ANDA 75-658 June 16, 2000

Mallinckrodt, Inc.
Attention: Ronald T. Groman
675 McDonnell Blvd.
P.O. Box 5840
St. Louis, MO 63134-0840

Dear Sir:

This is in reference to your abbreviated new drug application dated June 30, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fluoxetine Capsules USP, 10 mg and 20 mg.

Reference is also made to your amendments dated July 30, 1999; and February 21, May 16, and June 9, 2000.

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), and is subject to change on the basis of new information that may come to our attention.

The listed drug product (RLD) referenced in your application, Prozac Capsules of Eli Lilly & Co., is subject to periods of patent protection which expire on February 2, 2001, (U.S. Patent No. 4,314,081 [the ‘081 patent]), and December 2, 2003, (U.S. Patent No. 4,626,549 [the ‘549 patent]). Your application contains a Paragraph III Certification to the ‘081 and ‘549 patents under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of the patents. Therefore, final approval of your application may not be made effective pursuant to 21 USC 355(j)(5)(B)(ii) of the Act until both patents have expired, i.e., currently December 2, 2003.

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. Your 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. As your amendment serves to reactivate this application in OGD, an amendment should be submitted even if no changes were made to the application since the date of this tentative approval letter. 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 changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (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 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”).

Before you submit the amendment(s), please contact Timothy Ames, R.Ph., Project Manager, at (301) 827–5798, for further instructions.

Sincerely yours,

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