

May 29, 1998

Granutec Inc.
Attention: Theresa M. Ast, Ph.D.
U.S. Agent for Novopharm Limited
4700 Novopharm Blvd.
Wilson, NC 27893



Dear Madam:

This is in reference to your abbreviated new drug application dated September 19, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Cimetidine Tablets USP, 200 mg.

Reference is also made to your amendments dated April 30, November 13, and December 12 and 22, 1997; and January 19, February 2, March 13, April 15, and May 14, 1998.

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 over-the-counter 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 of the facilities used in the manufacturing 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 upon which you have based your application is subject to a period of market exclusivity and therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(4)(D) of the Act until the period has expired, i.e., June 19, 1998.

Please amend this application to identify changes, if any, in the conditions under which the product was tentatively approved. The amendment should be received by this office at least 2 weeks prior to the expiration of the market exclusivity, and should include updated information such as 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 as a MINOR AMENDMENT in your

cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above. 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 change in the conditions outlined in this abbreviated application requires Agency approval before the change 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, published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to June 19, 1998, you should amend your application accordingly.

At the time you submit any amendments, you should contact Kassandra Sherrod, Project Manager, at (301) 827-5849, 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