DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-626

Lupin Pharmaceuticals, Inc.
Attention: Leslie Sands
Director, Regulatory Affairs (USA)
U.S. Agent for: Lupin Limited
Harborplace Tower
111 South Calvert Street, 21st Floor
Baltimore, MD 21202

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 18, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg.

Reference is also made to the tentative approval letter issued by this office on May 12, 2008, and to your amendments dated November 8, 2005; March 18, and July 10, 2006; and May 13, 2008. Reference is also made to your correspondence dated May 19, 2008 pertaining to the patent issues associated with this ANDA.

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 effective on the date of this letter. The Division of Bioequivalence has determined your Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Altace Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg, respectively, of King Pharmaceuticals Inc. (King). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, King's Altace Capsules, is subject to periods of patent protection. The following patents with their expiration dates 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
5,061,722 (the '722 patent)	October 29, 2008
5,403,856 (the '856 patent)	April 4, 2012
7,368,469 (the '469 patent)	August 30, 2020

With respect to the '856 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that this is a method of use patent, and that this patent does not claim any indication for which you are seeking approval under your ANDA.

With respect to the '722 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 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 Lupin Limited (Lupin) for infringement of the listed '722 patent. This action must have been brought against Lupin prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Lupin complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Lupin Limited for infringement of the '722 patent in the Eastern District of Virginia for the [Aventis Pharma Deutschland GBMH v. Lupin Ltd., Civil Action No. 05CV-421]. Lupin then appealed to the United States Court of Appeals for the Federal Circuit [Appeals Nos. 2006-1530, -1555] which reversed the earlier decision found by the Eastern District of Virginia, finding that the '722 patent is invalid, unenforceable, or not infringed.

With respect to the '469 patent, your ANDA contains a paragraph IV certification stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg, under this ANDA. You have notified the agency that Lupin complied with the requirements of section 505(j)(2)(B) of the Act. The agency recognizes that, under the Act (as amended in 2003 by the Medicare Prescription Drug, Improvement and Modernization Act) no 30-month stay of approval stay can arise

from this certification and, therefore, the '469 patent does not present a barrier to approval of this ANDA at this time.

With respect to 180-day generic drug exclusivity, we note that Lupin was the first ANDA applicant with a substantially complete ANDA for Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg, to submit a paragraph IV certification to the '469 patent. Therefore, with this approval, Lupin is eligible for 180-days of generic drug exclusivity for Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 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.

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

[1] As noted in our May 12, 2008 tentative approval letter, there was at one ANDA for Ramipril Capsules, 1.25 mg, 2.5 mg, 5 mg and 10 mg, with a paragraph IV certification filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) on December 8, 2003. Therefore, this reference to the 180-day exclusivity provision is to that 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 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

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
6/9/2008 02:46:24 PM
Deputy Director, for Gary Buehler