DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-445

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 26, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pravastatin Sodium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg.

Reference is also made to the tentative approval letter issued by this office on September 30, 2003, and to your amendments dated July 16, and August 28, 2003; December 21, 2005; January 24, February 15, March 10, March 29, March 30, April 3, April 7, April 17, April 19, April 27, November 2, November 3, and November 30, 2006; and February 12, March 13, March 16, March 20, April 9, and April 17, 2007. We also acknowledge receipt of your correspondence dated August 14 and 20, October 10, and November 26, 2002; and September 25, 2003, pertaining to the patent issues noted below.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that 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 Pravastatin Sodium Tablets, 10 mg, 20 mg, 40 mg, and 80 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Pravachol Tablets, 10 mg, 20 mg, 40 mg, and 80 mg, respectively, of Bristol Myers Squibb (BMS). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

As discussed in our tentative approval letter, the RLD upon which you have based your ANDA, BMS's Pravachol Tablets, is subject to periods of patent protection. The following unexpired 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") for this drug product:

U.S. Patent Number	Expiration Date
5,030,447 (the '447 patent)	January 9, 2009
5,180,589 (the '589 patent)	January 9, 2009
5,622,985 (the '985 patent)	October 22, 2014

With respect to the '985 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act indicating that this is a method of use patent, and that it does not claim any of the indications for which you are seeking approval.

With respect to the '447 and '589 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of this drug product. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action was brought against Ranbaxy Laboratories Limited (Ranbaxy) for infringement of one or more of these patents that were the subjects of the certifications. You have notified the FDA that Ranbaxy complied with the requirements of section 505(j)(2)(B) of the Act and that no action for infringement of either the '447 patent or the '589 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 for Pravastatin Sodium Tablets, 80 mg, the agency has concluded that Ranbaxy was the first ANDA applicant to submit a substantially complete ANDA for Pravastatin Sodium Tablets, 80 mg, with a paragraph IV certification to the '447 and '589 patents. Therefore, with this approval, Ranbaxy is eligible for 180 days of generic drug exclusivity for Pravastatin Sodium Tablets, 80 mg. This exclusivity, which is provided for under section

505(j)(5)(B)(iv) of the Act,[1] will begin to run upon first commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to your ANDA informing the agency of the date 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.

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.

Sincerely yours,

{See appended electronic signature page}

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

[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

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
4/23/2007 03:13:04 PM
for Gary Buehler