ANDA 75-465 June 26, 2001

Reddy - Cheminor Inc.
U.S. Agent for Dr. Reddy's Laboratories Limited
Attention: Paul V. Campanelli
66 South Maple Avenue
Ridgewood, New Jersey 07460

Dear Sir:

This is in reference to your abbreviated new drug application dated September 24, 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 your amendments dated March 30 and September 26, 2000; and February 5, March 8, March 30, and May 25, 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 of the facilities used in the manufacturing and testing of the drug product) and is therefore 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 and Company, is currently 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 4,625,549 [the '549 patent]). Your application contains a Paragraph III Certification under Section 505(j)(2)(A)(vii)(III) of the Act to the '081 patent stating that you will not market this drug product prior to the expiration of this patent. Your application also 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. However, litigation is underway in the United States District Court for the Southern District of Indiana, Indianapolis Division involving a challenge to the patent (Eli Lilly and Company v. Cheminor Drugs, Ltd. and Reddy-Cheminor, Inc., Civil Action No. IP99-0024 C B/S). Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii) since the date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,

   b. the date of court decision [505(j)(5)(B)(iii)(I), (II), or (III)], which has been interpreted by the Agency to mean the date of the final order or judgement of that court from which no appeal can be or has been taken, or,

   c. the patent has expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

We also note that should the patent litigation be resolved in favor of Cheminor Drugs, Ltd. and Reddy-Cheminor, Inc. prior to the expiration of the ‘081 patent which is the subject of a Paragraph III Certification, 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 ‘081 patent has expired, 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 this application prior to final approval and should be submitted even if none of these changes were made since the date of this tentative approval letter. This amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. With respect to the patent issues noted

above, this amendment should also provide information such as a copy of a final order or judgement from the court, a notice of a settlement agreement between the parties, a licensing agreement between you and the patent holder, or any other relevant information as appropriate to address these unexpired patents.

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.

Please note that this drug product 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 final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to June 2, 2004, you should amend your application accordingly.

At the time you submit any amendments, you should 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