



MYLAN PHARMACEUTICALS INC

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May 4, 2004

VIA FEDERAL EXPRESS

**Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 200857**

**RE: Generic Drug Issues; Request for Comments
Docket No. 2004N-0087**

Dear Sir/Madam:

Mylan Pharmaceuticals Inc. ("Mylan") submits this Comment in response to FDA's request for public comments on whether additional regulatory steps are warranted in light of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). As a result of MMA's recent changes to the 180-day exclusivity provisions of Hatch-Waxman, Mylan believes the FDA has an obligation to address the immediate threat of "authorized generics" to the generic industry.

Title XI of MMA further strengthens the 180-day generic drug exclusivity provisions of Hatch-Waxman by eliminating the "court decision" trigger of the exclusivity and retroactively changing the definition of court decision to mean a final decision of a court from which no appeal has been or can be taken for applications submitted prior to December 8, 2003. Additionally, Title XI of MMA codifies FDA's long-standing position that the commercial marketing of the listed drug by the first applicant triggers exclusivity. (This essentially converts a NDA under section 505(b) to an ANDA under section 505(j) for purposes of exclusivity.) Clearly, Congress recognizes the importance of the 180-day exclusivity period to the generic industry as evidenced by these changes. However, FDA's continued rubberstamp approval of "authorized generics" for marketing during a first applicant's 180-day exclusivity gives a brand company the unilateral power to render meaningless and eviscerate this exclusivity. Accordingly, Mylan requests the FDA to maintain the spirit and intent of the 180-day exclusivity by taking immediate regulatory action to prohibit the marketing and distribution of "authorized generics" during the first applicant's 180-day generic drug exclusivity period.

2004N-0087

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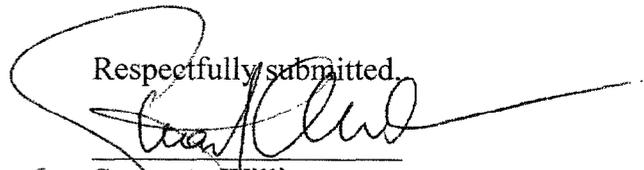
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One regulatory mechanism the FDA could choose to implement is to require authorized generic applicants to follow an abbreviated approval process. The approval process need not be a burdensome requirement for either the FDA or the applicant. For example, the FDA could require the authorized generic applicant to submit a one-page application to identify the manufacturer and distributor of the drug product. If it is determined that no "true" generic drug applicant is eligible for exclusivity, the FDA would grant final approval to the application. However, if a generic applicant is eligible for exclusivity, the FDA would give tentative approval until the expiration of the first applicant's exclusivity period.

In the alternative, the FDA could choose to require authorized generics to be listed with the FDA prior to commercial marketing. Section 510 of the FDCA and 21 CFR part 207 require all establishments upon first engaging in the manufacturing, propagation, preparation, compounding or processing of human drugs to register their establishment and submit listing information for all drugs in commercial distribution. Registrants must update their listing every June and December of each year to include information for drugs that have not been previously listed. The FDA could simply require authorized generic applicants to list the authorized generic product prior to commercial marketing and prohibit entry into the market until the expiration of the first generic applicant's exclusivity period.

The alternatives outlined above are respectfully submitted as suggestions only. The FDA may choose to implement a different regulatory mechanism which accomplishes the same objective.

Respectfully submitted,



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