

May 31, 2001

TEVA Pharmaceuticals USA  
Attention: Phillip Erickson  
1090 Horsham Road  
North Wales, PA 19454-1090

Dear Sir:

This is in reference to your abbreviated new drug application dated December 30, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Tablets USP, 10 mg.

Reference is also made to our tentative approval letter dated October 15, 1998, and to your amendments dated November 22, December 1, and December 7, 2000; and January 25, January 26, February 5, and February 19, 2001.

The listed drug product referenced in your application, Pepcid AC Tablets, 10 mg of Merck Research Laboratories, is subject to period 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 patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Famotidine Tablets USP, 10 mg will not infringe on the '794 patent or that this patent is otherwise invalid or unenforceable. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action is brought prior to the expiration of forty-five (45) days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified the agency that Teva Pharmaceuticals USA (Teva) complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement of the '794 patent was brought against Teva within the statutory forty-five day period. Teva has also included a "method of use" statement in accord with Section 505(j)(2)(A)(viii) with regard to the '267 patent. The statement notes that '267 patent does not claim the proposed indications for which you are seeking approval.

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.

Furthermore, we note that Teva was the first ANDA applicant to submit a substantially complete ANDA containing a Paragraph IV Certification to the '794 patent. Therefore, with this approval Teva is eligible for 180-days of generic drug market exclusivity. Such exclusivity will commence on the date Teva begins commercial marketing of the drug product.

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commenced commercial marketing of this product.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the Agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

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