

June 14, 2000

Barr Laboratories, Inc.
Attention: Christine Mundkur
2 Quaker Road
P.O. Box 2900
Pomona, NY 10970-0519

Dear Madam:

This is in reference to your abbreviated new drug application dated December 9, 1995, 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 June 6, 1997; April 29, June 15, and August 18, 1998; April 12, April 30, May 14, May 21, June 7, August 26, and December 17, 1999; and February 2, March 7, March 17, and April 18, 2000. Reference is also made to your correspondence dated March 13, March 14, and April 17, 1996.

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. This letter does not address the notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

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 IV Certification to the '081 and '549 patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on these patents or that the patents are invalid or unenforceable. You have notified the agency that Barr Laboratories, Inc. has complied with the notification requirements of Section 505(j)(2)(B) of the Act. Subsequently, the patent and NDA holder initiated a patent infringement suit against Barr et al. in the United States District Court for the Southern District of Indiana (Eli Lilly and Company v. Barr Laboratories, Inc., Apotex Inc., Interpharm Inc., Bernard C. Sherman, and Geneva Pharmaceuticals, Inc., Civil Action No. IP 96-0491C B/S). On January 25, 1999, the district court entered a Final Judgement and Injunction in this case which states that the '081 and '549 patents were not proven to be invalid or unenforceable and that Barr et al. infringed the patents by filing the ANDA. Furthermore, the district court prohibited the agency from approving any ANDA for this drug product subject to the injunction before the expiration of the '549 patent, subject to further rulings by the courts. You have informed the agency that the district court decision was appealed to the U.S. Court of Appeals, Federal Circuit in Washington, D.C., and that oral arguments were heard before this court on March 8, 2000. The Appeals Court's decision is currently pending.

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 documentation such as a copy of a final order or judgement from the Court of Appeals, or a settlement agreement between the parties, whichever is applicable, a licensing agreement between you and the patent holder, or any other relevant information. The amendment should also provide 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