CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75465

APPROVAL LETTER

ANDA 75-755

AUG 2 2001

King and Spalding
US Agent for Alphapharm Pty. Ltd.
Attention: Christina Markus
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-4706

Dear Madam:

This is in reference to your abbreviated new drug application dated December 6, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fluoxetine Hydrochloride Tablets, 10 mg and 20 mg.

Reference is also made to the Tentative Approval letter issued on June 29, 2001 and your amendments dated December 4, 2000, January 26, 2001, and July 12, 2001.

The listed drug product referenced in your application is subject to a period of pediatric exclusivity that expires on August 2, 2001. In addition the listed drug product 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 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. You informed us that Eli Lilly and Company initiated a patent infringement action against you on your Paragraph IV Certification on the challenged claim in United States District Court for the Southern District of Indiana (Eli Lilly and Company v. Alphapharm Pty. Ltd., Civil Action No. IP00-0761 C-B/S). You have also notified us that you prevailed on one claim of the '549 patent in both the district court and in the court of appeals and made a Method of Use Statement to another claim.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Fluoxetine Hydrochloride Tablets, 10 mg and 20 mg to be bioequivalent and, therefore, therapeutically

equivalent to the listed drug (Prozac® Tablets, 10 mg and 20 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.

With respect to 180-day generic drug exclusivity, we note that Alphapharm Pty. Ltd. was the first to submit a substantially complete ANDA with a Paragraph IV Certification. Therefore, with this approval Alphapharm Pty. Ltd. is eligible for 180-days of market exclusivity. Subsequent applications for these drug products will be eligible for final approval not earlier than one hundred eighty days after:

(1) the date the Secretary receives notice from the applicant under the previous application of first commercial marketing, or

(2) the date of a decision of a court in action described in clause (ii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier [Section 505(j)(B)(iv)].

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this product, or the date of a decision of the court holding the relevant patent invalid, unenforceable or not infringed.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the Agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change 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 campaigns. 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 FD-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 our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/

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

8/2/04