



NATIONAL PHARMACEUTICAL ALLIANCE

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VIA HAND DELIVERY

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

Re: Submission to Docket No. 98N-0339: Public Meetings on Section 406(b) of the FDA Modernization Act of 1997

Dear Sir or Madam:

The National Pharmaceutical Alliance ("NPA") submits the attached comments to Docket No. 98N-0339 in response to the Food and Drug Administration's July 24, 1998 *Federal Register* notice. In that notice, FDA requested comments on how the agency can best meet its statutory obligations under the Federal Food, Drug, and Cosmetic Act, as amended by the Food and Drug Administration Modernization Act of 1997.

Thank you for the opportunity to provide comments on this important matter.

Respectfully submitted,

Christine Sizemore IKLD

Christine Sizemore
Executive Director

Enclosure(s)

98N-0339

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**COMMENTS OF
THE NATIONAL PHARMACEUTICAL ALLIANCE
TO DOCKET NO. 98N-0339**

**HOW BEST CAN FDA MEET ITS
STATUTORY OBLIGATIONS UNDER FDAMA?**

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The National Pharmaceutical Alliance (NPA) is a national trade association consisting of approximately 160 firms dedicated to the manufacture and distribution of cost-effective pharmaceutical products. NPA supports public policies that ensure the availability of affordable, quality pharmaceuticals to consumers. In accordance with this tenet, NPA submits the following comments for FDA's consideration regarding how best to meet the agency's statutory obligations, which includes the statutory mandate to review affordable pharmaceuticals within 180 days. We provide below a brief introduction regarding the impact of generic drugs on the American health care system, and then address the specific questions raised by FDA in its July 24, 1998 *Federal Register* notice.

BACKGROUND

Recent information confirms that safe, effective and affordable pharmaceuticals have a profound impact on health care costs in the U.S. In particular, generic drugs have played an important role in holding down national spending on prescription drugs, saving consumers about \$8 to \$10 billion in 1994 alone. See July 1998 Congressional Budget Office Report. In 1996, 43% of the prescription drugs sold in the U.S were generic, most of which were priced at least 25% less than their brand drug counterparts. Id. Affordable pharmaceuticals accordingly provide a cost-effective means of reducing the nation's sky-rocketing health care costs, while also providing quality therapeutic medications.

Yet, these enormous economic and public health benefits cannot be realized unless and until FDA complies with its obligation to review generic drug applications (ANDAs) within 180 days, as mandated by Congress. NPA submits that FDA must mobilize its resources and appropriately prioritize its statutory obligations. At a minimum, FDA priority areas should include reducing the ANDA backlog and providing timely and efficient generic drug approvals. The failure to support these priorities could have devastating national consequences by adversely affecting the public health and medical expenses.

1. What Do You Believe FDA Should Do To Adequately Meet The Demands That Are Beginning To Burden The Application Review Process, Especially For Non-User Fee Products, So That It Can Meet Its Statutory Obligations To Achieve Timely Product Reviews? What Suggestions Do You Have For The Agency To Eliminate Backlogs In The Review Process?

- Increase OGD funding and other necessary resources so that the agency can meet its the statutorily-required 180-day time frame for completing generic drug reviews. Our recommendations for specific FDA measures are set forth below.

- ⇒ Hire additional scientific experts and application reviewers in OGD.
- ⇒ Place additional medical specialists in OGD, including a medical review officer. This would eliminate lengthy “consults” with the new drug division and accelerate the generic approval process.
- ⇒ Hire at least one full-time statistician for OGD.
- ⇒ Continue to identify “streamlining” initiatives to make the generic drug approval process more efficient, as OGD has done in the past.
- ⇒ Upgrade information technology, including hardware and software, to ensure proper computer support for OGD staff.

- While NPA is sensitive to FDA’s budgetary plight, FDA must not and cannot sacrifice current resources to fund non-essential programs. Rather, FDA must earmark agency resources for the performance of its statutory approval obligations and responsibilities. See H.R.Rep.No. 105-178, 105th Cong., 1st Sess. (1997). Specifically, FDA should:

- ⇒ Eliminate discretionary agency programs and other initiatives that are not statutorily mandated.
- ⇒ Restructure certain responsibilities so that they are borne more fairly between user fee and non-user fee industries. For example, the requisite resources to respond to citizen petitions should be borne by the new drug division and OGD concurrently. This reallocation of resources is necessary because, although the citizen petitions examined by OGD may relate to generic drugs, the vast majority of them are submitted by the brand drug companies.

- The agency should continue to support efforts by outside parties to secure an increase in budget appropriations for OGD. For example, NPA has requested that Congress provide a direct appropriation of \$1 million for OGD, above its FY 1998 funding level.

2. How Can The Agency Maximize The Availability And Clarity Of Information Concerning New Products?

- To maximize the availability of affordable pharmaceuticals, FDA should adhere to approving ANDA products within the statutory 180-day deadline. While this requirement has been part of the Federal Food, Drug, and Cosmetic Act since 1984, today FDA approves only about half of all generic drug applications within this time frame. The median review time for all ANDAs is three times longer than the 180-day time frame. To diffuse doubt on whether timely product approvals are to be a supreme FDA priority, Congress recently reaffirmed this message by enhancing the agency's Mission Statement. See Section 406 of FDAMA.
- To correct misconceptions about FDA-regulated products, FDA should implement measures to dispel innovator misinformation about safe, effective and therapeutically equivalent generic drugs. In particular, FDA should implement and/or enhance agency initiatives to counter misinformation campaigns which dispute the safe substitution of therapeutically equivalent pharmaceuticals and erode consumer confidence in FDA's drug approval process. For example, FDA should proceed with efforts to address the current misleading campaigns on narrow therapeutic index drugs and so-called critical drugs. FDA also should clarify generic product information. Specifically, FDA should undertake efforts to educate the medical community, policy makers, and consumers about FDA's rigorous generic drug approval process, its post-approval product surveillance programs, and the reliability of FDA's therapeutic equivalence determinations.
- To further maximize the availability of affordable pharmaceuticals, FDA should permit variations of the same generic drug to be submitted in one ANDA. For example, FDA could more efficiently provide consumers with affordable pharmaceuticals if the agency permitted a manufacturer to submit one application supporting variants of the same drug (i.e., different dosage forms such as tablet, capsule, etc.).
- FDA also should pursue scientific research initiatives in the bioequivalence field, with a special focus on non-systemically absorbed pharmaceuticals. By increasing the breadth and depth of scientific data on pharmaceutical bioequivalence, FDA can accelerate generic drug approvals for a variety of therapeutic classes.
- To achieve the statutorily created balance between the development of innovator drugs and the availability of affordable pharmaceuticals, the agency should not adversely expand the market exclusivity provisions to the detriment of the generic industry and the American public. Specifically, FDA should narrowly interpret the Act's market exclusivity provisions for "new chemical entities," "new clinical studies that support a change in an application," and new 505(b)(1) antibiotics.

- FDA should reexamine the list of drugs which are eligible for pediatric studies, and its pediatric exclusivity guidance. NPA will address these issues in detail in a separate document, which will be submitted to FDA in the near future.

3. How Can FDA Work With Its Partners To Ensure That Products – Both Domestic And Foreign – Produced And Marketed By The Regulated Industry Are Of High Quality And Provide Necessary Consumer Protection; And How Can FDA Best Establish And Sustain An Effective, Timely, And Science-Based Postmarketing Surveillance System For Reporting, Monitoring, Evaluating, And Correcting Problems Associated With Use/Consumption Of FDA-Regulated Products?

- To preserve the high quality of both domestic and foreign drug products, FDA must ensure full and fair participation by all industry segments in international standard-setting bodies, such as ICH and TABD. When considering the impact of internationally-initiated measures, FDA must be prepared to take strong actions, such as to recuse itself from such international bodies until all affected industries are represented. As FDA is aware, the generic industry is concerned that certain international bodies permit only limited industry participation. As a result, the organizations' initiatives are anti-competitive, such as:

- ⇒ Applying the ICH standards of stability testing and impurity specifications for innovator drugs to generic drugs.
- ⇒ Repealing "Bolar"- type research and testing laws in other countries.
- ⇒ Lobbying for longer patent terms for pharmaceuticals.

- Once FDA receives information on a manufacturer's intent to withdraw a life-saving product from the market (see Section 131 of FDAMA), the agency should furnish that information to the pharmaceutical industry to foster the development of an equivalent or alternative therapeutic treatment to protect the public health.

4. What Approach Should FDA Use To Assure An Appropriate Scientific Infrastructure, With Continued Access To The Scientific And Technical Expertise Needed To Meet Its Statutory Obligations And Strengthen Its Science-Based Decisionmaking Process?

- Immediately implement Section 119 of FDAMA to provide for FDA/sponsor meetings for the purpose of agreeing on bioequivalence protocol requirements. FDA also must recognize that, if the parties enter into a binding bioequivalence agreement, a subsequent citizen petition opposing that drug application must not undermine the agreement and, ultimately, product approval. In other words, FDA should proceed with product approval even in the face of such a citizen petition.

- Provide more efficient resolution of scientific controversies by enhancing the advisory committee process. See Section 404 of FDAMA. Also work closely with its advisory committees, where necessary, to produce sound, scientific bioequivalence protocols in an efficient and timely manner.

- Panels of experts established under Section 120 of FDAMA for providing scientific advice to FDA should include as a member at least one representative of the generic drug industry, where appropriate.

5. What Can FDA Do To Improve Its Explanation Of The Agency's Submission Review Processes, And Make Explanations More Available To Product Sponsors And Other Interested Parties?

- As discussed above:
 - ⇒ Educate the medical community and consumers by providing pertinent information on FDA's drug approval process for therapeutically equivalent generic drugs.
 - ⇒ Conduct oral presentations/interviews at professional forums, news programs, and state regulatory and administrative bodies.
 - ⇒ Provide written materials to interested parties.
- Expand the scope of existing SUPAC- type guidance documents and extend them to other dosage forms. Also, continue to routinely review and, when warranted, revise application guidance documents.

6. What Other Objectives Related To The Agency's Statutory Obligations Or Public Expectations – Beyond The Six Objectives – Should Be Included In The FDA Plan?

- FDA has the authority, and should assert that authority, to establish a generic approval process for biologics. In particular, Section 123 of FDAMA provides that biologic products are subject to the FDCA and that all provisions of the FDCA apply equally to drugs and biologics. Furthermore, the statute provides that FDA must take measures to minimize the differences in the review and approval of drugs and biologics. Thus, the plain language of FDAMA indicates that biologic products are eligible for approval under section 505 of the FDCA, including section 505(j) for abbreviated new drug applications. FDA should, therefore, accept and approve ANDAs for biologic products.