ANDA 75-167 May 4, 2000

Apotex Corp.
U.S. Agent for: Torpharm Inc.
Attention: Marcy Macdonald
50 Lakeview Parkway
Suite 127
Vernon Hills, IL 60061

Dear Madam:

This is in reference to your abbreviated new drug application dated July 10, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ranitidine Tablets USP, 75 mg.

Reference is also made to your amendments dated September 17, 1999; and March 7, and April 24, 2000.

The listed drug product referenced in your application is subject to period of patent protection which expire on December 4, 2002, (U.S. Patent No. 4,521,431 [the '431 patent]) and November 13, 2008 (U.S. Patent No. 4,880,636 [the '636 patent]), respectively. Your application contains patent certifications to each patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on either patent. Section 505(j)(4)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action is brought for infringement of one or more of the patents which are the subject of the certification 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 Apotex Corp. has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Apotex Corp. within the statutory forty-five day period.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Ranitidine Tablets USP, 75 mg, to be bioequivalent to the listed drug (Zantac-75 Tablets of Warner Lambert Co., Consumer Products Division). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

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