



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 78-734

Ranbaxy Inc.  
Attention: Usha Sankaran  
U.S Agent for: Ranbaxy Laboratories Limited  
600 College Road East  
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 22, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxcarbazepine Oral Suspension, 300 mg/5 mL.

Reference is also made to your amendments dated August 3, August 17, September 11, and September 17, 2007; December 1, 2008; and May 21, and June 25, 2009.

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 your Oxcarbazepine Oral Suspension, 300 mg/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Trileptal Oral Suspension, 300 mg/5 mL, of Novartis Pharmaceuticals Corp. (Novartis). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, Novartis' Trileptal Oral Suspension, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 7,037,525 (the '525 patent) is scheduled to expire on August 12, 2018 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '525 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Oxcarbazepine Oral Suspension, 300 mg/5 mL, under this ANDA. You have notified the agency that Ranbaxy Laboratories Limited (Ranbaxy) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '525 patent was brought against Ranbaxy 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 180-day generic drug exclusivity, we note that Ranbaxy was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '525 patent. Therefore, with this approval, Ranbaxy is eligible for 180-days of generic drug exclusivity for Oxcarbazepine Oral Suspension, 300 mg/5 mL. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the commercial marketing date 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.

We 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.

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "**Miscellaneous Correspondence - SPL for Approved ANDA 78-734**".

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  
6/26/2009 11:40:33 AM  
Deputy Director, for Gary Buehler