



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 77-660

King and Spalding  
U.S. Agent for: Alphapharm Pty. Ltd.  
Attention: Christina Markus  
1700 Pennsylvania Avenue, N.W.  
Washington, D.C. 20006-4706

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 2, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Escitalopram Oxalate Capsules, 5 mg (base), 10 mg (base) and 20 mg (base).

Reference is also made to your amendments dated August 15 (2 amendments), September 16, September 30, and October 7, 2005; June 19, and June 30, 2006; and January 25, February 2, May 29, and July 20, 2007. We also acknowledge receipt of your correspondence dated August 12, 2005, and May 22, 2006, concerning the patent issues associated with this ANDA. Reference is also made to the ANDA Suitability Petition providing for a change in dosage form (from tablet to capsule), submitted under section 505(j)(2)(c) of the Act and approved on March 29, 2005. The reference listed drug (RLD) is only marketed as a tablet dosage form. This approved petition allows the agency to accept an ANDA for Escitalopram Oxalate Capsules.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined that your drug product, Escitalopram Oxalate Capsules, 5 mg (base), 10 mg (base) and 20 mg (base), can be expected to have the same therapeutic effect as that of the referenced listed drug product upon which the agency relied as the basis of safety and effectiveness. Your dissolution testing

should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. This is an application for a new dosage form; the agency has waived the pediatric study requirement for this application.

The referenced listed drug (RLD) upon which you have based your ANDA, Lexapro, Tablets 5 mg (base), 10 mg (base), and 20 mg (base), of Forest Laboratories, Inc. (Forest), is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 6,916,941 (the '941 patent) and RE34712 (the '712 patent) are scheduled to expire (with pediatric exclusivity added) on January 25, 2023, and March 14, 2012, respectively.

With respect to both these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Escitalopram Oxalate Capsules, 5 mg (base), 10 mg (base) and 20 mg (base), under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Alphapharm Pty. Ltd. (Alphapharm) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You have notified the agency that Alphapharm complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Alphapharm within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, the agency has determined that Alphapharm was the first ANDA applicant to submit a substantially complete ANDA for Escitalopram Oxalate Capsules, 5 mg (base), 10 mg (base) and 20 mg (base), with a paragraph IV certification to the '941 and '712 patents. Therefore, with this approval, Alphapharm is eligible for 180 days of generic drug exclusivity for Escitalopram Oxalate Capsules, 5 mg (base), 10 mg (base) and 20 mg (base). This exclusivity, which is provided for under section

505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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

Postmarketing reporting requirements for this ANDA 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

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

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Robert L. West  
7/31/2007 09:46:27 AM  
for Gary Buehler