ANDA 75-872

May 31, 2001

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

Dear Sir:

This is in reference to your abbreviated new drug application dated May 16, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fluoxetine Hydrochloride Tablets, 10 mg (base).

Reference is also made to your amendments dated November 1, 2000; February 21, March 15, March 27 and April 23, 2001.

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 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 (CGMPs) of the facilities used in the manufacturing and testing of the drug product), and is 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)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your application, Prozac® Tablets of Eli Lilly & Co., is subject to periods of patent protection which expire on August 2, 2001 (U.S. Patent No. 4,314,081 [the ‘081 patent]), and June 2, 2004, (U.S. Patent No. 4,626,549 [the ‘549 patent]). Your application contains a Paragraph IV Certification and a Method of Use Statement under Section 505(j)(2)(A)(vii)(IV) and Section 505(j)(2)(A)(viii) of the Act to the ‘549 patent. 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 infringement against the '549 patent was brought against TEVA Pharmaceuticals USA within the statutory forty-five day period. In addition, your application contains a Paragraph III Certification to the '081 patent under Section 505(j)(2)(A) (vii)(III) of the Act. Therefore, final approval of this application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the period has expired i.e., currently August 2, 2001.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 60-days (but not more than 90-days) prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the drug product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing and controls data, as appropriate. This amendment also serves to reactivate the application and should be submitted even if none of these changes were made to the application since the date of this tentative approval. This amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the date of final approval that you submit an additional amendment containing the information described above. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application as well as the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures (CGMPs) are subject to Agency review before final approval of the application will be made.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic

Equivalence Evaluations" list, the “Orange Book”, published by the Agency.

Prior to submitting the amendment(s), please contact Bonnie McNeal, Project Manager, at (301) 827–5849, for further instructions.

Sincerely yours,

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

TENTATIVE APPROVAL