ANDA 75-049/S-002 through S-010

Geneva Pharmaceuticals, Inc.
Attention: Beth Brannan
2655 W. Midway Blvd.
Broomfield, CO 80038-0446

Dear Madam:

This is in reference to your supplemental new drug applications dated August 13, October 24, and November 14, 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, 10 mg and 20 mg.

Reference is also made to your amendments dated September 17, 2001 (S-002), November 14, 2001 (S-008) and January 14, 2002 (S-002, S-003, S-004, S-005, S-010).

The supplemental applications provide for:

S-002: additional strength of Fluoxetine Capsules USP, 40 mg;

S-003: labeling revisions associated with the new 40 mg strength;

S-004: associated control revisions for the new dosage strength;

S-005: associated formulation revisions for the new strength;

S-006: bioequivalence data to support the new dosage strength;

S-007: new package sizes for the 10 mg strength;

S-008: labels and labeling for the 10 mg strength;

S-009: control revisions for the 20 mg strength; and,

S-010: additional labeling revisions for 10 mg, 20 mg, and 40 mg strengths. The insert labeling submitted with this supplement supercedes the insert labeling provided for in S-003 and S-008.

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 10 mg strength, and for Barr Laboratories, Inc. for their 20 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 Barr Laboratories, Inc. became eligible for 180 days of market exclusivity commencing on the date of first commercial marketing. According to the "Orange Book", your and Barr's market exclusivity expired on January 29, 2002.

We have completed the review of these supplemental applications as amended, and have concluded that the new 40 mg strength of the drug product and the previously tentatively approved 20 mg strength of the drug product are safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are approved. The Division of Bioequivalence has determined your Fluoxetine Capsules USP 40 mg and 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Prozac® Capsules, 40 mg and 20 mg, respectively, 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 20 mg and

40 mg strengths. 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