ANDA 76-016

August 24, 2001

ESI Lederle
Attention: Nicholas C. Tantillo
401 North Middletown Road
Pearl River, NY 10965-1299

Dear Sir:

This is in reference to your abbreviated new drug application dated October 31, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fluoxetine Oral Solution USP, 20 mg/5 mL.

Reference is also made to your amendment dated April 10, 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 manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The listed drug product referenced in your application, Prozac Oral Solution of Eli Lilly and Company, is subject to a period of patent protection which expires on June 2, 2004, (U.S. Patent No. 4,626,549 [the '549 patent]). Your application contains a Paragraph III Certification to the ‘549 patent under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product until the expiration of the ‘549 patent. With regard to the expiration of this patent, we refer to the recent decision of the United States District Court for the Southern District of Indiana (Eli Lilly and Company v. Barr Laboratories, Inc. et al., Civil Action No. IP 96-0491 C B/S) in which the court ruled that the U-84 claim (uptake of monoamines by the brain) of the ‘549 patent is invalid. However, the court

did not find the entire patent (i.e., the U-154 claim for appetite disorder) to be invalid. This decision was upheld by the Court of Appeals. Thus, the '549 patent will remain listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") until patent expiry, currently June 2, 2004. Thus your application is eligible for approval upon the expiration of the '549 patent, currently June 2, 2004.

In order to reactivate your application prior to final approval, please submit a MINOR AMENDMENT – FINAL APPROVAL REQUESTED approximately 60 days prior to the date when you believe your application will be eligible for final approval. Your amendment must provide:

1. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this tentatively approved abbreviated application, or

2. a statement that no such changes have been made to the application since the date of tentative approval.

Should you believe there is justification for granting final approval prior to June 2, 2004, please include detailed legal/regulatory documentation to support your position in addition to the documentation requested above.

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

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

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 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 amendment should be designated as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED in your cover letter. Before you submit the amendment, please contact Bonnie McNeal, Project Manager, at 301-827-5849, for further instructions or to inquire about the status of your application.

Sincerely yours,

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

TENTATIVE APPROVAL