ANDA 76-136 December 26, 2001

Teva Pharmaceuticals USA
Attention: Philip Erickson
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454-1090

Dear Sir:

This is in reference to your abbreviated new drug application dated March 21, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ciprofloxacin Tablets USP, 250 mg, 500 mg, and 750 mg.

Reference is also made to your amendments dated August 10, October 18, October 23, and October 29, 2001.

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). The determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your application, Cipro Tablets of Bayer Corporation, is currently subject to periods of patent protection which expire on December 9, 2003 (U.S. patent 4,670,444 [the ‘444 patent]), and February 15, 2011 (U.S. patent 5,286,754 [the ‘754 patent]). Your application contains a Paragraph IV Certification to the ‘754 patent under Section 505(j)(2)(A)(vii)(IV) of the Act. This certification states that the ‘754 patent will not be infringed by the manufacture, use, or sale of this drug product. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug application shall be made effective immediately, unless an action is brought against TEVA

Pharmaceuticals USA (TEVA) for infringement of the ‘754 patent before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received. You have notified FDA that TEVA has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement against the '754 patent was brought against TEVA within the statutory forty-five day period.

In addition, your application contains Paragraph III Certification to the '444 patent under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of this patent. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the ‘444 patent has expired, i.e., currently December 9, 2003.

In order to reactivate your application prior to final approval, please submit an amendment 60 to 90 days prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED. In addition to this amendment, the Agency may request at any time prior to the final date of 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 significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

Please note that 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 final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21

U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to December 9, 2003, you should amend your application accordingly.

At the time you submit any amendments, or for information about the status of your application, please contact Sarah Ho, R.Ph., Project Manager, at 301-827-5848.

Sincerely yours,

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

cc: ANDA 76-136
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205

Endorsements:
HFD-629/K.Woodland/12/18/01
HFD-625/J.Fan/12/18/01
HFD-617/S.Ho/12/18/01
HFD-613/L.Golson/12/18/01
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F/T by: DJ 12/11/01

TENTATIVE APPROVAL