ANDA 75-610 March 12, 2002

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 29, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Tablets USP, 10 mg (OTC).

Reference is made to your amendments dated April 16 and June 21, 1999; May 17, June 22, and September 28, 2001; and Janaury 31, 2002.

The listed drug product referenced in your application, Pepcid AC Tablets, 10 mg of Merck Research Laboratories, is subject to periods of patent protection which expire on November 2, 2015, (U.S. Patent No. 5,667,794 – the "794 patent") and June 29, 2016 (U.S. Patent No. 5,854,267 – the "267 patent"). Your application contains a revised patent certification dated April 16, 1999, 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 the '267 patent. Your application also contains a "method of use (MOU)" statement in accord with Section 505(j)(2)(A)(viii) of the Act stating that your are not seeking approval for the use claimed by the '794 patent (U-205 – a method for treating heartburn). You notified the agency that TorPharm complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement of the '267 patent was brought against TorPharm within the statutory forty-five day period. Subsequently, the ANDA was amended to change the prior "paragraph IV" certification to the '267 patent to a MOU stating that you are not seeking approval for the method of use claimed

by the ‘267 patent (U-267 – prevention when administered from 15 minutes up to, but not including, 1 hour).

Because you have submitted MOU statements to each patent, the agency recognizes that a “paragraph IV certification” submitted under Section 505(j)(2)(A)(vii)(IV) of the Act by another ANDA holder to either patent will not block approval of your application.

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 Famotidine Tablets USP, 10 mg, to be bioequivalent to the listed drug (Pepcid AC Tablets, 10 mg, of Merck Research Laboratories. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

As a result of your submission of method of use statements to the ‘794 and ‘267 patents, and the existing exclusivity (D-47), the approved labeling for your application is currently limited to the **prevention** of heartburn associated with acid indigestion and sour stomach, and is also limited to administration **one hour prior** to eating food or drinking beverages that may cause the conditions previously stated.

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
Director
Office of Generic Drugs
Center for Drug Evaluation and Research