DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-607

Food and Drug Administration
Rockville MD 20857

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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 December 27, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Quinapril Tablets USP, 5 mg, 10 mg, 20 mg, and 40 mg.

Reference is also made to the Tentative Approval letter issued by this office on March 12, 2004, and to your amendments dated March 17, April 8, September 8, October 27, December 1, December 10, and December 15, 2004. We also acknowledge receipt of your correspondence dated April 14, April 25, and June 12, 2003; and March 17, December 1, and December 15, 2004, addressing the patent and exclusivity issues noted below.

The listed drug product (RLD) referenced in your application, Accupril Tablets, 5 mg, 10 mg, 20 mg, and 40 mg of Pfizer Pharmaceuticals Ltd., is subject to periods of patent protection. The following patents for this drug product are currently listed in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book):

Patent Number	Expiration Date
4,743,450 (the '450 patent)	August 24, 2007
5,684,016 (the '016 patent)	May 4, 2015
5,747,504 (the '504 patent)	October 10, 2005

Your application contains patent statements under section 505(j)(2)(A)(viii) of the Act indicating that the '016 and '504 patents are method of use patents, and that these patents do not

claim any proposed indication for which you are seeking approval under your ANDA.

Your application also contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act to the '450 patent stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Quinapril Tablets USP, 5 mg, 10 mg, 20 mg, and 40 mg, under this ANDA. As noted in our tentative approval letter of March 12, 2004, you 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 '450 patent, 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).[1]

At the time of our tentative approval letter, we were unable to grant full approval to your ANDA because of the eligibility of TEVA Pharmaceuticals USA (TEVA) for 180-day generic drug exclusivity for this drug product under section 505(j)(5)(B)(iv) of the Act. As you are aware, effective December 15, 2004, TEVA has relinquished its eligibility for 180-day exclusivity, thereby permitting the immediate full approval of your application. Furthermore, by relinquishing it eligibility for 180-day exclusivity, TEVA recognizes that the relinquishment will also apply to all ANDAs for this drug product, and that the Office of Generic Drugs may approve any such application without regard to the 180-day exclusivity period specified in Section 505(j)(5)(B)(iv).

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Quinapril Tablets USP, 5 mg, 10 mg, 20 mg, and 40 mg, to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Accupril Tablets, 5 mg, 10 mg, 20 mg, and 40 mg, respectively, of Pfizer Pharmaceuticals Ltd. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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[1] Because information on the '450 patent was submitted to FDA before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescriptionb Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) was enacted. See MMA § 1101(c)(3).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application 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
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

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