MYLAN PHARMACEUTICALS INC
781 Chestnut Ridge Road • P. O. Box 4310 • Morgantown, West Virginia 26504-4310 U.S.A. • (304) 599-2595

February 17, 2004

VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Citizen Petition

Dear Sir/Madam:

Please find enclosed Mylan's Citizen Petition requesting the FDA to prohibit the marketing and distribution of "Authorized Generics" until the expiration of the first generic applicant's exclusivity period.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Stuart Williams/DGB

Stuart A. Williams
Chief Legal Officer

cc: Janet Woodcock, MD, Center Director
Gary J. Buehler, Director, Office of Generic Drugs
Daniel E. Troy, Chief Counsel

2004P-0075

CP1

Department—Fax Numbers
Accounting (304) 285-6403
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Sales & Marketing (304) 598-3232

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CITIZEN PETITION
EXPEDITED DECISION REQUESTED

The undersigned, Mylan Pharmaceuticals Inc. ("Mylan"), submits this Petition under section 505 of the Federal Food, Drug and Cosmetic Act ("FDCA"), and 21 C.F.R. §§ 10.30 and 10.35 to request the Commissioner of Food and Drugs (hereinafter, the "Commissioner") to prohibit the marketing and distribution of "authorized generic" versions of brand name products, until the expiration of any 180-day generic drug exclusivity to which an ANDA applicant is entitled. ("Authorized generic" is a term of art commonly used in the pharmaceutical industry to describe a drug product, which is a private label version of a brand name product supplied by the brand company.) The basis of this petition, as discussed in more detail below, is that authorized generic drugs are the same as true "generic" drugs, and therefore, should be prohibited from being marketed during the exclusivity period. Allowing an authorized generic version to be marketed during the exclusivity period is contrary to the letter and intent of the law. Because Mylan and other ANDA holders are eligible for 180-days of generic drug exclusivity for "true" generic versions of several brand name drugs, Mylan respectfully requests that consideration of this Petition be expedited.

BACKGROUND

The first sponsor to file an abbreviated new drug application ("ANDA") for a reference listed drug containing a challenge to the innovator's listed patents covering that drug product ("Paragraph IV ANDA") becomes eligible for 180-days of exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv) as to that product. Accordingly, under the FDCA, any subsequent ANDA applicant for that product would be ineligible for final approval until 180-days after the first commercial marketing of the product by the first Paragraph IV ANDA applicant. 21 U.S.C. § 355(j)(5)(B)(iv)(I). (For Paragraph IV ANDA applications filed before December 8, 2003, a final decision finding the patent to be invalid or not infringed will also trigger the exclusivity.) The Congressional intent of the exclusivity

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was recently highlighted by the United States Court of Appeals for the District of Columbia. The Court noted "[t]o encourage the marketing of low-cost generic drugs, the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act grant companies that successfully challenge drug patents the right to sell their generic drugs without competition for 180 days." *Purepac Pharmaceutical Co. v. Tommy G. Thompson, et al.*, No. 02-5410, slip op. at 2 (Fed. Cir. January 20, 2004). The emerging trend of marketing "authorized generics" during the first generic applicant's exclusivity period will negatively affect the incentive given to generic manufacturers to challenge drug patents. Publicly available information evidences that brand companies have entered into numerous arrangements under which authorized generics will be launched upon the entry of a true "generic".

A. Action Requested

This petition requests the Commissioner to prohibit the marketing and distribution of "authorized generic" versions of brand name drugs until the expiration of the first generic applicant's 180-day exclusivity period. The FDA has ample authority under several provisions of law and regulations to prohibit the marketing of such drugs during the first generic applicant's exclusivity period. Accordingly, Mylan urges the FDA to implement an authorized generic approval requirement, which would prevent the sale of an authorized generic until the expiration of the true generic applicant's exclusivity period.

B. Statement of Grounds

Under a typical authorized generic scheme, a brand company licenses a drug to a company while continuing to market the same drug as a "brand" drug. The licensed product is manufactured by the brand company, but it is packaged with the licensee's label and NDC number. Most importantly, the license typically does not permit the commercial marketing of the product until after the commercial marketing of the first true AB-rated "generic" product has begun. The arrangement is designed to cripple the Paragraph IV ANDA applicant's exclusivity.

Authorized generic agreements are structured so that the product competes with the true "generic" version as opposed to competing against the "brand" with respect to marketing and pricing. The classification of authorized generics as true "generic" drugs, though misleading, is critical to the brand company's strategy for entering into such arrangements. Because authorized generics are the "exact same drug" (known to be manufactured by the brand company), they are being treated in the same manner as an AB-rated "generic" drug, thus allowing unrestricted substitution. In addition, by using a generic pricing structure, authorized generics are directly competing with true "generics" with respect to cost to consumers and reimbursement and rebate calculations by the government. The companies entering into these transactions believe they can treat the product sold to the licensee as a generic for marketing and pricing while avoiding the regulatory approval process under the FDCA.

The FDA has viewed authorized generics as true generics. On August 9, 2000, Teva Pharmaceuticals USA, Inc. ("Teva") submitted a citizen petition requesting the FDA to determine that Mylan's marketing of Pfizer's extended-release nifedipine tablets triggered Mylan's 180-day exclusivity. *See* Teva's Citizen Petition (Docket No. 00P-1446, August 9, 2000). The FDA agreed with Teva and most importantly noted that Mylan's Chairman, CEO, and President stated in a press release that Mylan was going to be the first company to offer its customers a generic extended-release product. *See* FDA's Response to Teva's Citizen Petition (Docket No. 00P-1446, February 6, 2001). The FDA explained its ruling by stating that "whether Mylan markets the produc[t] approved in its ANDA or the produc[t] approved is Pfizer's NDA is of little import to the statutory scheme; Mylan has begun commercial marketing of gene[r]ic nifedipine, permitting Mylan to market nifedipine without triggering the beginning of the exclusivity would be inconsistent with the intent of the statutory scheme." *Mylan Pharmaceuticals Inc. v. Tommy G. Thompson, et al.,* 207 F.Supp.2d 476 (N.D.WV. 2001). The consequences of FDA's actions resulted in converting an NDA under section 505(b) of the FDCA into an ANDA under section 505(j).

Mylan believes the FDA has an obligation to implement a policy which is consistent with existing laws and regulations, to prohibit the marketing and distribution of authorized generics until the expiration of the first generic applicant's exclusivity period. According to the FDCA, all AB-rated generic drugs must be approved by the FDA as bioequivalent to the reference listed drug prior to marketing. *See* 21 U.S.C. § 355(j). Although authorized generics lack the required AB-rating, they are permitted to be marketed in the same manner as an AB-rated generic and therefore, are fully substitutable for the brand drug. Authorized generics are allowed to be marketed as "generics" for purposes of pricing and reimbursement/rebate calculations. Mylan believes, therefore, that authorized generics should be required to follow an approval process prior to marketing.

The approval process need not be a burdensome requirement for either the FDA or the authorized generic applicant. For example, the FDA could require the authorized generic applicant to submit a one-page application to identify the distributor and manufacturer of the drug. If it is determined that no generic applicant is eligible for exclusivity, the FDA would grant final approval to the application. On the other hand, if a generic applicant is eligible for exclusivity, the FDA would give tentative approval to the application until the expiration of the first generic applicant's exclusivity period.

In the alternative, the FDA could implement a policy which requires authorized generics to be listed with the FDA (as currently required by the FDCA and implementing FDA regulations) prior to commercial marketing and to wait until the expiration of the first generic applicant's exclusivity period to market and distribute the "authorized generic" version. Section 510 of the FDCA and 21 CFR part 207, require all establishments (e.g., manufacturers, repackers, and relabelers) upon first engaging in the manufacture, preparation, propagation, compounding, or processing of human drugs to register their establishments and submit listing information for all drugs in commercial distribution. In addition, registrants must update listing information every June and

December of each year to include information for drugs that have not been previously listed. *See* 21 U.S.C. § 510, *see also* 21 C.F.R. part 207. The failure to comply with section 510 of the FDCA renders drugs misbranded. *See* 21 U.S.C. § 502(o). The submission of this information helps the FDA maintain a catalog of all human drugs in commercial distribution in the United States. Based on existing statutory requirements, the FDA could implement a policy which would require listing of authorized generics prior to commercial marketing and prohibit entry into the market until the expiration of the first generic applicant's exclusivity period.

The concepts discussed above are respectfully submitted as suggestions. Mylan understands that the FDA may choose to implement a different procedure which accomplishes the same objective. Mylan requests that this very important issue receive expedited attention.

C. Environmental Impact

The actions requested herein are subject to categorical exclusion under 21 C.F.R. § 25.31.

D. Economic Impact

An economic impact statement will be submitted at the request of the Commissioner.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Respectfully Submitted,

February 17, 2004
Date

Stuart Williams/PAB

Stuart A. Williams
Chief Legal Officer
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, WV 26505

Telephone: (304) 599-2595
Facsimile: (304) 598-5408

cc: w/encl. Janet Woodcock, MD, Center Director
Gary J. Buehler, OGD Director
Daniel E. Troy, Chief Counsel