



ANDA 65-382

Ranbaxy Inc.  
U.S. Agent for: Ranbaxy Laboratories Limited  
Attention: Mr. Scott D. Tomsy  
600 College Road East  
Princeton, NJ 08540

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 30, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Clarithromycin for Oral Suspension USP, 125 mg/5 mL and 250 mg/5 mL. We note that this product is subject to the exception provisions of section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated July 17, 2006; and March 8, May 17, June 18, July 5, and July 31, 2007.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Clarithromycin for Oral Suspension USP, 125 mg/5 mL and 250 mg/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Biaxin® Granules (Clarithromycin for Oral Suspension, USP), 125 mg/5 mL and 250 mg/5 mL, of Abbott Laboratories. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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.

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(s) 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.

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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Gary Buehler  
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