

ANDA 74-803/S-004, S-005, S-006, S-007, S-008, S-009

Barr Pharmaceuticals, Inc.
Attention: Christine Mundkur
300 Corporate Drive, Unit 10
Blauvelt, NY 10813

Dear Madam:

This is in reference to your supplemental new drug applications dated August 21, September 17, and November 30, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Fluoxetine Capsules USP, 20 mg.

The supplemental applications provide for:

- S-004: final printed container labels (30s and 2000s) for both the 10 mg and 20 mg strengths and final printed package insert labeling;
- S-005: scale-up of the manufacturing process from 1,000,000 capsules to 2,000,000 for the 10 mg strength;
- S-006: addition of new package sizes of 30s and 2000s for both the 10 mg and 20 mg strengths;
- S-007: an alternate manufacturing and packaging site located at 2150 Perrowville Road, Forest, VA for the 10 mg capsules;
- S-008: revisions made to the manufacturing process used by Laboratori MAG S.P.A. in the production of Fluoxetine HCL drug substance; and,
- S-009: final approval of the previously tentatively approved 10 mg strength.

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 Method of Use Statement under Section 505(j)(2)(A)(viii) of the Act to the '549 patent.

As you are aware and 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 your 20 mg strength, and for Geneva Pharmaceuticals, Inc. for their 10 mg strength on August 2, 2001. These applications contained Paragraph IV Certifications and were the first applications received by the Agency for this drug product. Consequently, you and Geneva Pharmaceuticals, Inc. became eligible for 180 days of market exclusivity commencing on the date of first commercial marketing. According to the "Orange Book", your and Geneva's market exclusivity expired on January 29, 2002.

We have completed the review of these supplemental applications as amended, and have concluded that your Fluoxetine Capsules USP, 10 mg are safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications including final approval of the additional 10 mg strength are approved. The Division of Bioequivalence has determined your Fluoxetine Capsules USP, 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Prozac® Capsules, 10 mg, 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.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any changes 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 campaign for the 10 mg strength. 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-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 the Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

The material submitted is being retained in our files.

Sincerely yours,

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