Branded Pharmaceutical Association
6 Office Park Circle Suite 301, Birmingham, Alabama 35223 • 205-879-9924 • FAX 205-879-9629

November 18, 2003

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: REQUEST FOR SOLICITATION OF COMMENTS ON PRESCRIPTION DRUG MONOGRAPH AND EXTENSION OF COMMENT PERIOD

Dear Food and Drug Administration:

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

BPA respectfully requests that FDA issue a revised solicitation for comments on this draft Compliance Policy Guide (CPG) on marketed unapproved drugs. The revised solicitation should present both the draft CPG and the prescription drug monograph system that Congress has directed FDA to consider. Thereby, the public comment period may assist FDA in assessing the relative merits of its proposed CPG and a prescription drug monograph system that would allow certain prescription drugs to be marketed without FDA premarket approvals. The comment period should also be extended to allow for meaningful public input.

* * *

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 approval. FDA acknowledges that there are thousands of such products in distribution. FDA has used its authority to inspect manufacturers of these products. Many of these products have long histories of safe and effective use.

The draft revised CPG stems from FDA's actions in 2002, when FDA forced manufacturers and distributors to remove their prescription extended-release guaifenesin products from the market after one company received premarket approval for an over-the-counter (OTC) extended-release product. FDA's action resulted in the loss of insurance reimbursement for the entire class of products, and a stunning 700% price increase for the approved product over the removed products.

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.

FDA's "Questions and Answers" (Q&A) (http://www.fda.gov/cder/compliance/CPG_QandA.htm) 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 perceives a connection between the draft CPG on drugs marketed outside of the present drug approval process, and the possible development of a prescription drug monograph system.

BPA notes that the draft CPG would have broad applicability. It would establish, as high priorities for enforcement action, products with potential safety risks, products lacking any evidence of efficacy, and products that are clearly fraudulent. BPA supports FDA's tentative decision to assign a high priority to these products. However, BPA believes FDA should consider the monograph approach for a subset of products within the scope of the draft CPG – prescription products with a long history of safe and effective marketing outside the premarket approval system.

As part of considering whether to finalize the draft CPG, FDA should consider less burdensome alternatives and explain the reasoning behind the acceptance of a particular regulatory path and the rejection of alternatives. Thus, BPA urges FDA to revise its solicitation for comments on this draft CPG to include assessment of the relative benefits of the draft CPG and a prescription drug monograph system in their respective effects on public health, consumer prices, and resources of FDA and the regulated industry. 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, aid in the refinement of the policies underlying the draft CPG, and permit affected regulated entities and consumers the opportunity to participate in policies affecting the public health.

* * *

As an alternative regulatory approach, a prescription drug monograph would have the following benefits:

- increased regulatory scrutiny of prescription drug products being marketed outside the FDA premarket approval system;

- lower cost to pharmaceutical consumers by avoiding the exorbitant prices associated with the short-term regulatory monopolies FDA establishes to encourage premarket approval application filing;

- availability of physician-supervised, reasonably priced pharmaceuticals covered by insurance reimbursement;

- a timeframe consistent with agency priorities because monographs would be addressed according to those priorities rather than the vagaries of a company deciding it may achieve advantage by filing a premarket approval application; and

- more efficient use of agency and industry resources since a single monograph could obviate industry development and agency review of numerous similar premarket approval applications.

BPA will address the benefits of a prescription drug monograph in greater detail if this request for expansion and extension of the comment period is granted.

* * *

FDA is also aware, from the recent history surrounding the approval of a single entity extended release guaifenesin products and the subsequent removal of all competing products, that the manufacturers and distributors involved in the marketing of older prescription pharmaceuticals outside of the present new drug approval process are generally small businesses. Finalization and implementation of the draft CPG would necessarily affect small businesses. FDA should ensure that small businesses do not bear a disproportionate share of regulatory costs and burdens. As the former FDA Acting Deputy Commissioner James S. 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. The agency should apply the principles underlying the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), in evaluating the draft CPG. Under such an approach, the agency would describe 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.

* * *

For the reasons discussed, FDA should expand and extend this comment period. FDA should solicit comments on the drug prescription drug monograph system, including but not limited to public comment on its draft report to Congress on this topic. This approach would ensure that both regulated entities and consumers have a chance to comment on an important topic that affects the public health.

We appreciate the agency's consideration of this request.

Respectfully submitted,

Perry N. Cole 24T

Perry N. Cole
President

PNC:jdc