

**NAPM**



**NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS**

3279 Veterans Memorial Highway, Suite D-7 • Ronkonkoma, NY 11779 • (631) 580-4252 • Fax: (631) 580-4256  
E-mail: [nabmgenc@aol.com](mailto:nabmgenc@aol.com) • Web site: [www.napmnet.org](http://www.napmnet.org)

7367 '00 SEP 19 19:26

COMMENTS OF

ROBERT S. MILANESE, PRESIDENT

NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS

FOOD AND DRUG ADMINISTRATION AND STAKEHOLDERS PUBLIC MEETING

REGARDING

THE PRESCRIPTION DRUG USER FEE ACT

SEPTEMBER 15, 2000

I am Robert Milanese, President of the National Association of Pharmaceutical Manufacturers (NAPM). NAPM is a national, not-for-profit trade association representing manufacturers and distributors of finished, multi-source generic pharmaceuticals, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic drug industry. NAPM appreciates the opportunity to comment on the features the Food and Drug Administration (FDA) should advocate in proposing new or amended legislation when the Prescription Drug User Fee Act (PDUFA) expires at the end of September 2002.

Since PDUFA was enacted, the time it takes FDA to review and approve an application for a new drug or biologic has dramatically decreased. As the agency said in its notice of this public meeting, PDUFA has provided FDA with additional revenue to "hire more reviewers and support staff and upgrade its information technology to speed up the application review process for human drug and biological products without compromising review quality." The success of PDUFA demonstrates the importance of consistent and stable funding for product application reviews.

Manufacturers of brand name drugs and biologics have realized dramatic reductions in the time it takes to get a product application approved. However, generic drug manufacturers - the segment of the pharmaceutical industry that makes pharmaceuticals more affordable to consumers and lowers health care costs -- have watched review times for their product applications increase. Ironically, it now takes FDA nearly twice as long to approve the far less complicated abbreviated new drug application (ANDA) for a generic drug product than it takes to review a far more complex NDA. Untreated, this problem likely would worsen over time.

00N-1364

TS 17

Over the next five years, the patents on many blockbuster and other brand name drugs are set to expire, which will result in a dramatic increase in the number of ANDAs filed with the agency.

Long ANDAs review times have a significant impact on public health. It is no secret that American consumers are becoming increasingly concerned about the rising cost of prescription drugs. A day does not go by without a news article or television story touching on these health issues. In many cases the lack of a safe, effective, low-cost generic alternative to a brand name drug forces consumers to choose between essential medicines and food, housing or heating oil. Generic drugs typically enter the market at 25-30% below the market price for brand name drugs. This savings typically increases to 60-70% after two years of generic competition.

NAPM believes that a user fee program for generic drugs is the best answer for ensuring adequate and appropriate FDA resources to prevent delays in generic competition caused by the inefficient and slow reviews of generic drug applications. NAPM believes that such a user fee program generally should mirror PDUFA. The objective of a generic drug user fee program should be to reduce the time it takes to review and approve applications for generic drug products to the statutory requirement of six months. If FDA can complete its review and approval of a complex NDA in 12 months, with additional resources it should be able to complete the review process of the much simpler ANDA within six months, if not less.

NAPM also believes that any funds collected through a generic drug user fee program must, like PDUFA, be in addition to, and not a replacement for, appropriated funds. Generic drug manufacturers should not be called upon to make up for cuts in the amounts Congress appropriates to FDA generally or FDA's Office of Generic Drugs (OGD), specifically. Therefore, before any user fees are assessed, Congress should be required to appropriate an inflation-adjusted portion of generic drug review costs to ensure that generic drug user fees are only used to fund those activities directly related to ANDA reviews. Fees paid by generic drug manufacturers should be used only to hire and train more reviewers and update computer and other technological systems.

I would now like to comment briefly on the four specific questions FDA posed regarding PDUFA and whether changes to that law are needed.

First, significant reductions in the time it takes FDA to review and approve an application for a new drug or biologic are proof positive that PDUFA has been a success. The improvements FDA has made under PDUFA have not only benefitted new drug and biologics manufacturers but also patients in desperate need for new and better medicines to treat their diseases or other medical conditions. NAPM believes that creating a generic drug user fee program would also benefit consumers by addressing another important public health issue -- assuring all consumers have access to affordable prescription drugs. As we all know, a drug that is too costly to purchase, is by definition, ineffective.

Second, the performance goals agreed upon by FDA and Congress have worked well in setting a course for FDA to meet its objective of reducing its review times for new drugs and biologics. As previously mentioned, NAPM believes that with additional resources from generic drug user fees FDA could meet, if not exceed, its six-month statutory deadline for review and approval of all generic drug applications. NAPM, however, also appreciates that FDA will not be able to reduce the backlog of pending ANDAs and review new ANDAs within the six-month statutory time frame overnight. Therefore, we would support a phased-in approach and believe that performance goals are the best method for ensuring agency progress toward meeting and exceeding the six-month statutory timeframe for ANDA reviews.

Third, user fees should be not be used to supplant appropriated funds. We support the provision in PDUFA that requires Congress to appropriate a certain amount of funds for new drugs, adjusted for inflation, before collecting user fees for new drug reviews. NAPM believes that such a provision also should be included in legislation authorizing FDA to collect user fees for generic drugs.

Fourth, NAPM does not believe that PDUFA fees, or any fees paid through a generic drug user fee program, should be used to pay the other costs FDA incurs to ensure that drugs in the marketplace are safe and effective. Protecting the public health and safety is FDA's primary mission. FDA enforcement and inspection activities should be funded with public monies, not industry cash, in order to eliminate even the appearance of a conflict of interest. As previously mentioned, the primary purpose of PDUFA has been to speed NDA reviews. NAPM believes that monies collected from any generic drug user fee program should be devoted solely to making the ANDA review process more efficient.

PDUFA has been a success and should be expanded to include generic drugs. NAPM respectfully requests that when FDA discusses PDUFA reauthorization with Congress, it propose to create a generic drug user fee program. NAPM commits to working with FDA and the Congress on this legislative effort. PDUFA has been instrumental in bringing new, life-saving drugs to market faster. But those drugs are of no help when consumers cannot afford them. It is time to improve consumer access to safe, effective, and low-cost generic drugs. It is time to establish a generic drug user fee program.

Thank you.