ANDA 75-506 August 2, 2001

TEVA Pharmaceuticals USA
Attention: Philip Erickson
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19943

Dear Sir:

This is in reference to your abbreviated new drug application dated November 20, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fluoxetine Oral Solution USP, 20 mg (base)/5 mL.

Reference is also made to your amendment dated May 17, 2001.

The listed drug product (RLD) referenced in your application, Prozac® Liquid of Eli Lilly and Company, is subject to a period of pediatric exclusivity which expires on August 2, 2001. In addition the listed drug product is subject to a period of patent protection which expires 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. You informed us that Eli Lilly and Company initiated a patent infringement suit against you for your Paragraph IV Certification on the challenged claim in the United States District Court for the Southern District of Indiana (Eli Lilly and Company v. TEVA Pharmaceuticals USA, Civil Action No. IP 98-1435 C B/S). You have also notified us that you prevailed on one claim of the '549 patent in both the district court and in the court of appeals and a Method of Use Statement to another claim.

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 labeling. Accordingly, the application is approved. The Division of

Bioequivalence has determined your Fluoxetine Oral Solution USP, 20 mg (base)/5 mL to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Prozac Liquid.

With respect to 180-day generic drug exclusivity, we note that TEVA Pharmaceuticals USA (TEVA) was the first to submit a substantially complete ANDA with a Paragraph IV Certification. Therefore, with this approval TEVA is eligible for 180-days of market exclusivity. Subsequent applications for this this drug product will be eligible for final approval not earlier than one hundred eighty days after:

the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing, or

the date of a decision of a court (ii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier [Section 505(j)(B)(iv)].

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 commence commercial marketing of this product, or the date of a decision of the court holding the relevant patent invalid, unenforceable or not infringed.

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.

We request that you submit, in duplicate, any proposed advertising or promotional copy, which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

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