NDA 20-885

SmithKline Beecham Pharmaceuticals
Attention: Thomas F. Kline
Manager, U.S. Regulatory Affairs
1250 South Collegeville Road, P.O. Box 5089
Collegeville, Pennsylvania 19426

Dear Mr. Kline:

Please refer to your pending New Drug Application dated December 22, and received December 24, 1997, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paxil (paroxetine hydrochloride) 10 mg, 20 mg, 30 mg, and 40 mg Capsules.

We acknowledge receipt of your submissions dated January 9, February 16, March 31, May 4, May 6, September 16, and September 28, 1998. The user fee goal for this application is December 24, 1998.

This new drug application provides for a new formulation of Paxil (paroxetine HCL) in a capsule dosage form.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your proposed draft labeling dated December 22, 1997. Accordingly, the application is approved effective on the date of this letter.

CLINICAL

The final printed labeling (FPL) must be identical to the last approved Paxil (paroxetine HCL) tablet labeling [PX:L12] except for the following revisions.

1. All references to the tablet and oral suspension may be removed in the **Description**, **Pharmacology**, **Indications**, **Dosage and Administration**, and **How Supplied** sections since you have requested that this FPL solely reflect the capsule formulation.

2. A new paragraph may be added in the **Description** and **How Supplied** sections to describe the capsule formulation. This should be identical to your draft labeling submitted on December 22, 1997.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC)

(b)(4)(CC)----------
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BIOPHARMACEUTICS

1. The bioequivalency study has adequately linked 10 and 40 mg Paxil capsules to the approved tablet formulation at the respective strengths.

2. The composition variation of (b)(4)(TS)---------- ----------and composition variation of(b)(4)(TS)-------- ----------xists for the filler material (b)(4)(CC)---------- the two middle strengths have demonstrated the same ----------st and the highest strengths of Paxil capsule. Therefore, the two middle strengths capsules can be granted a waiver of bio-studies.

3. The dissolution data for individual capsules at(b)(4)(CC)--are not available. The submitted dissolution data shows that capsules at all stre----------dissolved (b)(4)(CC)---------- Therefore, the following method for dissolution and specificatio-- ---------- the 10 mg, 20 mg, 30 mg, and 40 mg capsule strengths:

    USP Apparatus I (Basket) 60 rpm
    900 mL Simulated Gastric Fluid (SGF) without enzymes at 37°C
    Sampling time: 15 minutes
    Specifications: NLT (b)

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-885." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.
We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Mr. Paul David, R.Ph., Project Manager, at (301) 594-5530.

Sincerely yours,

Paul Leber, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research