DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-635

OCT 31 2005

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 31, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fenofibrate Tablets, 54 mg, 107 mg, and 160 mg.

Reference is also made to the Tentative Approval letter issued by this office on May 27, 2004, and to your amendments dated May 8, 2003; January 9, March 1, and April 7, 2004; and June 10, July 21, and August 23, 2005.

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 Fenofibrate Tablets, 54 mg, and 160 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Tricor Tablets, 54 mg, and 160 mg, respectively, of Abbott Laboratories. Your Fenobibrate Tablets 107 mg can be expected to have the same therapeutic effect as that of the reference listed drug product upon which the agency relied as the basis of safety and effectiveness. 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 listed drug product (RLD) referenced in your ANDA, Tricor Tablets of Abbott Laboratories, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Tricor Tablets:

| U.S. Patent Number | Expiration Date |
|---|---|
| 4,895,726 (the '726 patent) | January 19, 2009 |
| 6,074,670 (the '670 patent) | January 9, 2018 |
| 6,277,405 (the '405 patent) | January 9, 2018 |
| 6,589,552 (the '552 patent) | January 9, 2018 |
| 6,652,881 (the '881 patent) | January 9, 2018 |

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Fenofibrate Tablets 54 mg, 107 mg, and 160 mg, under this ANDA.

Section 505(j)(4)(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 subjects of the paragraph IV certifications. This action must have been brought against Ranbaxy prior to the expiration of 45 days from the date the notices you provided under section 505(j)(2)(B)(i) were received by the NDA/patent holder(s).[1] You have notified the agency that Ranbaxy complied with the requirements of section 505(j)(2)(B) of the Act. As a result, litigation was brought against Ranbaxy in the United States District Court for the District of New Jersey involving challenges to the '405, '552, and '881 patents (Abbott Laboratories, Fournier Industrie et Sante, and Laboratories Fournier S.A. v. Ranbaxy Pharmaceuticals, Inc. and Ranbaxy Laboratories, LTD., Civil Action Nos. 03-2170, 03-4067, and 04-249). Furthermore, you have informed us that, subsequent to the consolidation of these three actions into Civil Action No. 03-2170, the parties stipulated to dismissal of the case with prejudice, and dismissal was ordered by the court on July 12, 2005.

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[1] Because information on the '726, '670, '405, and '552 patents was submitted before August 18, 2003, this reference to section 505(j)(5)(B)(iii) of the Act is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3). However, information on patent '881 was submitted on December 12, 2003 (i.e., after submission of your ANDA and after August 18, 2003), and your certification to patent '881 was submitted in an amendment to your ANDA, so there was no 30-month stay with respect to the '881 patent. See current section 505(j)(5)(B)(iii) of the Act.

With respect to 180-day generic drug exclusivity:

54 mg and 160 mg strengths. Teva Pharmaceuticals USA (Teva) was the first to submit a substantially complete ANDA with a paragraph IV certification to the '726, '670 and '405 patents. Ranbaxy was the first to submit a substantially complete ANDA with a paragraph IV certification to the '552 patent. Ranbaxy and Impax Laboratories, Inc. (Impax) were both first to submit substantially complete ANDAs with a paragraph IV certification to the '881 patent. Therefore, with this approval, Ranbaxy is eligible for 180-days of shared exclusivity with Teva and Impax for Fenofibrate Tablets, 54 mg and 160 mg.

107 mg strength. Par Pharmaceutical, Inc. (Par) was the first to submit a substantially complete ANDA with a paragraph IV certification to the '726, '670, and '405 patents. Ranbaxy was the first to submit a substantially complete ANDA with a paragraph IV certification to the '522 and '881 patents. Therefore, with this approval, Ranbaxy is eligible for 180-days of shared exclusivity with Par for Fenofibrate Tablets, 107 mg.

This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act,[2] runs from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(iv). Please submit correspondence to the 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.

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 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

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[2] 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).

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 materials for any subsequent advertising or promotional campaign be submitted to our 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