

September 29, 1998

Apotex Corp.
U.S. Agent for: Torpharm Inc.
Attention: Marcy Macdonald
50 Lakeview Parkway
Suite #127
Vernon Hills, Ill 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 16, 1997, January 27, July 29 and September 3, 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) therefore subject to change on the basis of new information that may come to our attention.

The listed drug product referenced in your application is subject to periods of patent protection which expires on June 4, 2002, (patent 4,521,431) and May 13, 2008 (patent 4,880,636), respectively. Your application contains patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, sale, or offer to sell Ranitidine Tablets USP, 75 mg, will not infringe on the patents. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent(s) which are the subject of the certifications 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 Torpharm Inc. has complied with the requirements of Section

505(j)(2)(B) of the Act and that no action for patent infringement was brought against Torpharm Inc. within the statutory forty-five day period. However, the reference listed drug product upon which you have based your application is also 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)(5)(D) of the Act until the period has expired, i.e., December 19, 1998.

Please provide the Agency, at least 60, but not more than 90, days prior to December 19, 1998, an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, 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 changes in the conditions outlined in this abbreviated application requires 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, published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to December 19, 1998, you should amend your application accordingly.

At the time you submit any amendments, you should contact Cassandra 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