

October 15, 1998

TEVA Pharmaceuticals, USA
Attention: Deborah A. Jaskot
1510 Delp Drive
Kulpsville, PA 19443

Dear Madam:

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 your amendments dated February 5, June 5 and 22, July 2 and 20, and August 18, 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 draft Over-the-Counter (OTC) 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. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(4)(B)(iv) of the Act.

The listed drug product referenced in your application is subject to periods of patent protection which expire on October 15, 2000, (patent 4,283,408 [the '408 patent]), and May 2, 2015 (patent 5,667,794 [the '794 patent]), respectively. 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 the '794 patent is invalid, or unenforceable. 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 which is 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 TEVA Pharmaceuticals, USA has complied with the requirements of Section 505(j)(2)(B) of the Act and that

no action for patent infringement was brought against TEVA Pharmaceuticals, USA within the statutory forty-five day period. However, your application also contains a patent certification under Section 505(j)(2)(A)(vii)(III) of the Act stating that TEVA Pharmaceuticals, USA will not engage in the commercial manufacture, use, or sale of the drug product until the expiration of the '408 patent. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(4)(B) of the Act until the period has expired, i.e., October 15, 2000.

Please provide the Agency, at least 60, but not more than 90, days prior to October 15, 2000, 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 final printed labels and 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 October 15, 2000, 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,

Roger L. Williams, M.D.
Deputy Center Director for Pharmaceutical Science
Center for Drug Evaluation and Research