



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 78-032

Kali Laboratories, Inc.  
Attention: Kala Patel, R.Ph.  
Director, Regulatory Affairs  
400 Campus Drive  
Somerset, NJ 08873

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 8, 2005, 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 December 27, 2006, and to your amendments dated May 4, May 31, and June 7, 2007.

We have completed the review of this ANDA as amended, and have concluded that the drug remains 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). 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 (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 the '941 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '941 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. 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 Kali Laboratories, Inc. (Kali) for infringement of the '941 patent that was the subject of the paragraph IV certification. You have notified the agency that Kali complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for patent infringement was brought against Kali 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 '712 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that Kali 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 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 501 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book." Should you believe that there are grounds for issuing the final approval letter prior to March 14, 2012, you should amend your ANDA accordingly.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Thomas Hinchliffe, Project Manager, at 301-827-5771.

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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Robert L. West  
7/30/2007 12:37:53 PM  
for Gary Buehler