ANDA 74-876 March 24, 1999

Novopharm NC Inc.
Attention: Dietrich Bartel
U.S. Agent for: Novopharm Limited
4700 Novopharm Blvd.
Wilson, NC 27893

Dear Sir:

This is in reference to your abbreviated new drug application dated March 27, 1996, 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 8, 1996; August 21, 1998; and February 1, 1999.

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. The listed reference drug product (RLD) upon which you have based your application, Cipro Tablets 250 mg, 500 mg, and 750 mg of Bayer Corporation, is subject to periods of patent protection [U.S. patent 5,286,754 (the ‘754 patent) expiring February 15, 2011 and U.S. patent 4,670,444 (the ‘444 patent) expiring December 9, 2003]. 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 latter period has expired, i.e., February 15, 2011 (the ‘754 patent).

To provide for final approval, please submit an amendment to this application at least 60 but not more than 90 days prior to the expiration of the latter patent, currently February 15, 2011.

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-printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. The amendment should be clearly designated as a MINOR AMENDMENT in your cover letter. In addition to or instead of this amendment, the Agency may request that you submit an amendment containing the same information at any time prior to the final date of approval.

Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant changes in the conditions outlined in this abbreviated application require Agency approval before the changes may be made effective.

Prior to issuance of a final approval letter by the Agency, your 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 February 15, 2011, you should amend your application accordingly.

At the time you submit any amendments, you should contact Joseph Buccine, Project Manager, at (301) 827–5848, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 331(d).

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research