legal to market both, may the prescription (Rx) and OTC products be legally sold in the same package? [ANPRM Q 3.A.]

8.1 - Yes

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Who cares? Yes. It's as legal as you want to say it is.

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
Yes, because it would be nessisary to ease confusion over the two options.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:
Yes if the labelling is adjusted appropriately.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
There would be no obvious reason why this would not be the case.

Commenter Organization Name: Reynolds, Charles
Comment Number: 2005N-0345-EC12
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Assuming there is no specific legal prevention, this would be acceptable.

Commenter Organization Name: Mershon, Claire-Helene
Comment Number: 2005N-0345-EC12379
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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?

Commenter Organization Name: Owens, B
Comment Number: 2005N-0345-EC14261
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Corlette, Chauncey
Comment Number: 2005N-0345-EC14491
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:
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.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Scott, Cindy
Comment Number: 2005N-0345-EC148
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
NEW - 8.8 - Examples of similar labeling of Rx and OTC products that are the same drug and dose, in the market place or previously marketed

Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Yao, Yvonne
Comment Number: 2005N-0345-EC1565
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Hutson, Paul
Comment Number: 2005N-0345-EC162
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Jones, Kim
Comment Number: 2005N-0345-EC16543
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
Yes, but see my comments below.

Commenter Organization Name: Murphy, Cynthia
Comment Number: 2005N-0345-EC176
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
of course.

Commenter Organization Name: Steward, Linda

Comment Number: 2005N-0345-EC181
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
yes.

Commenter Organization Name: Wilson, Rhianna
Comment Number: 2005N-0345-EC186
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 1.2 - Specific comments on drug approval process for Morning-after Pill/Plan B
Excerpt Text:
Yes. There should be more information about Plan B on the FDA website and should be readily available to all consumers.

Commenter Organization Name: Morrisroe, Julia
Comment Number: 2005N-0345-EC194
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Yes, again this seems like your making problems in order to avoid making a decision on this drug.

Commenter Organization Name: Hibberd, Rachel
Comment Number: 2005N-0345-EC196
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Gay, Sarah
Comment Number: 2005N-0345-EC199
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
I frankly don't see why this is an issue. Yes.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Yes, but this is just administrative wrangling...complicating things by trying to "please" a certain political constituency.

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 8.9 - Miscellaneous arguments/discussions

Excerpt Text:
Yes, unquestionably. The only people that would complain would be the pharmacy who can mark up their product more than OTC.

Commenter Organization Name: Cepeda, Baudi
Comment Number: 2005N-0345-EC226
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
YES

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 8.3.4 - Other legal arguments supporting one package label
Excerpt Text:
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)

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
They are the same product, so it would be unnecessary to have different packaging.

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Levinson, R. Saul
Comment Number: 2005N-0345-EC297
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
YES

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Llewellyn, Heather
Comment Number: 2005N-0345-EC325
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
Of course - but the package should have warnings, just like alcohol and tobacco do.

Commenter Organization Name: McLeod, Doug
Comment Number: 2005N-0345-EC364
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:

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 medecine 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.

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
YES! I see no reason for different packaging.

Commenter Organization Name: Bilz, Michael
Comment Number: 2005N-0345-EC4
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
Why not? They both do the same thing and the manufacturer sells these very same products in slightly more socially-concious 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.

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 7.5.3 - Actual compliance will be difficult/impossible/burdensome to achieve
Excerpt Text:
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

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.3.4 - Other legal arguments supporting one package label
Excerpt Text:
YES,WITH A DISCLOSURE

Commenter Organization Name: Padden, Phillip
Comment Number: 2005N-0345-EC505
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Katrib, Elise
Comment Number: 2005N-0345-EC516

Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Yes

Commenter Organization Name: Dolinski, Elizabeth
Comment Number: 2005N-0345-EC522
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
YES, of course.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
Certainly. There is nothing whatsoever to prevent it.

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.9 - Miscellaneous arguments/discussions
Excerpt Text:
It would not make a difference if the packaging contained language that indicated that two applications existed for the same product.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
Sure. The packaging would make no difference --- it's the person making the purchase who makes the difference.

Commenter Organization Name: Carter, Thomas
Comment Number: 2005N-0345-EC691
Excerpt Number: 6

Excerpt Status: NEW
Excerpt Text:
This question is a little beyond my knowledge, but on the face of it, I believe so.

Commenter Organization Name: Dawson, Jennifer
Comment Number: 2005N-0345-EC7
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
I see no problem with selling prescription and OTC medicines in the same package, so long as their distribution is controlled.

Commenter Organization Name: Rosati, Lucia
Comment Number: 2005N-0345-EC76
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
Certainly. I don't see why packaging would have to change. Only the manner in which it is sold would have to change.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
Yes they may legally sold in the same package.

Commenter Organization Name: Macdonell, Megan
Comment Number: 2005N-0345-EC779
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
I believe that they should be allowed to be sold in the same package.

Commenter Organization Name: Oberst, Sara
Comment Number: 2005N-0345-EC860
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
NEW - 8.3.4 - Other legal arguments supporting one package label
Excerpt Text:
Yes, as long as the appropriate warning is on the outside of the package.

Commenter Organization Name: Wurtz, Richard
Comment Number: 2005N-0345-EC94
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:

YES

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 16
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Etter, Eleanor
Comment Number: 2005N-0345-EC96
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
Of course. Doing otherwise would cause unnecessary expense to women.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:
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.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
NEW - 9.2.1 - Specific circumstances
NEW - 9.3 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
NEW - 7.4.4 - Require identification for age
Excerpt Text:
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 were marketing the drug as both over the counter and prescription is the most practical approach. Imposing age restrictions on the purchase drugs, such a 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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 1
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
NEW - 4.1 - Yes
NEW - 6.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

8.2 - No

Commenter Organization Name: Alterton, Faith
Comment Number: 2005N-0345-C83
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
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.

Commenter Organization Name: Dorn, Kellie
Comment Number: 2005N-0345-EC117
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.5.1 - FD&C Act - Legal differences between statutory requirements for Rx and OTC
Excerpt Text:
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.

Commenter Organization Name: Slee, April
Comment Number: 2005N-0345-EC121
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
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.

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 3
Excerpt Status: MODIFIED
Other Sections: NEW - 8.9 - Miscellaneous arguments/discussions
Excerpt Text:

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.

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
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.

Commenter Organization Name: Loomis, Shirley
Comment Number: 2005N-0345-EC147
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
They should be packaged differently to help alleviate confusion for those responsible for handling them.

Commenter Organization Name: Academy of Managed Care Pharmacy
Comment Number: 2005N-0345-EC15687
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
The Academy believes that the two products must be sold in different packaging.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 9

Excerpt Status: NEW
Other Sections: NEW - 8.7 - Examples of Rx and OTC labeling that is similar but with one or two differences - e.g., dosage/age distinction
Excerpt Text:
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.

Commenter Organization Name: Subcommittee on Criminal Justice, Drug Policy
Comment Number: 2005N-0345-EC16770
Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Witherwax, Carol
Comment Number: 2005N-0345-EC193
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
I think that the packaging should be different (maybe just in color) so that the prescription drug is more distinquishable from the OTC product.

Commenter Organization Name: Oyen, Duane
Comment Number: 2005N-0345-EC2107
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
The different products should not be sold in the same packaging.

Commenter Organization Name: Rankis, A
Comment Number: 2005N-0345-EC22
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
no

Commenter Organization Name: Pechacek, Deborah
Comment Number: 2005N-0345-EC27
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
NO - they need to be in 2 separate packages.

Commenter Organization Name: Endris, Kelle
Comment Number: 2005N-0345-EC278
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:

NO!

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
I belive 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.

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
When there would be significant confusion as to the intended recipiant 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.

Commenter Organization Name: Collum, Mark
Comment Number: 2005N-0345-EC33
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
No. Their packaging should be different and distinct.

Commenter Organization Name: Hudson, Ralph
Comment Number: 2005N-0345-EC34
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Only if the goal is mass confusion and the complete breakdown of requiring that any drugs are dispensed only by a doctor's prescription.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 11
Excerpt Status: NEW

Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Kulshrestha, Vikram V
Comment Number: 2005N-0345-EC405
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Duchon, Kathleen
Comment Number: 2005N-0345-EC426
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
No, I would think to clarify the confusion you would have to mandate different packaging.

Commenter Organization Name: Lamermayer, Richard J
Comment Number: 2005N-0345-EC43
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
NO.

Commenter Organization Name: Kowalczyk, Brigid
Comment Number: 2005N-0345-EC518
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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.

Commenter Organization Name: Zahn, Steven
Comment Number: 2005N-0345-EC52
Excerpt Number: 6
Excerpt Status: NEW

Excerpt Text:
No.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 10
Excerpt Status: NEW
Other Sections: NEW - 8.5.4 - Other legal arguments opposing one package
Excerpt Text:
However, differences in packaging would make control of violations (sales to minors, for instance) easier to detect and, perhaps, prosecute.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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.

Commenter Organization Name: Della Paolera, Mark
Comment Number: 2005N-0345-EC555
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 10
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
No, because of the harmful side effects of this drug.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
It should not be legal.

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:

No.

Commenter Organization Name: Billingsley, Daniel
Comment Number: 2005N-0345-EC609
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
What would be the distinction in product? Would this not cause more confusion?

Commenter Organization Name: Billingsley, Daniel
Comment Number: 2005N-0345-EC609
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
I don't believe the two products could be sold or packaged in a single package.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
NO. Again, that is totally irresponsible, insane, ludicrous.

Commenter Organization Name: Ray, Amy
Comment Number: 2005N-0345-EC65
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
NO

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
No, different strenghts of product, different and separate packaging.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.5.4 - Other legal arguments opposing one package
NEW - 8.9 - Miscellaneous arguments/discussions
Excerpt Text:
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 procurred as a prescription and when it was procurred 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.

Commenter Organization Name: Ricci, Stephen
Comment Number: 2005N-0345-EC73
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.8 - Examples of similar labeling of Rx and OTC products that are the same drug and dose, in the market place or previously marketed
Excerpt Text:
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

Commenter Organization Name: Carlson, Brent
Comment Number: 2005N-0345-EC77
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:
The "legend" would have to be modified to read "for patients under 17 years of age".

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 9.2.2 - All circumstances (i.e., it's always appropriate, there are no inappropriate circumstances)
Excerpt Text:
Not at all.

Commenter Organization Name: Smith, Rodney
Comment Number: 2005N-0345-EC83
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
No.

Commenter Organization Name: Jago, Laura
Comment Number: 2005N-0345-EC839
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
no.

Commenter Organization Name: Townsend, Elisha
Comment Number: 2005N-0345-EC90
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.6.3 - Same packaging permits/encourages trading/swapping
Excerpt Text:
IF you are planning on enforcing the legality of who can have it, you must have diferent packaging and

the pills should look different as well.

Commenter Organization Name: Stockton, Melissa
Comment Number: 2005N-0345-EC99
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
No

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

8.3 - Legal arguments supporting one package label for Rx and OTC sales

8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 29
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 30
Excerpt Status: NEW
Excerpt Text:
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).

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 31
Excerpt Status: NEW
Excerpt Text:
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)(1l)(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).

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 32
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 33
Excerpt Status: NEW
Excerpt Text:
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(6)(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 S03(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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 34
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 7

Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
Yes if the labelling is adjusted appropriately.

Commenter Organization Name: Clague, Alexander
Comment Number: 2005N-0345-EC13
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
NEW - 8.7 - Examples of Rx and OTC labeling that is similar but with one or two differences - e.g., dosage/age distinction
Excerpt Text:
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.

Commenter Organization Name: Corlette, Chauncey
Comment Number: 2005N-0345-EC14491
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 13
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: TomHon, Catherine

Comment Number: 2005N-0345-EC281
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: McLeod, Doug
Comment Number: 2005N-0345-EC364
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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 medecine 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.

Commenter Organization Name: Carlson, Brent
Comment Number: 2005N-0345-EC77

Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
The "legend" would have to be modified to read "for patients under 17 years of age".

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Typically, OTC and prescription formulations have different packaging, and I believe it is appropriate to do so if it is deamed necessary to have pertinent health and usage information clearly displayed on the packaging. Typically, presription 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.

Commenter Organization Name: Oberst, Sara
Comment Number: 2005N-0345-EC860
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.3.4 - Other legal arguments supporting one package label
Excerpt Text:
Yes, as long as the appropriate warning is on the outside of the package.

Commenter Organization Name: Kopp, Margaret
Comment Number: 2005N-0345-EC903
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
It depends on whether the written patient instructions accompanying the package could be made clear and un-ambiguous under those circumstances.

Commenter Organization Name: Keys, Lori
Comment Number: 2005N-0345-EC98
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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.

8.3.2 - Do not need separate National Drug Code (NDC) numbers

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415

Excerpt Number: 35
Excerpt Status: NEW
Excerpt Text:
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.

8.3.3 - Court cases

8.3.4 - Other legal arguments supporting one package label

Commenter Organization Name: Nguyen, Marie
Comment Number: 2005N-0345-EC13851
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kisly, Anne
Comment Number: 2005N-0345-EC212
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.9 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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)

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5

Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
YES,WITH A DISCLOSURE

Commenter Organization Name: Macdonell, Megan
Comment Number: 2005N-0345-EC779
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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 procautionary measure included in the OTC meds.

Commenter Organization Name: Oberst, Sara
Comment Number: 2005N-0345-EC860
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:
Yes, as long as the appropriate warning is on the outside of the package.

8.4 - Policy arguments supporting one package label for Rx and OTC sales

8.4.1 - Other policy arguments supporting one package label

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
Yes, because it would be nessisary to ease confusion over the two options.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670

Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
It would be inappropriate to charge any additional fee for either package; the price should be the same.

Commenter Organization Name: Mershon, Claire-Helene
Comment Number: 2005N-0345-EC12379
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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?

Commenter Organization Name: Dougherty, Anne
Comment Number: 2005N-0345-EC126
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Connors, Meaghan
Comment Number: 2005N-0345-EC141
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
If they are in fact the same product with the same specifications, I don't see the relevance of this question.

Commenter Organization Name: Owens, B
Comment Number: 2005N-0345-EC14261
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Yao, Yvonne
Comment Number: 2005N-0345-EC1565
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 19
Excerpt Status: MODIFIED
Other Sections: MODIFIED - 7.4 - Other point-of-sale enforcement suggestions
Excerpt Text:
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.

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.2 - Risk of medication errors or threats to patient safety
NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 12
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Tuchinsky, Marla
Comment Number: 2005N-0345-EC201
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 13
Excerpt Status: NEW
Other Sections: NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:
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.

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
They are the same product, so it would be unnecessary to have different packaging.

Commenter Organization Name: TomHon, Catherine
Comment Number: 2005N-0345-EC281
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:
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.

Commenter Organization Name: Hagan, Jane
Comment Number: 2005N-0345-EC32
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.3 - Alcohol and tobacco enforcement
Excerpt Text:
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.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:
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.

Commenter Organization Name: Bilz, Michael
Comment Number: 2005N-0345-EC4
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
Why not? They both do the same thing and the manufacturer sells these very same products in slightly more socially-concious 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.

Commenter Organization Name: Clason, Dennis
Comment Number: 2005N-0345-EC47
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 9.2.1 - Specific circumstances
Excerpt Text:
If the indications are the same for the OTC and prescription product, then I think that differentiated packaging is silly.

Commenter Organization Name: Dolinski, Elizabeth
Comment Number: 2005N-0345-EC522
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
To require different packaging would raise the price for no good purpose.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
Sure. The packaging would make no difference --- it's the person making the purchase who makes the difference.

Commenter Organization Name: Rosati, Lucia
Comment Number: 2005N-0345-EC76
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
Certainly. I don't see why packaging would have to change. Only the manner in which it is sold would have to change.

Commenter Organization Name: Phlips, Thomas
Comment Number: 2005N-0345-EC788
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 16
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 18
Excerpt Status: NEW

Excerpt Text:
In fact, separate packaging might encourage consumers to think (erroneously) that the two are different or should be used differently.

Commenter Organization Name: Etter, Eleanor
Comment Number: 2005N-0345-EC96
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
Of course. Doing otherwise would cause unnecessary expense to women.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 9.2.1 - Specific circumstances
NEW - 9.3 - Miscellaneous arguments/discussions
Excerpt Text:
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.

8.5 - Legal arguments opposing one package for Rx and OTC sales

Commenter Organization Name: Black, Jerrold
Comment Number: 2005N-0345-EC111
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 7
Excerpt Status: NEW

Excerpt Text:
As discussed previously, ease of enforcement and concerns about vendor and/or customer confusion would warrant selling the products under different labeling.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
Differentiation should only be required if it can facilitate enforcement.

Commenter Organization Name: Pinkerton, Mike
Comment Number: 2005N-0345-EC171
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
When the package differentiation is necessary as part of enforcement procedure.

Commenter Organization Name: Wagner, Patricia
Comment Number: 2005N-0345-EC813
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
It would seem to be an invitation for lawsuits against pharmaceutical manufacturers.

Commenter Organization Name: Hawkins, Susan
Comment Number: 2005N-0345-EC91
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.9 - Miscellaneous arguments/discussions
Excerpt Text:
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.

8.5.1 - FD&C Act - Legal differences between statutory requirements for Rx and OTC

Commenter Organization Name: Pfizer, Inc.
Comment Number: 2005N-0345-C407
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.3.3 - Other arguments related to FD&C Act
Excerpt Text:
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 2 1 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.]

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 3.3.2 - FD&C Act is clear regarding when a drug should be prescription only
Excerpt Text:
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, 2457 (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).

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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, 2l 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.

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Dorn, Kellie
Comment Number: 2005N-0345-EC117
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: Academy of Managed Care Pharmacy
Comment Number: 2005N-0345-EC15687
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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."

Commenter Organization Name: Labbe, Carl

Comment Number: 2005N-0345-EC408
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
As I see it, under current regulations, different labeling is required.

8.5.2 - Court cases arguments opposing one package

8.5.3 - Need separate National Drug Code (NDC) numbers for billing

Commenter Organization Name: Reynolds, Charles
Comment Number: 2005N-0345-EC12
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Academy of Managed Care Pharmacy
Comment Number: 2005N-0345-EC15687
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 7.4.3 - Monitor compliance and enforcement / conduct random inspections
Excerpt Text:
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.

8.5.4 - Other legal arguments opposing one package

Commenter Organization Name: Kirkpatrick & Lockhart Nicholson Graham on behalf of Concerned Women for America, et al.
Comment Number: 2005N-0345-C414
Excerpt Number: 27
Excerpt Status: NEW
Other Sections: NEW - 3.7.1 - Other legal arguments supporting rulemaking
Excerpt Text:

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 l4: 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.

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Selling them in OTC packages would be inappropriate. That would essentially remove all restrictions on the prescriptive ingredient.

Commenter Organization Name: Kulshrestha, Vikram V
Comment Number: 2005N-0345-EC405
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 10
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
However, differences in packaging would make control of violations (sales to minors, for instance) easier to detect and, perhaps, prosecute.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 7
Excerpt Status: NEW

Other Sections: NEW - 8.2 - No
NEW - 8.9 - Miscellaneous arguments/discussions
Excerpt Text:
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 procurred as a prescription and when it was procurred 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.

Commenter Organization Name: Hager, Joseph R
Comment Number: 2005N-0345-EC716
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
There is no way to control the dispensing that "medicine" if packaged the same.

Commenter Organization Name: Guy, Katie
Comment Number: 2005N-0345-EC896
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

8.6 - Policy arguments opposing one package for Rx and OTC sales

Commenter Organization Name: Ladd, Judy
Comment Number: 2005N-0345-EC1032
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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?

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 8.6.3 - Same packaging permits/encourages trading/swapping
NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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?

Commenter Organization Name: Oyola, Sandra
Comment Number: 2005N-0345-EC85
Excerpt Number: 5

Excerpt Status: NEW
Other Sections: NEW - 8.7 - Examples of Rx and OTC labeling that is similar but with one or two differences - e.g., dosage/age distinction
Excerpt Text:
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 presciption product. This information is included on the packaging. It could also affect insurance coverage/reimbursement.

8.6.1 - Single package contrary to meaningful difference standard

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 5
Excerpt Status: MODIFIED
Other Sections: MODIFIED - 8.6.2 - Risk of medication errors or threats to patient safety
NEW - 8.9 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
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.

8.6.2 - Risk of medication errors or threats to patient safety

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 5
Excerpt Status: MODIFIED
Other Sections: MODIFIED - 8.6.1 - Single package contrary to meaningful difference standard
NEW - 8.9 - Miscellaneous arguments/discussions

Excerpt Text:
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.

Commenter Organization Name: Ruckdeschel, Diana
Comment Number: 2005N-0345-C71
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Alterton, Faith
Comment Number: 2005N-0345-C83
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 1.2.3 - Maintain Rx only
NEW - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: Slee, April
Comment Number: 2005N-0345-EC121
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 4.1 - Yes
NEW - 8.2 - No

Excerpt Text:
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.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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.

Commenter Organization Name: Loomis, Shirley
Comment Number: 2005N-0345-EC147
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
They should be packaged differently to help alleviate confusion for those responsible for handling them.

Commenter Organization Name: Reusch, Elizabeth
Comment Number: 2005N-0345-EC165
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
I belive 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.

Commenter Organization Name: Zahn, Steven
Comment Number: 2005N-0345-EC52
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
There would be too much confusion among packaging, leading too errors in dispensing the wrong products or packaging.

Commenter Organization Name: Ray, Amy
Comment Number: 2005N-0345-EC65
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
although it is dangerous to market as both OTC and prescription status due to possible double dosing, overdosing, and lack of apropriate medical guidance regarding diagnosis and treatment.

Commenter Organization Name: Ray, Amy
Comment Number: 2005N-0345-EC65
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Socha, Kathleen
Comment Number: 2005N-0345-EC678
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
It would make it easier for the kids to get the right one.

Commenter Organization Name: Wagner, Patricia
Comment Number: 2005N-0345-EC813

Excerpt Number: 1
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Wagner, Patricia
Comment Number: 2005N-0345-EC813
Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.1 - Yes
Excerpt Text:
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 dissimular that the ordinary customer will identify them as two different products.

Commenter Organization Name: Burns, Ben
Comment Number: 2005N-0345-EC93
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
no, it would cause confusion.

Commenter Organization Name: Brakman, Anita
Comment Number: 2005N-0345-EC97
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 8.6.3 - Same packaging permits/encourages trading/swapping
Excerpt Text:
It is advisable to use different packaging to help ease enforcement and prevent mistakes in distribution.

8.6.3 - Same packaging permits/encourages trading/swapping

Commenter Organization Name: Rucker, Gwendolyn
Comment Number: 2005N-0345-EC1080
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 8.6 - Policy arguments opposing one package for Rx and OTC sales
NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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?

Commenter Organization Name: Townsend, Elisha
Comment Number: 2005N-0345-EC90
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
IF you are planning on enforcing the legality of who can have it, you must have diferent packaging and the pills should look different as well.

Commenter Organization Name: Brakman, Anita
Comment Number: 2005N-0345-EC97
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
It is advisable to use different packaging to help ease enforcement and prevent mistakes in distribution.

Commenter Organization Name: Stockton, Melissa
Comment Number: 2005N-0345-EC99
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
to discourage buying and redistributing, they should be in different packages.

8.6.4 - Other arguments opposing one package

Commenter Organization Name: White, Alan
Comment Number: 2005N-0345-EC1121
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 6.6.1 - State and local agencies have authority to enforce point-of-sale (e.g., recent limitations on cold medicines)
Excerpt Text:
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.

Commenter Organization Name: Peters, Jeanette
Comment Number: 2005N-0345-EC132
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
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.

Commenter Organization Name: Soriano, Lauren
Comment Number: 2005N-0345-EC14388
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.4.6 - Other actions
Excerpt Text:
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.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 9.1.2 - All circumstances (i.e., it's always inappropriate)
Excerpt Text:
That would cause undue confusion at the store level. Prescription drugs and their over-the-counter equivalents should always be packaged differently.

Commenter Organization Name: Moon, Kristin
Comment Number: 2005N-0345-EC1927
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Oyen, Duane

Comment Number: 2005N-0345-EC2107
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
There should be signficant alert notices on the OTC package and the rules regarding consumer eligibility shoud be broadly disseminated to enhance enforcement success.

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Wu, Jackie
Comment Number: 2005N-0345-EC307
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
Not critical. For practical manner, different package is easy to handle.

Commenter Organization Name: Collum, Mark
Comment Number: 2005N-0345-EC33
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 9.1.2 - All circumstances (i.e., it's always inappropriate)
Excerpt Text:
It is inapprorpiate to allow one single package to represent two products...that is deceptive to all parties involved.

Commenter Organization Name: Kowalczyk, Brigid
Comment Number: 2005N-0345-EC518
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: Rommel, Scott
Comment Number: 2005N-0345-EC54
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: Della Paolera, Mark
Comment Number: 2005N-0345-EC555
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: Burgess, Annette
Comment Number: 2005N-0345-EC566
Excerpt Number: 10
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
No, because of the harmful side effects of this drug.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
If you ever actually went down that path you'd have to have some way to determine the differenct in the general population, or you would NEVER be able to enforce the controls.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
If the FDA would seek to undermine public confidence in its purpose and effectiveness then such a plan should be pursued.

Commenter Organization Name: O'Hagan, James
Comment Number: 2005N-0345-EC827
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 8.6 - Policy arguments opposing one package for Rx and OTC sales
NEW - 8.6.3 - Same packaging permits/encourages trading/swapping
Excerpt Text:
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?

Commenter Organization Name: Vander Bleek, Luke
Comment Number: 2005N-0345-EC870
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 3.8.8 - Other policy arguments opposing a rulemaking

Excerpt Text:
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.

Commenter Organization Name: Mock, Suzanne
Comment Number: 2005N-0345-EC940
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Mock, Suzanne
Comment Number: 2005N-0345-EC940
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 9.1.2 - All circumstances (i.e., it's always inappropriate)
Excerpt Text:
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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

8.7 - Examples of Rx and OTC labeling that is similar but with one or two differences - e.g., dosage/age distinction

Commenter Organization Name: Clague, Alexander
Comment Number: 2005N-0345-EC13

Excerpt Number: 2
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
NEW - 8.3.1 - FD&C Act arguments (e.g., single label could be created that satisfies both sets of statutory requirements)
Excerpt Text:
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.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 20
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Dolinski, Elizabeth
Comment Number: 2005N-0345-EC522
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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 ibruprofen.

Commenter Organization Name: Oyola, Sandra
Comment Number: 2005N-0345-EC85
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.6 - Policy arguments opposing one package for Rx and OTC sales

Excerpt Text:
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 presciption product. This information is included on the packaging. It could also affect insurance coverage/reimbursement.

8.8 - Examples of similar labeling of Rx and OTC products that are the same drug and dose, in the market place or previously marketed

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
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 form 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.

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 12
Excerpt Status: NEW
Other Sections: MODIFIED - 9.1.1 - Specific circumstances
Excerpt Text:
B. While not entirely clear as a broad rule, there are circumstances were 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, and the 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.

Commenter Organization Name: Scott, Cindy
Comment Number: 2005N-0345-EC148
Excerpt Number: 1
Excerpt Status: NEW

Other Sections: NEW - 3.9.1 - Drug approval examples
NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
I'm not sure how Claritin does it. You could look to that as a model.

Commenter Organization Name: Ellis, Pamela
Comment Number: 2005N-0345-EC216
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Ricci, Stephen
Comment Number: 2005N-0345-EC73
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
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

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951
Excerpt Number: 17
Excerpt Status: NEW
Other Sections: NEW - 3.9.1 - Drug approval examples
Excerpt Text:
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.

8.9 - Miscellaneous arguments/discussions

Commenter Organization Name: Arnall Golden Gregory LLP
Comment Number: 2005N-0345-C403
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: MODIFIED - 8.6.1 - Single package contrary to meaningful difference standard
MODIFIED - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
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.

Commenter Organization Name: Ladd, Judy
Comment Number: 2005N-0345-EC1032
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Pruis, Trisha
Comment Number: 2005N-0345-EC1044
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Chihane, Ziad
Comment Number: 2005N-0345-EC13197
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: MODIFIED - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: Smart, Stephanie
Comment Number: 2005N-0345-EC16
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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 ingrediant is available OTC and by prescription then wouldn't they automatically have different packaging becasue they would have different uses>

Commenter Organization Name: Smart, Stephanie
Comment Number: 2005N-0345-EC16
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
What two products? This is not clear. If you are referreing to the above question it doesn't make sense. They wouldn't be in the ame package if one is by prescription and one is OTC.

Commenter Organization Name: Kisly, Anne
Comment Number: 2005N-0345-EC212
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.3.4 - Other legal arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Kisly, Anne
Comment Number: 2005N-0345-EC212
Excerpt Number: 8
Excerpt Status: MODIFIED
Excerpt Text:
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?

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 9
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
Yes, unquestionably. The only people that would complain would be the pharmacy who can mark up their product more than OTC.

Commenter Organization Name: Rupp, Charles
Comment Number: 2005N-0345-EC323
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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 meaningless 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.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: McGhee, Tim
Comment Number: 2005N-0345-EC53
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Peer, Gerald
Comment Number: 2005N-0345-EC626
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
It would not make a difference if the packaging contained language that indicated that two applications existed for the same product.

Commenter Organization Name: Gordon, Jennifer
Comment Number: 2005N-0345-EC677
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
NEW - 8.5.4 - Other legal arguments opposing one package
Excerpt Text:
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 procurred as a prescription and when it was procurred 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.

Commenter Organization Name: Schulz, Stan
Comment Number: 2005N-0345-EC680
Excerpt Number: 10
Excerpt Status: NEW
Excerpt Text:
There are not "two products". They would be the same with just different locations and sales restrictions.

Commenter Organization Name: Hager, Joseph R
Comment Number: 2005N-0345-EC716
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Are you asking a legal question of non-legally trained people?

Commenter Organization Name: Hager, Joseph R
Comment Number: 2005N-0345-EC716
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
Without a parent's approval.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 11
Excerpt Status: NEW
Excerpt Text:
In fact, a more useful law would be one preventing pharmaceutical companies from artificially inflating the price of either the OTC or prescription version.

Commenter Organization Name: Oyola, Sandra
Comment Number: 2005N-0345-EC85
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Kopp, Margaret
Comment Number: 2005N-0345-EC903
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Hawkins, Susan
Comment Number: 2005N-0345-EC91
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.5 - Legal arguments opposing one package for Rx and OTC sales
Excerpt Text:
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.

Commenter Organization Name: Syed, Misbah
Comment Number: 2005N-0345-EMC368
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
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.

9 - If they can be legally sold in same package, under what circumstances would it be inappropriate to do so? [ANPRM Q 3.B.]

9.1 - Circumstances in which it is inappropriate to distribute products in a single package

9.1.1 - Specific circumstances

Commenter Organization Name: GlaxoSmithKline
Comment Number: 2005N-0345-C307
Excerpt Number: 10
Excerpt Status: MODIFIED
Excerpt Text:
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).

Commenter Organization Name: Consumer Healthcare Products Association
Comment Number: 2005N-0345-C412
Excerpt Number: 12
Excerpt Status: MODIFIED
Other Sections: NEW - 8.8 - Examples of similar labeling of Rx and OTC products that are the same drug and dose, in the market place or previously marketed
Excerpt Text:
B. While not entirely clear as a broad rule, there are circumstances were 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, and the 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.

Commenter Organization Name: Duramed Research, Inc. and Duramed Pharmaceuticals, Inc.
Comment Number: 2005N-0345-C415
Excerpt Number: 36
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Speight, Thomas
Comment Number: 2005N-0345-EC1041
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Burometto Jr, Charles
Comment Number: 2005N-0345-EC109
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
When the directions for use are so vastly different that confusion could occur when reading the instructions leading to inappropriate use.

Commenter Organization Name: Paslawsky, JoAnn
Comment Number: 2005N-0345-EC1129
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Different packaging should only be needed when formulations differ, including but not limited to active ingredient.

Commenter Organization Name: Reynolds, Charles
Comment Number: 2005N-0345-EC12
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.5.3 - Need separate National Drug Code (NDC) numbers for billing
Excerpt Text:
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.

Commenter Organization Name: Slee, April
Comment Number: 2005N-0345-EC121
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
If the risks are different, you need different warnings.

Commenter Organization Name: Steele, Robert
Comment Number: 2005N-0345-EC146
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 9.2.2 - All circumstances (i.e., it's always appropriate, there are no inappropriate circumstances)
Excerpt Text:
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 to 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.

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: American Pharmacists Association
Comment Number: 2005N-0345-EC16675
Excerpt Number: 20
Excerpt Status: NEW
Other Sections: NEW - 8.7 - Examples of Rx and OTC labeling that is similar but with one or two differences - e.g., dosage/age distinction
Excerpt Text:
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.

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
NEW - 8.6.2 - Risk of medication errors or threats to patient safety
Excerpt Text:
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.

Commenter Organization Name: Hein, Rachel
Comment Number: 2005N-0345-EC168
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Only if there is a proven danger of bodily harm to the actual user.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 12
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Gibbons, Bridget
Comment Number: 2005N-0345-EC2009
Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:
If the products differed in dosage or content, it would be inappropriate to sell them in a single package.

Commenter Organization Name: Tuchinsky, Marla
Comment Number: 2005N-0345-EC201
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:

If the dosage were different. If they were manufactured by different companies.

Commenter Organization Name: Kisly, Anne
Comment Number: 2005N-0345-EC212
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Waychoff, W. Aaron
Comment Number: 2005N-0345-EC311
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
When there would be significant confusion as to the intended recipiant 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.

Commenter Organization Name: McLeod, Doug
Comment Number: 2005N-0345-EC364
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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 consuption 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 menstral cycle.

Commenter Organization Name: Tufts, Gillian
Comment Number: 2005N-0345-EC399
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: Labbe, Carl
Comment Number: 2005N-0345-EC408
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Certain, product-specific information or condition-specific information may need to be presented in different ways to different individual patients.

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416

Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
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.

Commenter Organization Name: Thompson, Donald
Comment Number: 2005N-0345-EC416
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Anytime there are biologic or behavioral safely issues associated with access to the products, it would be inappropriate to sell such a product in the same package.

Commenter Organization Name: Duchon, Kathleen
Comment Number: 2005N-0345-EC426
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
When it is given to an under age consumer

Commenter Organization Name: Clason, Dennis
Comment Number: 2005N-0345-EC47
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:
If the indications were different for the OTC and prescription products, I would expect that different packaging would be required and reasonable.

Commenter Organization Name: Cunningham, Laura
Comment Number: 2005N-0345-EC5
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
IF THERE WAS A DIFFERENCE IN PRODUCT INGREDIENTS

Commenter Organization Name: Dolinski, Elizabeth
Comment Number: 2005N-0345-EC522
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.7 - Examples of Rx and OTC labeling that is similar but with one or two differences - e.g., dosage/age distinction
Excerpt Text:
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 ibruprofen.

Commenter Organization Name: Venturella, Vincent
Comment Number: 2005N-0345-EC58
Excerpt Number: 8

Excerpt Status: NEW
Excerpt Text:
When one cannot be secure in the knowledge that the "Prescription Only" product will be available to only the restricted group.

Commenter Organization Name: Goodman, Evan
Comment Number: 2005N-0345-EC6
Excerpt Number: 11
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
No, different strenghts of product, different and separate packaging.

Commenter Organization Name: Baird, Debora
Comment Number: 2005N-0345-EC66
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
None as long as "Plan B" Morning After pill is sold in a different strength and dosage, they are not the same.

Commenter Organization Name: Socha, Kathleen
Comment Number: 2005N-0345-EC678
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
When the product can kill a person. Adults die from this drug too.

Commenter Organization Name: Carter, Thomas
Comment Number: 2005N-0345-EC691
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Dawson, Jennifer
Comment Number: 2005N-0345-EC7
Excerpt Number: 5
Excerpt Status: NEW

Other Sections: NEW - 8.1 - Yes
Excerpt Text:
I see no problem with selling prescription and OTC medicines in the same package, so long as their distribution is controlled.

Commenter Organization Name: Schmierer, Ann
Comment Number: 2005N-0345-EC81
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Oberst, Sara
Comment Number: 2005N-0345-EC860
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Guy, Katie
Comment Number: 2005N-0345-EC896
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
In the circumstance of the drug Plan B it would be unequivocally inappropriate to do so!!

Commenter Organization Name: Kopp, Margaret
Comment Number: 2005N-0345-EC903
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Wurtz, Richard
Comment Number: 2005N-0345-EC94
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Brass, Kathryn
Comment Number: 2005N-0345-EC951

Excerpt Number: 16
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:
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.

Commenter Organization Name: Thames, Samuel
Comment Number: 2005N-0345-EMC374
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
Excerpt Text:
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.

Commenter Organization Name: Vu, Tram
Comment Number: 2005N-0345-EMC397
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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.

9.1.2 - All circumstances (i.e., it's always inappropriate)

Commenter Organization Name: Dorn, Kellie
Comment Number: 2005N-0345-EC117
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
It would never be appropriate.

Commenter Organization Name: Bachelor, Emiliann
Comment Number: 2005N-0345-EC160
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
That would cause undue confusion at the store level. Prescription drugs and their over-the-counter equivalents should always be packaged differently.

Commenter Organization Name: Pechacek, Deborah
Comment Number: 2005N-0345-EC27
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
ANY TIME

Commenter Organization Name: Endris, Kelle
Comment Number: 2005N-0345-EC278
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Over the Counter

Commenter Organization Name: Collum, Mark
Comment Number: 2005N-0345-EC33
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
It is inapprorpiate to allow one single package to represent two products...that is deceptive to all parties involved.

Commenter Organization Name: Kowalczyk, Brigid
Comment Number: 2005N-0345-EC518
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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!

Commenter Organization Name: Zahn, Steven
Comment Number: 2005N-0345-EC52
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Koch, Frances
Comment Number: 2005N-0345-EC610

Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:
It would NEVER be appropriate to do so. Under ALL circumstances it should be considered inappropriate to sell them in a single package.

Commenter Organization Name: Friedl, Mary Frances
Comment Number: 2005N-0345-EC671
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Under all purposes.

Commenter Organization Name: Gorini, Joseph
Comment Number: 2005N-0345-EC717
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
Always.

Commenter Organization Name: Phlips, Thomas
Comment Number: 2005N-0345-EC788
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Any.

Commenter Organization Name: Mock, Suzanne
Comment Number: 2005N-0345-EC940
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.6.4 - Other arguments opposing one package
Excerpt Text:
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.

Commenter Organization Name: Stockton, Melissa
Comment Number: 2005N-0345-EC99
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
I feel the best case scenario would be to have the packages differ. It would simply cause the fewest problems.

9.2 - Circumstance in which it is appropriate to distribute in single package

9.2.1 - Specific circumstances

Commenter Organization Name: Paslawsky, JoAnn

Comment Number: 2005N-0345-EC1129
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 9.3 - Miscellaneous arguments/discussions
Excerpt Text:
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.

Commenter Organization Name: Mershon, Claire-Helene
Comment Number: 2005N-0345-EC12379
Excerpt Number: 5
Excerpt Status: NEW
Excerpt Text:
I don't know what circumstances would make it inappropriate, but I don't believe that this is one of them.

Commenter Organization Name: Ross, Angela
Comment Number: 2005N-0345-EC172
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 9.2.2 - All circumstances (i.e., it's always appropriate, there are no inappropriate circumstances)
Excerpt Text:
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.

Commenter Organization Name: National Research Center for Women
Comment Number: 2005N-0345-EC2314
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Hagan, Jane
Comment Number: 2005N-0345-EC32
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
I cannot think of any, assuming that enforcement of restrictions is done at the point of sale.

Commenter Organization Name: Clason, Dennis
Comment Number: 2005N-0345-EC47
Excerpt Number: 4
Excerpt Status: NEW
Other Sections: NEW - 8.4.1 - Other policy arguments supporting one package label
Excerpt Text:

If the indications are the same for the OTC and prescription product, then I think that differentiated packaging is silly.

Commenter Organization Name: Katrib, Elise
Comment Number: 2005N-0345-EC516
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
They may be sold in a single package if they have the same active ingredients.

Commenter Organization Name: McGhee, Tim
Comment Number: 2005N-0345-EC53
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
Let's say the drug maker gets a green like 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.

Commenter Organization Name: Vander Bleek, Luke
Comment Number: 2005N-0345-EC870
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
Two products could be packaged in a single package techniqe, 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 of remain unchanged.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.4.1 - Other policy arguments supporting one package label
NEW - 9.3 - Miscellaneous arguments/discussions
Excerpt Text:
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.

9.2.2 - All circumstances (i.e., it's always appropriate, there are no inappropriate circumstances)

Commenter Organization Name: White, Molly
Comment Number: 2005N-0345-EC107
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
None.

Commenter Organization Name: McCormick, Michelle
Comment Number: 2005N-0345-EC1086
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
I am not sure if I can think of a situation.

Commenter Organization Name: Farren, Wanda
Comment Number: 2005N-0345-EC11670
Excerpt Number: 13
Excerpt Status: NEW
Excerpt Text:
I can't imagine why it would be inappropriate to have simultaneous distribution channels, under any circumstances. This would be regulation run amok.

Commenter Organization Name: Scott, Cindy
Comment Number: 2005N-0345-EC148
Excerpt Number: 2
Excerpt Status: NEW
Excerpt Text:
NONE

Commenter Organization Name: Lamotte, Diane
Comment Number: 2005N-0345-EC155
Excerpt Number: 14
Excerpt Status: NEW
Excerpt Text:
Don't know of any

Commenter Organization Name: Walsh, Melissa
Comment Number: 2005N-0345-EC15931
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 9.1.1 - Specific circumstances
Excerpt Text:
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 to 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.

Commenter Organization Name: Blume, John
Comment Number: 2005N-0345-EC167
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
I don't see any.

Commenter Organization Name: Ross, Angela
Comment Number: 2005N-0345-EC172
Excerpt Number: 3
Excerpt Status: NEW
Other Sections: NEW - 9.2.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Ross, Angela
Comment Number: 2005N-0345-EC172
Excerpt Number: 4
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Murphy, Cynthia
Comment Number: 2005N-0345-EC176
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
none.

Commenter Organization Name: Steward, Linda
Comment Number: 2005N-0345-EC181
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:

None.

Commenter Organization Name: Morrisroe, Julia
Comment Number: 2005N-0345-EC194
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
None

Commenter Organization Name: Dowell, Duane
Comment Number: 2005N-0345-EC195
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 3.4 - Administrative Procedures Act (APA) arguments
Excerpt Text:
None

Commenter Organization Name: Gay, Sarah
Comment Number: 2005N-0345-EC199
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
None.

Commenter Organization Name: Levy, Gayle
Comment Number: 2005N-0345-EC206
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
I can't think of any.

Commenter Organization Name: Goggin, Terresa
Comment Number: 2005N-0345-EC213
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rankis, A
Comment Number: 2005N-0345-EC22
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
none

Commenter Organization Name: Roettcher, Phil
Comment Number: 2005N-0345-EC224
Excerpt Number: 10
Excerpt Status: NEW

Excerpt Text:
None

Commenter Organization Name: Salvo, Aaron
Comment Number: 2005N-0345-EC24
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
I see no time that it would be inappropriate to sell the two products in a single package.

Commenter Organization Name: Cunningham, Wayne
Comment Number: 2005N-0345-EC240
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
None

Commenter Organization Name: Deneris, Angela
Comment Number: 2005N-0345-EC365
Excerpt Number: 8
Excerpt Status: NEW
Excerpt Text:
NONE

Commenter Organization Name: Bilz, Michael
Comment Number: 2005N-0345-EC4
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
I can't think of a situation where it would be an issue.

Commenter Organization Name: Schulman, Marvin
Comment Number: 2005N-0345-EC418
Excerpt Number: 6
Excerpt Status: NEW
Excerpt Text:
None

Commenter Organization Name: Della Paolera, Mark
Comment Number: 2005N-0345-EC555
Excerpt Number: 7
Excerpt Status: NEW
Other Sections: NEW - 7.4.1 - Implement "behind-the-counter" system (pharmacist distributed)
Excerpt Text:
There is none. It needs to remain behind the counter.

Commenter Organization Name: Peer, Gerald
Comment Number: 2005N-0345-EC626
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:

None

Commenter Organization Name: Rosati, Lucia
Comment Number: 2005N-0345-EC76
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
I cannot think of any.

Commenter Organization Name: Long, Laura Jean
Comment Number: 2005N-0345-EC762
Excerpt Number: 12
Excerpt Status: NEW
Excerpt Text:
I find no circumstances in which it would be inappropriate to do so.

Commenter Organization Name: Cahoon, Clifton
Comment Number: 2005N-0345-EC80
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 8.2 - No
Excerpt Text:
Not at all.

Commenter Organization Name: Etter, Eleanor
Comment Number: 2005N-0345-EC96
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 9.3 - Miscellaneous arguments/discussions
Excerpt Text:
None. Although, it would be unethical to charge more for Plan B dispensed by prescription rather than over-the-counter.

9.3 - Miscellaneous arguments/discussions

Commenter Organization Name: Paslawsky, JoAnn
Comment Number: 2005N-0345-EC1129
Excerpt Number: 6
Excerpt Status: NEW
Other Sections: NEW - 9.2.1 - Specific circumstances
Excerpt Text:
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.

Commenter Organization Name: Clague, Alexander
Comment Number: 2005N-0345-EC13
Excerpt Number: 3
Excerpt Status: NEW
Excerpt Text:

only if the "package insert" information is not available for the "prescription" sale.

Commenter Organization Name: Connors, Meaghan
Comment Number: 2005N-0345-EC141
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: Rectenwald, Theodore
Comment Number: 2005N-0345-EC535
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
On the (false) assumption that it should be legal, the packaging would be irrelevant.

Commenter Organization Name: Card, Alan
Comment Number: 2005N-0345-EC61
Excerpt Number: 9
Excerpt Status: NEW
Excerpt Text:
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.

Commenter Organization Name: DeWitte, Conrad
Comment Number: 2005N-0345-EC623
Excerpt Number: 8
Excerpt Status: NEW
Other Sections: NEW - 1.2 - Specific comments on drug approval process for Morning-after Pill/Plan B
Excerpt Text:
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 labling, 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.

Commenter Organization Name: Kortebein, Peter
Comment Number: 2005N-0345-EC654
Excerpt Number: 7
Excerpt Status: NEW
Excerpt Text:
This question would be resolved by the debate in a rulemaking discussion.

Commenter Organization Name: Etter, Eleanor
Comment Number: 2005N-0345-EC96
Excerpt Number: 8

Excerpt Status: NEW
Other Sections: NEW - 9.2.2 - All circumstances (i.e., it's always appropriate, there are no inappropriate circumstances)
Excerpt Text:
None. Although, it would be unethical to charge more for Plan B dispensed by prescription rather than over-the-counter.

Commenter Organization Name: Temple, Jennie
Comment Number: 2005N-0345-EMC355
Excerpt Number: 5
Excerpt Status: NEW
Other Sections: NEW - 8.1 - Yes
NEW - 8.4.1 - Other policy arguments supporting one package label
NEW - 9.2.1 - Specific circumstances
Excerpt Text:
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.