

Branded Pharmaceutical Association

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April 23, 2004

HAND DELIVERED

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

Re: Docket No. 2003D-0478: Draft Compliance Policy Guide On Marketed
Unapproved Drugs

Dear Food and Drug Administration:

This comment is submitted by Branded Pharmaceutical Association. BPA is a trade association that represents over 70 manufacturers and distributors of a variety of prescription drug products for human use. The great majority of BPA member firms are small businesses.

In the Federal Register for October 23, 2003 (68 Fed. Reg. 60,702), FDA invited public comment on a draft revised CPG regarding the exercise of its enforcement discretion with regard to drugs marketed in the United States without FDA premarket approval. In lieu of the draft CPG approach -- which is based on the unrealistic premise that all prescription drug products will eventually be the subject of an approved NDA or ANDA -- FDA should establish a prescription drug monograph system for a subset of these drug products. The monograph system, which could be established and implemented under FDA's existing statutory authority, would offer many public health, public policy, and economic benefits in comparison with the approach set forth in the draft CPG.

I. FDA SHOULD ESTABLISH A PRESCRIPTION DRUG MONOGRAPH SYSTEM FOR "OLDER" DRUG PRODUCTS

BPA requests that FDA adopt a prescription drug monograph system to address a subset of all prescription drug products marketed without FDA premarket approval: products that have long histories of safe and effective use, in many cases extending over a number of decades. For brevity, these products are referred to as "older" drug products in this comment. These "older" products are used under physician supervision; thus, they are subject to government and private insurance reimbursement. In addition, the manufacturers and distributors of these "older" products operate in a very competitive marketplace, helping ensure that the prices of these products remain reasonable.

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FDA has ample legal authority to establish and implement a prescription drug monograph system. Such a system would be consistent with the structure of the Federal Food, Drug, and Cosmetic Act and the definition of a “new drug” in 21 U.S.C. § 321(p). Through notice-and-comment rulemaking, FDA would establish binding regulations that set forth the conditions under which particular categories of “older” drug products would be “generally recognized as safe and effective” by qualified experts for their intended uses, and therefore not “new drugs” requiring FDA premarket approval. The monographs would also establish the conditions under which these “older” drug products are not misbranded under the FDC Act. Thus, a prescription drug monograph would typically address permitted active ingredient or ingredients and permitted ranges of concentrations, labeling requirements, and other areas that the agency deems appropriate. This is the same approach that FDA has followed with its over-the-counter drug monograph system for the last 30 years.

As with the OTC monograph system, an “older” prescription drug product would have to have been marketed and used “to a material extent” and “for a material time” to avoid “new drug” status and therefore be eligible for regulation under a monograph. See 21 U.S.C. § 321(p). FDA’s implementing regulation contemplates that a minimum of five continuous years of marketing would satisfy the “material extent” and “material time” criteria for OTC products. 21 C.F.R. § 330.14(b)(2). BPA suggests that the same five continuous year marketing criterion apply to “older” prescription drug products.

II. A PRESCRIPTION DRUG MONOGRAPH SYSTEM FOR “OLDER” PRODUCTS WOULD OFFER MANY BENEFITS IN COMPARISON WITH THE DRAFT CPG APPROACH

A. Alternative to the Draft CPG

We start with the observation that a prescription drug monograph system for “older” products should be considered, as part of this proceeding, in deciding whether to finalize the draft CPG. FDA’s “Questions and Answers” that accompanied the draft revised CPG contained the following exchange:

Has FDA considered a monograph system that would allow certain prescription drugs to be marketed without individual FDA approvals for each?

FDA is examining whether any class or classes of prescription drugs might be regulated under a monograph system in lieu of requiring individual applications. The Agency will be preparing a report to Congress, in the coming months, that considers the feasibility and cost of such a system. Although FDA has considered and declined this approach on several past occasions, the agency will consider whether new, relevant factors affect our analysis as we re-visit the question.

Thus, there can be no question that the agency recognizes a connection between the draft CPG on drugs currently marketed outside of the present drug approval process, and the possible development of a prescription drug monograph system.

As part of considering whether to finalize the draft CPG, FDA should consider less burdensome alternatives. BPA believes FDA should consider the monograph approach for “older” products as a less burdensome alternative.

In July 2003, both the Senate and House Agriculture Appropriations reports for FY 2004 called on FDA to study, and report on, the feasibility and cost of a prescription drug monograph system, modeled after FDA’s longstanding monograph system for OTC drug products. In complying with this Congressional request, BPA believes that FDA should make a draft report available for public comment. Public comment on a draft report on a prescription monograph system would assist the agency in the development of its final report to the Congress. FDA should consider seeking comment on a draft report as part of this proceeding.

B. Benefits Of A Prescription Monograph System

As an alternative regulatory approach, a prescription drug monograph system for “older” products would have many benefits, discussed separately below.

1. Public Health Benefits

Perhaps most importantly, a prescription drug monograph system for “older” products would have the public health benefit of increased regulatory scrutiny of prescription drug products currently being marketed outside the FDA premarket approval system. Under a monograph system, FDA – with input from industry – would evaluate all “older” prescription drug products without approved applications, for safety and effectiveness, based on publicly available information. This would be a proactive approach, under timeframes established by the agency. In comparison, under the approach set forth in the draft CPG, FDA would not review “older” products unless and until one firm obtained an NDA approval. That approach is reactive, not proactive.

A monograph system would also promote the public health by preserving the availability of physician-supervised, reasonably priced pharmaceuticals covered by insurance reimbursement, with two public health benefits.

First, a monograph system would ensure the continued availability of the products as prescription products, with the accompanying public health benefits that accompany prescription products. When the physician is removed from the drug usage decision, there is a greater opportunity for adverse drug interactions and other problems. In addition, if many "older" prescription products are converted to OTC status, then the likelihood that individuals would see their physicians goes down, with the accompanying consequences of possibly erroneous self medication, incorrect diagnosis, and lack of physician oversight.

Second, a prescription drug monograph system would result in lower costs to pharmaceutical consumers by avoiding the potentially exorbitant prices associated with short-term regulatory monopolies under the draft CPG approach. Typically, the first approval would be for a 505(b)(2) NDA. The sponsor of a 505(b)(2) NDA that is supported by a clinical study (other than a bioavailability study) is entitled to three years of Hatch-Waxman exclusivity, during which period no other 505(b)(2) NDA or ANDA based on the "first" product can be approved. Under the draft CPG approach, the sponsor of the first approved 505(b)(2) NDA would, in many cases, receive a three year monopoly, during which time it could charge unreasonably high prices as it would face no competition in the marketplace. Even if no three year exclusivity is granted, marketplace disruption and higher prices will occur. For example, FDA's approach on extended release guaifenesin resulted in an effective monopoly (even without three-year Hatch-Waxman exclusivity) and (at least during some periods of time) sudden manifold price increases. The loss of insurance reimbursement (for what became an OTC product), coupled with these price increases, undoubtedly deprived some consumers of safe and effective guaifenesin drug products, a result that did not promote the public health.

2. Agency Resource Benefits

A prescription drug monograph system would offer many benefits to FDA with regard to the efficient use of scarce agency resources. It would allow FDA to proceed in a timeframe consistent with its own priorities because monographs would be addressed according to those priorities rather than the vagaries of a company deciding it may achieve an advantage by filing an NDA. It would

also result in more efficient use of agency and industry resources since a single monograph could obviate industry development and agency review of numerous similar NDAs or ANDAs.¹

3. Small Business Benefits

Most of the firms involved in the manufacture, distribution, and marketing of “older” prescription pharmaceuticals outside of the present new drug approval process are small businesses. Finalization and implementation of the draft CPG would necessarily have a disproportionate negative effect on small businesses, as firms involved with the manufacture and distribution of “older” drug products would eventually have to obtain NDA or ANDA approvals.

In all likelihood, the first approval for an “older” drug product would be in the form of a 505(b)(2) NDA, where some or all of the information needed to support the safety and effectiveness of the product for its intended uses would be derived from the published literature. The information available to BPA suggests that the total cost of preparing a 505(b)(2) NDA for an “older” product likely ranges from about \$3 million to \$20 million or more. The costs include the following:

- literature search and preparation of report
- prepare and submit IND
- manufacture of pilot batch (100,000 units minimum) for chemistry-manufacturing-controls development, validation, bioavailability study, and clinical studies
- analytical methods development (if needed)
- bioavailability study (including protocol development)
- limited human clinical study or studies needed to support approval
- compile, write, and submit NDA
- prescription drug user fee for the NDA
- interaction with FDA during the planning and review process (including consultants, legal counsel, or both where appropriate)
- maintenance of NDA after approval (includes cost of first year of preparing and submitting required annual report, first year of annual prescription drug product fee and prescription drug establishment fee)

¹ BPA believes that this conclusion would be supported by an analysis of FDA data relating to the amount of staff time and resources spent on the review and processing of NDAs and ANDAs, compared with resources the amount of staff time and resources spent on the OTC monographs. Despite a diligent search, BPA was not able to locate the relevant data. Thus, BPA believes that FDA itself is the only one in a position to address this issue.

In deriving these cost estimates, BPA notes that it is typically not possible to develop an accurate estimate before meeting with FDA to discuss the specifics of a proposed product, such as during a pre-IND meeting. If anything, costs are far more likely to increase rather than decrease based on FDA's views as to the appropriate contents of a 505(b)(2) NDA.²

In some cases, an ANDA may be appropriate where an NDA has already been approved for a similar product. Where an ANDA is appropriate, BPA's estimates range from about \$225,000 to \$2.5 million or more. This estimate includes the following:

- prepare and submit ANDA suitability petition if needed, for permitted changes from reference product
- manufacture of a pilot batch (100,000 units minimum)
- bioequivalency study (including protocol development)
- compile, write, and submit a complete ANDA
- interaction with FDA during the planning and review process (including consultants or legal counsel where appropriate)
- annual maintenance (cost of first year of preparation of annual report)

The costs associated with NDAs and ANDAs increase rapidly as the number of active ingredients increases. Thus, applications for combination drug products with multiple active ingredients will be at the higher ends of the ranges set forth above.

The costs of preparing and submitting an NDA or ANDA are substantial, particularly for small businesses. FDA should ensure that small businesses do not bear a disproportionate share of regulatory costs and burdens. By so doing, FDA would ensure that its actions are consistent with the purposes of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law No. 104-121, § 203, 110 Stat. 847, 857. In relevant part, those purposes include the following:

- To encourage the effective participation of small business in the Federal regulatory process.

² For example, it is BPA's understanding that FDA has requested information regarding genotoxicity, carcinogenicity, reproductive toxicology, and the like for active ingredients with a long history of safe and effective use to support a 505(b)(2) NDA. Similarly, FDA may want information to characterize the potential pharmacological interaction between two active ingredients. FDA also may want a patient side-effect study to screen for adverse events that appear to be more common or more severe than for existing approved products. These information "requests" help drive up the cost of a 505(b)(2) NDA for an "older" product.

- To create a more cooperative regulatory environment among agencies and small businesses that is less punitive and more solution-oriented.

As discussed above, a prescription drug monograph system would encourage the manufacturers and distributors of “older” prescription pharmaceutical products that are small businesses to participate in the regulatory process of establishing monographs. It would represent a more cooperative regulatory environment that is more solution-oriented (namely, aimed towards bringing all “older” prescription pharmaceutical products under active regulation under a monograph system) and less punitive (thereby avoiding enforcement action, as contemplated by the draft CPG).

Long before SBREFA was enacted, former FDA Acting Deputy Commissioner James S. Benson recognized the importance of small businesses and their contributions to the public health. As Mr. Benson stated in testimony before the Senate Small Business Committee on June 13, 1989:

Often the innovation, dynamism, and entrepreneurial attitude of the American free enterprise system is concentrated in small businesses. *** The costs of regulatory compliance may sometimes place a disproportionately large burden on small businesses. The majority of the firms regulated by FDA – foods, drug, medical devices, cosmetics, and veterinary products – are classified as small businesses. The Agency makes every effort to minimize regulatory burdens consistent with the law in order to encourage technological innovation, which in turn, can lead to improvements in the public health.

FDA should carry out the thrust of Mr. Benson’s remarks, as well as the principles of SBREFA, in evaluating whether to finalize the draft CPG. The agency should consider alternatives to the draft CPG – such as the prescription drug monograph system – that would accomplish the agency’s public health objectives while minimizing unnecessary significant economic impact on small entities.

As small businesses, BPA member firms embody “the innovation, dynamism, and entrepreneurial attitude of the American free enterprise system,” as noted by Mr. Benson. These firms operate best in a competitive atmosphere where all firms – both large and small – can compete in the marketplace, thereby resulting in lower costs for consumers. A prescription drug monograph system for “older” prescription drug products would allow this competitive marketplace to continue. In comparison, the approach under the draft CPG encourages seeking NDA or ANDA approval for these products, thereby likely benefiting larger firms at the expense of smaller ones. The result would be the potential loss of a competitive marketplace, leading to higher prices for consumers.

BPA's suggested prescription drug monograph system for "older" products would allow the continued availability of these products as prescription products. These products are typically "detailed" by sales representatives to practicing physicians, who prescribe them by brand name. In comparison, OTC drug products are typically marketed and sold to major retail pharmacy chains and wholesale distributors in completely different ways. BPA member firms typically do not have the infrastructure or personnel to engage in the marketing of OTC drug products. Thus, in addition to the public health consequences discussed in Section II.B.1 above, the loss of prescription status for these products would cause serious economic harm to BPA's members.

4. Transparency And Public Participation Benefits

Like the OTC monographs, monographs for "older" prescription drug products would be developed in a transparent fashion using public rulemaking dockets. Thus, BPA members and other affected industry firms, healthcare professionals, consumers, and anyone else who is interested could comment and review the comments of others. As with any rulemaking, FDA would have to explain its actions in Federal Register preambles. In comparison, under the approach set forth in the draft CPG, nothing about current enforcement decisions or pending NDAs is public until after the fact; even after the fact very little information is publicly available.

Thus, under a prescription drug monograph system, there should not be any "surprises" – either in substance or in timing – about where FDA is headed. In comparison, under the draft CPG, there is no advance notice that an NDA is pending and that related products will need to be the subject of approved applications within a short timeframe.

C. Apparent Concerns

A number of apparent concerns with a prescription drug monograph system have been raised. While some of these concerns may appear to be valid at first blush, BPA does not believe they have merit when given closer scrutiny.

Some at FDA have defended the regulatory approach set forth in the draft CPG as necessary to maintain incentives for seeking NDA approvals for "older" drug products. BPA believes that argument is based on a faulty premise: there is a legitimate reason to get approval for "older" products in the first place. For the reasons discussed above, BPA believes that a prescription drug monograph system is a better regulatory alternative that should be adopted. As noted, a prescription monograph system would be consistent with the structure of the FDC Act. We note that this issue has nothing to do with maintaining incentives for research and development leading to truly new drug products.

Some have raised a concern that a prescription monograph system would unduly “tie FDA’s hands.” This assertion is without merit. If a monograph system is adopted, FDA’s legal authority to take appropriate enforcement action against unsafe, ineffective, or improperly manufactured “older” drug products would not be affected in any way. In fact, BPA supports the three priorities for enforcement action set forth in the draft CPG: products with potential safety risks, products lacking any evidence of effectiveness, and health fraud products.

Some FDA representatives have informally raised their view that a prescription drug monograph system would be inconsistent with the way the U.S. Supreme Court has interpreted the relationship between “new drugs” requiring premarket approval and “old” drugs that fall outside the premarket approval system because they are generally recognized as safe and effective for their intended uses. This concern is based on the Supreme Court’s language in Weinberger v. Hynson, Westcott and Dunning, Inc., 412 U.S. 609, 631, 93 S. Ct. 2469, 2484 (1973):

[T]he act is designed so that drugs on the market, unless exempt, will have mustered the requisite scientifically reliable evidence of effectiveness long before they are in a position to drop out of active regulation by ceasing to be a “new drug.”

BPA submits that reliance on that language is misplaced. While the Supreme Court’s language might be appropriate for a newly introduced drug product, it does not apply to the class of drug products that are the subject of this comment, namely, “older” drug products that have a long history of marketing for their intended uses, such that (to use the language of the “new drug” definition in 21 U.S.C. § 321(p)) they have been used “to a material extent” and “for a material time.” The relevant inquiry today is not whether these drug products should have been the subject of premarket approval when they were first introduced into the market years ago; rather, the only relevant issue is the appropriate prospective regulatory mechanism for these products.

Some at FDA have raised a possible fundamental difference between prescription and OTC drug products, such that the monograph system may not be appropriate for prescription products. This contention is quickly dismissed by the fact that FDA itself has considered a prescription drug monograph system on two separate occasions, as discussed in Section IV below.

Finally, some would criticize a prescription drug monograph system as too time-consuming, given the lack of scarce FDA resources. A prescription drug monograph system may not be the perfect answer, but BPA believes it is a much preferable approach than the status quo (FDA’s approach for extended release guaifenesin and the draft CPG). As discussed above, BPA believes that, under a prescription drug monograph system, FDA would review – and bring under active regulation – all “older” prescription products sooner and more cheaply than under the draft CPG approach. In light of FDA’s institutional knowledge with the OTC monograph system, BPA is

optimistic that FDA – with industry input – can develop a process that is more efficient and streamlined than the OTC monograph process.

III. FDA SHOULD PUBLISH A FEDERAL REGISTER NOTICE TO “GET THE BALL ROLLING” ON THE PRESCRIPTION MONOGRAPH SYSTEM

FDA should publish a Federal Register notice on establishing a prescription drug monograph system. Ideally, this Federal Register notice would be an advance notice of proposed rulemaking, in which FDA sets forth its preliminary thinking on how it would develop the prescription drug monograph system. FDA has used the ANPR concept many times in the early stages of a new regulatory program. Alternatively, FDA could publish a Federal Register notice seeking comment on the feasibility of a prescription drug monograph system for “older” drug products. This is the approach FDA used in 1991 when it last considered the monograph system (see discussion in Section IV below). The ANPR or Federal Register notice, and comments received, would allow FDA to develop a proposed rule on the procedures to be used for the prescription monograph system. FDA would then engage in notice-and-comment rulemaking, with adoption of a final rule establishing a prescription drug monograph system if supported by the comments received on the proposed rule.

A. Drug Product Categories

Without doubt, a prescription drug monograph system will be a substantial undertaking. To tackle such a large project, we assume the agency will want to proceed on a category-by-category basis as it has done for the OTC monographs. This topic should be addressed in FDA’s ANPR or Federal Register notice. In BPA’s view, logical candidates for the initial categories for drug products reviewed under the monograph system are those categories of drug products of greatest public health concern to the agency. Alternatively, FDA could focus on those categories of drug products with the largest number of “older” products either in numbers or dollar volume.

For FDA’s information, BPA surveyed its members regarding the different categories of drug products they manufacture and distribute, using the product categories from the Physician’s Desk Reference. Detailed results appear in Attachment A. While the products manufactured and distributed by BPA members span the entire spectrum of drug products, the most common categories are the following: antihistamines and combinations, antitussives, cough and cold preparations, cough preparations, expectorants, and respiratory agents.

B. Information On Safety And Effectiveness

Presumably, the agency will consider the use of outside expert panels, as was done for the OTC monographs and for the review of DESI drug products, based on industry data submissions. However, other options should also be explored and public comment should be sought.

FDA should consider conducting its own review of available published literature to assess safety and effectiveness, such as was done recently for positron emission tomography drug products. FDA concluded that "this would be the most efficient way to develop new approval procedures for these drugs," and announced its safety and effectiveness findings in a Federal Register notice. 65 Fed. Reg. 12,999, 13,000 (March 10, 2000).

C. Interim Compliance Policy

A Federal Register notice or ANPR should address FDA's compliance policy in the interim before final monographs are adopted. Either by regulation (such as 21 C.F.R. § 330.13 for OTC drugs) or by Compliance Policy Guide, FDA should recognize that, absent specific safety or effectiveness concerns, it will not bring enforcement action with respect to "older" products currently on the market while monographs are planned or pending. FDA's compliance policy should also address the situation where an NDA for an "older" product is submitted to FDA for review while a relevant drug monograph is under consideration or is pending. Under these circumstances, it is BPA's tentative view that review of the application should be allowed to proceed in the usual fashion. However, approval of the NDA should not by itself provide a basis for FDA to take enforcement action against those firms manufacturing and distributing similar products. Once a relevant monograph is finalized, the NDA product could (to use the Supreme Court's language quoted above) be "in a position to drop out of active regulation by ceasing to be a 'new drug.'"

D. Miscellaneous Regulatory Issues

As FDA considers and develops the prescription drug monograph system, BPA urges the agency to keep the following in mind: For maximum benefit, prescription drug monographs should be broad in scope, with no categories of drug products automatically excluded from consideration. For example, many of the "older" products manufactured and distributed by BPA members are controlled release drug products. Pursuant to 21 C.F.R. § 310.502(a)(14), all controlled release drug products are deemed to be "new drugs" requiring premarket approval. However, the predecessor to

that regulation was first adopted in 1959 (see 24 Fed. Reg. 3,756 (May 9, 1959)).³ In 1959, controlled release drug technology had been recently developed, supporting FDA's then view that all controlled release products should be regulated through the premarket approval system. Now, almost two generations later, controlled release drug products are commonplace and the technology is well understood by industry. It is BPA's view that the regulation in question is outdated and no longer necessary. As part of considering the prescription drug monograph system, FDA should eliminate unnecessary, outmoded regulations like § 310.502(a)(14), so that, where appropriate, controlled release drug products can be regulated under the monograph system.

Similarly, combination "older" drug products with multiple active ingredients should be eligible for inclusion in the prescription drug monograph system. The OTC monographs include many combination drug products, and there is no reason why a prescription drug monograph system should not do likewise. To the extent that the agency deems it appropriate, the fixed-combination prescription drug policy, 21 C.F.R. § 300.50, can be taken into account in developing specific monographs.

IV. PRESCRIPTION DRUG MONOGRAPH SYSTEM – AN IDEA WHOSE TIME HAS COME

FDA has formally considered a prescription drug monograph, albeit in slightly different contexts, on two occasions in the past.

First, in the March 1974 issue of Food, Drug, Cosmetic Law Journal, a then-FDA official discussed the prescription monograph concept.⁴ FDA recognized that a monograph system would have a number of benefits, including the elimination of burdensome preapproval requirements and the freeing of agency resources. Consistent with the predictions of this article, in 1975 FDA published a proposed rule to establish a monograph system for prescription drug products reviewed under the DESI program. 40 Fed. Reg. 26,141 (June 20, 1975). FDA stated that it would require NDAs or ANDAs only for those DESI drugs posing special problems. 40 Fed. Reg. at 26,148. The proposed rule also stated that procedures regarding establishment of prescription drug monographs were then under development. 40 Fed. Reg. at 26,151. For reasons not disclosed in the public

³ In fact, the predecessor to § 310.502(a)(14) was adopted in 1959 as only a "statement of general policy or interpretation," not as a binding regulation with the force and effect of law. See Shalala v. Guernsey Mem. Hosp., 514 U.S. 87, 99 (1995) (interpretative rules "do not have the force and effect of law and are not accorded that weight in the adjudicatory process").

⁴ M.A. McEniry, "Drug Monographs," Food, Drug, Cosmetic Law Journal, March 1974, Vol. 29, p. 168.

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record, FDA did not follow through with its announced intent. Instead, FDA withdrew the proposal in 1991. See 56 Fed. Reg. 42,668 (Aug. 28, 1991) and 56 Fed. Reg. 67,440 (Dec. 30, 1991).

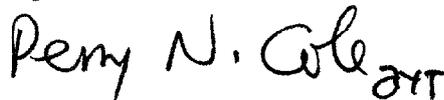
Second, in 1991, FDA published a Federal Register notice, requesting comments and recommendations on the development of a monograph system for generic drugs. 56 Fed. Reg. 24,060 (May 28, 1991). That docket is still open. Again, the public record does not indicate why FDA did not follow through on this Federal Register notice.

Thus, the notion of a prescription drug monograph system is hardly a new idea for FDA. For the many reasons discussed above, it is an idea whose time has finally come.

* * *

BPA and its members look forward to working with the agency to develop and implement a prescription drug monograph system. We appreciate the agency's consideration of this comment.

Respectfully submitted,

A handwritten signature in black ink that reads "Perry N. Cole" followed by a stylized flourish or initials.

Perry N. Cole
President

PNC:jdc

Attachment

A - BPA member survey – “older” drug product categories

ATTACHMENT A

BRANDED PHARMACEUTICAL ASSOCIATION Member Survey April 2004

PRODUCT CATEGORIES	NUMBER OF PRODUCTS
Acne Preparations	2
Analgesics	8
Anesthetics	1
Anorectal Products	2
Antacids	7
Antibiotics	1
Anticonvulsants	1
Antidepressants	2
Antiemetics	1
Antihistamines & Combinations	85
Anti-Inflammatory Agents	3
Antipyretics	5
Antispasmodics	5
Antitussives	55
Antivirals	1
Appetite Suppressants	1
Arthritis Medications	1
Barbiturates	2
Bronchial Dilators	4
Cancer Preparations	1
Cardioprotective Agents	1
Central Nervous System Agents	1
Cold & Cough Preparations	245
Cough Preparations	129
Cystic Fibrosis Management	5
Decongestants	13
Dietary Supplements	3
Duodenal Ulcer Adherent Complex	2
Ear Wax Removal	1
Enzymes	2
Expectorants	70
Fluoride Preparations	4
Gastrointestinal Agents	8
Head Lice Relief	2
Hematinics	4
Hemorrhoidal Preparations	1

Histamine (H2) Receptor Antagonists	5
Immunosuppressives	2
Iron Deficiency	3
Laxatives	6
Liver Disorder Products	1
Magnesium Preparations	1
Motion Sickness Products	2
Mucolytics	13
Muscle Relaxants	1
Nail Preparations	1
Narcotics	42
Nausea Medications	1
Nutritionals	5
Otic Preparations	9
Pain Relievers	21
Phosphorus Preparations	4
Photosensitizers	1
Potassium Supplements	3
Psychotherapeutic Agents	4
Respiratory Agents	58
Sedatives & Hypnotics	2
Seizure Disorder Products	1
Skin Bleaches	1
Skin Care Products	1
Steroids	3
Tourette's Syndrome Agents	1
Tranquilizers	1
Urinary Tract Agents	8
Vaginal Preparations	3
Vitamins	9