ANDA 75-868 February 20, 2002

IMPAX Laboratories, Inc.
Attention: Mark C. Shaw
30831 Huntwood Avenue
Hayward, CA 94544

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 9, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fenofibrate Capsules (Micronized), 67 mg, 134 mg and 200 mg.

Reference is also made to your amendment dated November 8, 2001, and to your communications dated July 11, August 29, November 2, and November 8, 2000; and February 23, and March 12, 2001.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). The determination is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your application, Tricor Capsules (Micronized) of Abbott Laboratories Pharmaceutical Products Division, is subject to a period of patent protection which expires on January 19, 2009, (U.S. Patent No. 4,895,726, the “726” patent). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use or sale of this drug product will not infringe the ‘726 patent. Section 505(j)(5)(B)(iii) of the Act provides that

approval of an ANDA shall be made effective immediately unless an infringement action is brought against you before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified the agency that IMPAX Laboratories, Inc. (IMPAX) complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, litigation is underway in the United States District Court for the Northern District of Illinois, Eastern Division, involving a challenge to the patent (Abbott Laboratories, Fournier Industrie Et Sante', and Laboratoires Fournier S.A., vs. IMPAX Laboratories, Inc., Civil Action Nos. 00C 5092, 00C 7865, and 01C 1648 as amended upon submission of additional strengths). Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii) since the last date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,

   b. the date of court decision [505(j)(5)(B)(iii) (I), (II), or (III)], or,

   c. the '726 patent has expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

Because the Agency is granting a tentative approval for this application, when you believe that your application may be considered for final approval, you must amend your application to notify the Agency whether circumstances have or have not arisen that may affect the effective date of final approval. Your amendment must provide:

1. A copy of an order or judgement, a settlement agreement between the parties, a licensing agreement between you and the patent holder, or any other relevant settlement information, and

2. a. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other significant change in the conditions outlined in this abbreviated application, or

b. a statement that no such changes have been made to the application since the date of tentative approval.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The amendment should be designated as a MINOR AMENDMENT in your cover letter. Before you submit the amendment, please contact Michelle Dillahunt, Project Manager, at 301-827-5848, for further instructions.

Sincerely yours,

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