DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 75-452

JAN 29 2002

TEVA Pharmaceuticals USA
Attention: Philip Erickson, R.Ph.
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application dated August 31, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fluoxetine Capsules USP, 10 mg, 20 mg, and 40 mg.

Reference is also made to our Tentative Approval letter dated January 3, 2000, and to your amendments dated August 8 and November 26, 2001.

The listed drug product referenced in your application 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 action against you on your Paragraph IV Certification for the 10 mg and 20 mg strengths on the challenged claim in United States District Court for the Southern District of Indiana (Eli Lilly and Company v. Teva Pharmaceuticals USA, Civil Action No. IP-98-1435C B/S. You have also notified us that you prevailed on one claim in both the district court and in the court of appeals and made a Method of Use Statement to another claim. You also notified the Agency that Teva Pharmaceuticals USA complied with the requirements for Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Teva within the statutory forty-five day period for the 40 mg strength.

Furthermore, the Act provides that approval of an abbreviated application that contains a certification described in Section 505(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), and that is for a drug product for which a previous abbreviated application has been submitted which also contains a Paragraph

IV Certification, shall be made effective not earlier than one hundred and eighty days after:

1. the date the Secretary receives notice of the first commercial marketing of the drug product under the previous application, or

2. the date of a final decision of a court holding the patent(s) which is the subject of the certification to be invalid or not infringed, whichever event occurs first {Section 505(j)(5)(B)(iv)}.

As noted in the Agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), an abbreviated new drug application for this drug product was approved for Geneva Pharmaceuticals, Inc. for the 10 mg strength, Barr Laboratories, Inc. for the 20 mg strength, and Dr. Reddy's Laboratories, Ltd. for the 40 mg strength on August 2, 2001. These applications also contained Paragraph IV Certifications and were the first applications received by the Agency for this drug product. Consequently, Geneva Pharmaceuticals, Inc., Barr Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd. became eligible for 180 days of market exclusivity commencing on the date of first commercial marketing. According to the "Orange Book", Geneva Pharmaceuticals Inc.'s, Barr Laboratories Inc.'s, and Dr. Reddy's Laboratories, Ltd.'s market exclusivity expired on January 29, 2002.

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 Capsules USP, 10 mg, 20mg, and 40mg to be bioequivalent to the listed drug (Prozac® Capsules) USP, 10 mg, 20 mg, and 40 mg, respectively, of Eli Lilly and Company. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

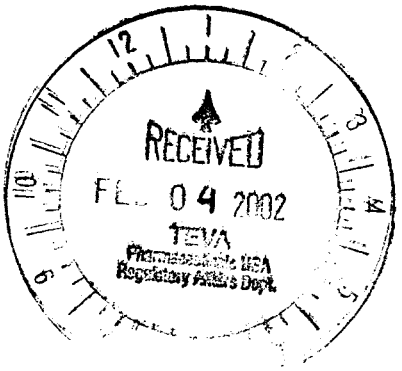
Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

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