DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090856

Lupin Pharmaceuticals Inc.
U.S. Agent for: Lupin Limited
Attention: Leslie Sands
Director, Regulatory Affairs
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 October 23, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fenofibrate Tablets, 48 mg and 145 mg.

Reference is also made to your amendments dated April 17, and April 29, 2009; January 29, and October 7, 2010; and February 21, July 29, August 26, and October 4, 2011. We also acknowledge receipt of your correspondence dated January 29, and March 24, 2009; and October 7, 2011, addressing the patent issues associated with this ANDA.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate 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 Fenofibrate Tablets, 48 mg and 145 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Tricor Tablets, 48 mg and 145 mg, respectively, of Abbott Laboratories (Abbott). 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, Abbott's Tricor Tablets, is subject to periods of patent protection. The following unexpired patents and 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
6,277,405 (the '405 patent)	January 9, 2018
6,375,986 (the '986 patent)	September 21, 2020
6,652,881 (the '881 patent)	January 9, 2018

7,037,529 (the '529 patent)	January 9, 2018
7,041,319 (the '319 patent)	January 9, 2018
7,276,249 (the '249 patent)	February 21, 2023
7,320,802 (the '802 patent)	February 21, 2023

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these seven patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Fenofibrate Tablets, 48 mg and 145 mg, under this ANDA. You have notified the agency that Lupin Limited (Lupin) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of all seven patents was initiated against Lupin within the statutory 45-day period in the United States District Court for the District of New Jersey [Abbott Laboratories and Laboratories Fournier S.A. v. Lupin Limited and Lupin Pharmaceuticals, Inc., Civil Action No. 09-cv-01007-SDW-MCA, for the '405, '529, and '319 patents; and Abbott Laboratories and Laboratories Fournier S.A. v. Lupin Limited and Lupin Pharmaceuticals, Inc., Civil Action No. 09-cv-01008-SDW-MCA, for the '249 and '802 patents]. You have also notified the agency that each case was dismissed.

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.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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
Office of Prescription Drug Promotion
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 Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

12/23/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.