ANDA 75-685 March 30, 2000

Mylan Pharmaceuticals, Inc.
Attention: Frank R. Sisto
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application dated August 12, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ciprofloxacin Tablets USP, 750 mg.

Reference is also made to your amendment dated March 6, 2000.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is tentatively approved. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your application, Cipro Tablets of Bayer Corporation, is subject to periods of patent protection which expire on December 9, 2003 (U.S. Patent No. 4,670,444), and February 15, 2011 (U.S. Patent No. 5,286,754). Your application contains a Paragraph IV Certification to each patent under Section 505(j)(2)(A)(vii)(IV) of the Act. This certification states that your manufacture, use, sale, offer for sale, or importation of this drug product will not infringe either of the patents. Section 505(j)(5)(B)(iii) of the Act provides

that the approval of an abbreviated new drug application shall be made effective immediately, unless an action is brought against Mylan Pharmaceuticals, Inc. (Mylan) for infringement of one or more of the patents that are the subject of the certifications. Such an action must be brought before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received. You have notified the agency that Mylan has complied with the requirements of Section 505(j)(2)(B) of the act, and that litigation is currently underway in the United States District Court for the District of New Jersey involving your challenge to the '444 patent [Bayer AG and Bayer Corporation v. Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc., Civil Action No. 99-4659 (GEB)]. Therefore, with respect to the '444 patent only, final approval of this application cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii) since the date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,

   b. the date of a court decision [505(j)(5)(B)(iii) (I), (II), or (III)], or,

   c. the '444 patent has expired, and

2. the Agency is assured there is no new information that would affect whether final approval should be granted.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 60-days (but not more than 90-days) prior to the date you believe your application will be eligible for final approval. This amendment should provide a copy of an order or judgment from the court, notification of a settlement or a licensing agreement between you and the patent holder, or any other relevant patent settlement information. This amendment should also provide updated information such as final-printed labeling, or chemistry, manufacturing and controls data, as appropriate. This amendment also serves to reactivate the application and should be submitted even if none of these

changes have been made to the application since the issuance of this tentative approval letter. This amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the information described above. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this abbreviated application as well as in the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures (CGMPs) are subject to Agency review before final approval of the application will be made.

This drug product may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list, the “Orange Book”, published by the agency.

Prior to submitting the amendment(s), please contact Elaine Hu, R.Ph., Project Manager, at (301) 827–5848, for further instructions.

Sincerely yours,

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