



ANDA 78-370

Roxane Laboratories, Inc.
Attention: Elizabeth Ernst
Director, Drug Regulatory
Affairs and Medical Affairs
1809 Wilson Road
Columbus, OH 43228

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 21, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Escitalopram Oxalate Tablets 5 mg (base), 10 mg (base), and 20 mg (base).

Reference is made to your amendments dated February 15, March 28, April 11, and May 31, 2007; May 5, September 30, October 21, October 30, December 5, and December 18, 2008; and January 21, and February 10, 2009.

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

The reference listed drug product (RLD) upon which you have based your ANDA, Lexapro, Tablets, 5 mg (base), 10 mg (base) and 20 mg (base) of Forest Laboratories, Inc., is subject to periods of patent protection.

The following patents with their expiration dates (pediatric exclusivity extensions added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
6,916,941 (the '941 patent)	February 12, 2023
7,420,069 (the '069 patent)	February 12, 2023
RE34712 (the '712 patent)	March 14, 2012

With respect to the '941 and '069 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Escitalopram Oxalate Tablets 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 Roxane Laboratories, Inc. (Roxane) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. This action must have been brought against Roxane prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Roxane complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Roxane 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 the '712 patent, your ANDA contains paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that Roxane will not market Escitalopram Oxalate Tablets, 5 mg (base), 10 mg (base), and 20 mg (base) prior to the expiration of this patent. Therefore, final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until the '712 patent, as extended by pediatric exclusivity, has expired, currently, March 14, 2012.

To reactivate your ANDA 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 for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and 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 ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA 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 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, 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 Thomas Hinchliffe, Project Manager, at (240) 276-8536.

Sincerely yours,

{See appended electronic signature page}

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

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

/s/

Robert L. West
3/30/2009 11:53:44 AM
Deputy Director, for Gary Buehler