



ANDA 078467

Sandoz Inc.
Attention: Bernadette Attinger
Director, Regulatory Affairs
506 Carnegie Center
Suite 400
Princeton, NJ 08540

Dear Madam:

This letter corrects the Tentative Approval letter dated March 3, 2011, in which we incorrectly stated the firm name in paragraph 6 of the original letter. This letter serves as the official document, retaining the tentative approval date of March 3, 2011.

This is in reference to your abbreviated new drug application (ANDA) dated August 24, 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 the tentative approval letter issued by this office on October 18, 2007, and to your amendments dated August 26, 2009, April 7, April 30, December 8, and December 17, 2010. Reference is also made to your patent amendments dated April 17, 2009, May 29, 2009, and January 11, 2011.

We have completed the review of this ANDA as amended, 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 remain unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA remains **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 manufacturing and testing of the drug product) and 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 reference listed drug (RLD) upon which you have based your ANDA, Lexapro Tablets of Forest Laboratories, Inc., is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

<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 patent 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. You have notified the agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Sandoz within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to the New Patient Population exclusivity which expires March 19, 2012, your ANDA contains a statement indicating that the exclusivity does not claim any proposed indication for which you are seeking approval under your ANDA.

With respect to the '712 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that Sandoz, Inc. 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 expiration of the pediatric exclusivity period attaching to the '941 patent, currently, March 14, 2012.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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 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 ANDA, or prior to submitting additional amendments, please contact Thomas Hinchliffe, Project Manager, at (240) 276-8433.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

03/03/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.