DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-276

Food and Drug Administration
Rockville MD 20857

OCT 15 2004

Mylan Pharmaceuticals, Inc.
Attention: S. Wayne Talton
781 Chesnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 16, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Levofloxacin Tablets, 250 mg and 500 mg.

Reference is also made to the Tentative Approval letter issued by this office on December 10, 2003, and to your amendments dated April 22, August 27, and September 23, 2004.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Levofloxacin Tablets, 250 mg and 500 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug Levaquin Tablets, 250 mg and 500 mg, respectively, of Ortho McNeil Pharmaceutical, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The listed drug product referenced in your application, Levaquin Tablets of Ortho McNeil Pharmaceutical Inc., is subject to a period of patent protection. As noted in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. patent No. 5,053,407 (the '407 patent) expires December 20, 2010. Your application contains a patent certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '407 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Levofloxacin Tablets, 250 mg and 500 mg under this ANDA. Section 505(j)(5)(B)(iii) of the Act

provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Mylan Pharmaceuticals Inc. (Mylan) for infringement of the '407 patent that was the subject of the paragraph IV certification. This action must have been brought against Mylan prior to the expiration of 45 days from the date of receipt of the notice you provided to the NDA/patent holder(s) under paragraph (2)(B)(i). You have informed the Agency that Mylan complied with the requirements of Section 505(j)(2)(B) of the Act, and that Ortho McNeil Pharmaceutical Inc. initiated a patent infringement suit against you in the United States District Court for the Northern District of West Virginia, Clarksburg Division (Ortho-McNeil Phamaceutical, Inc., Johnson & Johnson Pharmaceutical Research & Development, LLC and Daiichi Pharmaceutical Co., Ltd. v. Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc., Civil Action No. 1-02-CV-32). Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application, has expired.

With respect to 180-day generic drug exclusivity, Mylan Pharmaceuticals Inc. (Mylan) was the first NDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '407 patent. Therefore, with this approval Mylan is eligible for 180 days of generic drug exclusivity for Levofloxacin Tablets 250 mg and 500 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act,[1] will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv). Please submit correspondence to this application informing the Agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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[1] Because your ANDA, which was the first to contain a paragraph IV certification to the patent on the listed drug, was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and
Communications (HFD-42)
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6) [redacted]

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research