DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-285

JUN 23 2006

Ranbaxy Inc.
Attention: Abha Pant
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 November 26, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Simvastatin Tablets USP, 5 mg, 10 mg, 20 mg, 40 mg, and 80 mg. This letter only addresses your Simvastatin Tablets USP, 80 mg.

Reference is also made to our tentative approval letter dated September 26, 2003, and to your amendments dated June 17, October 7, and December 4, 2002; June 6, 2003; and January 18, February 8, May 2, May 24, June 16, June 20, and June 22, 2006. We also acknowledge receipt of your correspondences dated March 8, and April 22, 2002; and June 17, and July 17, 2003, addressing the patent issues noted below.

We have completed the review of this ANDA and have concluded that your Simvastatin Tablets USP, 80 mg, are safe and effective for use as recommended in the submitted labeling. Accordingly, your Simvastatin Tablets USP, 80 mg are approved. This approval pertains only to Simvastatin Tablets USP, 80 mg manufactured at Ohm Laboratories, Inc., 14 Terminal Road, New Brunswick, New Jersey, and tested at Ohm Laboratories, Inc., 1385 Livingston Ave., North Brunswick, New Jersey.

The Division of Bioequivalence has determined your Simvastatin Tablets USP, 80 mg to be bioequivalent, and therefore, therapeutically equivalent to the listed drug, Zocor Tablets, 80 mg, of Merck Research Laboratories. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

As discussed in our tentative approval letter, the referenced listed drug (RLD) upon which you have based your ANDA, Zocor Tablets, 80 mg, of Merck Research Laboratories, 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") for this drug product:

U.S. Patent Number	Expiration Date
4,444,784 (the '784 patent)	June 23, 2006
RE36,481 (the '481 patent)	January 10, 2008
RE36,520 (the '520 patent)	November 26, 2009

Your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act to the '784 patent, which states that you will not market this drug product prior to the expiration of the patent. The '784 patent, with pediatric exclusivity added, expired on June 23, 2006.

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '481 and '520 patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Simvastatin Tablets USP, 80 mg 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 Ranbaxy Laboratories Limited (Ranbaxy) for infringement of one or more of these patents that were the subject of the paragraph IV certifications. You notified the agency that Ranbaxy complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of either the '481 or '520 patents was brought against Ranbaxy within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, Ranbaxy was the first ANDA applicant to submit a substantially complete ANDA for Simvastatin Tablets USP, 80 mg, with a paragraph IV certification to the '481 and '520 patents. Therefore, with this approval, Ranbaxy is eligible for 180 days of generic drug

exclusivity for Simvastatin Tablets USP, 80 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act[1], will begin to run from the earlier of the commercial marketing or court decision dates 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.

Post-marketing 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 your Simvastatin Tablets USP, 80 mg.

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

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[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MAA) (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).

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign 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,

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