ANDA 74-994 October 25, 1999

Novopharm N.C., 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 October 31, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ticlopidine Hydrochloride Tablets, 250 mg.

Reference is also made to your amendments dated October 20, 1998; and September 17, (2 submissions), and September 28, 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, Ticlid Tablets, 250 mg, of Syntex U.S.A., Inc., is subject to a period of patent protection (U.S. Patent 4, 591,592, “the ‘592 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 expiration of the ‘592 patent, i.e., May 27, 2003.

To provide for final approval, please submit an amendment to this application at least 60 days (but not more than 90 days) prior to May 27, 2003. 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. This submission 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 the agency to issue the final approval letter prior to May 27, 2003, you should amend your application accordingly.

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

Please contact Kassandra Sherrod, Project Manager, at (301) 827-5849, for further instructions prior to amending your application.

Sincerely yours,

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