DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-509

IMPAX Laboratories, Inc.
Attention: Mark C. Shaw, Vice President
Regulatory Affairs and Compliance
30831 Huntwood Avenue
Hayward, CA 94544

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 27, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fenofibrate Tablets, 54 mg and 160 mg.

Reference is also made to the tentative approval letter issued by this office on March 5, 2004, and to your amendments dated April 14, 2003; November 21, 2007; and January 10, January 15, and January 30, 2008. In addition, we also acknowledge receipt of your correspondence dated March 10, 2004, and March 5, 2008, addressing the patent issues associated with this ANDA.

We note that the reference listed drug (RLD) upon which you have based your ANDA, Tricor Tablets, 54 mg and 160 mg, of Abbott Laboratories (Abbott) is no longer being marketed in the United States and is currently listed in the discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). Reference is made to the Federal Register notice issued on September 6, 2007 (72 FR 51232) in which the agency announced its determination that Tricor Tablets, 54 mg and 160 mg, were not withdrawn from sale for reasons of safety or effectiveness. Under 21 CFR 314.161, this determination allows the agency to continue to approve ANDAs that reference Tricor Tablets, 54 mg and 160 mg.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that your Fenofibrate Tablets, 54 mg and 160 mg, are 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, 54 mg and 160 mg, to be bioequivalent and, therefore, therapeutically equivalent to the RLD, Tricor Tablets, 54 mg and 160 mg of Abbott Laboratories. 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, 54 mg and 160 mg, is subject to periods of patent protection. The following patents and their expiration dates are currently listed for Abbott's Tricor Tablets in the Orange Book:

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
7,037,529 (the '529 patent)	January 9, 2018
7,041,319 (the '319 patent)	January 9, 2018

With respect to the '726, '670, '405, '552, and '881 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Fenofibrate Tablets, 54 mg and 160 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 IMPAX Laboratories, Inc. (IMPAX) for infringement of one or more of these patents that were the subject of the paragraph IV certifications. You have notified the agency that IMPAX complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against IMPAX for infringement of the '670, '405, and '552 patents within the statutory 45-day period in the United States District Court for the District of Delaware [Abbott Laboratories v. IMPAX

Laboratories, Inc., Civil Action No. 03-CV-00120-SLR]. You have informed the agency that on July 27, 2005, the parties agreed to dismiss all patent claims and declaratory judgment counterclaims.

With respect to the '529 and '319 patents, FDA has determined that information on these patents was submitted by the NDA holder more than 30 days after the patent was issued by the U.S. Patent and Trademark Office. Therefore, under 21 CFR 314.94(a)(12)(viii), no person with an appropriate patent certification at the time of the submission of the patent was required to submit an amended patent certification to address the '529 and '319 patents. You elected not to submit an amended patent certification with respect to these patents.

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

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
3/26/2008 09:11:09 AM
Deputy Director, for Gary Buehler