



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ANDA 76-981

Food and Drug Administration
Rockville MD 20857

MAY 31 2006

King and Spalding
U.S. 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 (ANDA) dated December 16, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Escitalopram Oxalate Tablets, 5 mg, 10 mg and 20 mg.

Reference is also made to your amendments dated September 10, 2004; and January 31, and May 5, 2005.

We have completed the review of this ANDA and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. However, your application is not eligible at this time to receive final approval because of the patent issue discussed below. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is therefore subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your application, Lexapro Tablets, 5 mg, 10 mg and 20 mg of Forest Laboratories, Inc., is subject to a period of patent protection. As noted in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent RE34712 (the '712 patent) expires June 8, 2009, with pediatric exclusivity until December 8, 2009.

Your ANDA contains a paragraph IV patent certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '712 patent is invalid, unenforceable, or will not be infringed by your manufacture, use or sale of Escitalopram Oxalate Tablets, 5 mg, 10 mg and 20 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless action is brought against Alphapharm Pty. Ltd. (Alphapharm) for infringement of the patent that was the subject of the paragraph IV certification. This action must be brought against Alphapharm prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B) was received by the NDA/patent holder(s). You have notified the Agency that Alphapharm complied with the requirements of section 505(j)(2)(B) of the Act, and that patent infringement litigation was brought against Alphapharm in the United States District Court for the Southern District of New York involving a challenge to the '712 patent [Forest Laboratories, Inc., Forest Laboratories Ireland, Ltd. and H. Lundbeck A/S, v. Alphapharm Pty. Ltd., Civil Action No. 04-CV-3844]. Therefore, final approval of this ANDA cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii),¹ or such shorter or longer period as the court may have ordered, or,
 - b. the date a court decides² that the '712 patent is invalid or not infringed (see section 505(j)(5)(B)(iii) (I), (II), and (III), of the Act), or,
 - c. the '712 patent has expired, and
2. The Agency is assured there is no new information that would affect whether final approval should be granted.

To reactivate your application prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible

¹ Because information on the '712 patent was submitted before August 18, 2003, this reference is to a section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

² This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

for final approval. This amendment should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the Agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to Agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under 21 U.S.C. 355, and will not be listed in the "Orange Book".

For further information on the status of this application, or prior to submitting additional amendments, please contact Lisa Kim, Project Manager, at 301-827-5746.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler". The signature is fluid and cursive, with a large initial "G" and "B".

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