ANDA 75-753 April 9, 2002

TEVA Pharmaceuticals USA
Attention: Deborah A. Jaskot
U.S. Agent for: Novopharm Limited
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 14, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Fenofibrate Capsules (Micronized), 67 mg. We also refer to your amendment dated March 31, 2000 providing for approval of the 200 mg strength, and to your amendment dated November 27, 2000 providing for approval of the 134 mg strength of this drug product.

Reference is also made to your amendments dated July 6, March 30, August 1, and August 21, 2000; August 29, and November 21, 2001; and March 22, March 27, April 1, and April 3, 2002.

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 Novopharm Limited (Novopharm) complied with the requirements of Section 505(j)(2)(B) of the Act. As a result,

Abbott Laboratories et al. filed lawsuits which were subsequently consolidated in the United States District Court for the Northern District of Illinois, Eastern Division involving a challenge to the ‘726 patent (Abbott Laboratories, Fournier Industrie Et Sante', and Laboratoires Fournier S.A., v. Novopharm Limited and TEVA Pharmaceutical Industries Ltd., Civil Action Nos. 00C 2141, 00C 5094, and 01C 1914). Your March 22, 2002 amendment informs the agency that on March 19, 2002, the U.S. District Court granted Summary Judgement of non-infringement of the ‘726 patent on behalf of Novopharm and TEVA.

We have completed the review of this abbreviated application and have concluded that your Fenofibrate Capsules (Micronized), 134 mg and 200 mg, are safe and effective for use as recommended in the submitted labeling. Accordingly, the 134 mg and 200 mg strengths of the drug product are approved. The Division of Bioequivalence has determined that your Fenofibrate Capsules (Micronized), 134 mg and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug [Tricor Capsules (Micronized) 134 mg and 200 mg, respectively, of Abbott Laboratories Pharmaceutical Products Division]. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Please note that at this time your Fenobibrate Capsules (Micronized), 67 mg, are regarded to be TENTATIVELY APPROVED; we are unable to grant final approval for this strength. This is because the agency’s Guidance for Industry issued March 2000 entitled “Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (“Guidance”) redefined the term “court” as found in Section 505(j)(5)(B)(iii)(I) and 505(B)(iv) to mean the first court that renders a decision finding a patent at issue invalid, unenforceable, or not infringed. In accord with this Guidance, when it is the district court that renders a decision, the agency may approve the ANDA as of the date of the court’s decision. This new definition of the term “court” became effective for ANDA’s accepted for filing after the publication of the guidance. Thus, the decision of the District Court in Novopharm’s (TEVA’s) favor permits the agency to approve only two of the three strengths of the product in this application at this time. The 134 mg and 200 mg strengths were accepted for filing as amendments to this application after the publication of the Guidance; these strengths are approved.

However, the 67 mg strength was accepted for filing prior to publication of the Guidance and is eligible for tentative approval at this time in accord with the agency's previous definition of the term "court". The previous definition of "court" is "the court that enters final judgement from which no appeal can be or has been taken" [21 CFR 314.107(e)(1)] [1999]. Thus, under the previous definition which applies only to ANDAs accepted for filing prior to publication of the Guidance, the March decision would not be a court decision unless it is not appealed. Under the new definition, the March decision is a court decision for purposes of ANDA approval and triggering 180-day exclusivity.

In addition, we note that Novopharm was the first ANDA applicant to submit a substantially complete ANDA containing a Paragraph IV Certification to the listed patent. Therefore, upon this approval, Novopharm is eligible for the remainder of the 180-day generic drug market exclusivity as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This 180-day exclusivity for the 134 mg and 200 mg strengths of the drug product commenced on March 19, 2002, the day of the District court ruling, and will end 180 days thereafter.

Under Section 505(A) of the Act, certain changes in the conditions described in this ANDA for the 134 mg and 200 mg strengths of the drug product require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for the 134 mg and 200 mg strengths of the drug product under 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 these two strengths.

We request that your submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns for the approved strengths of drug product. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of

Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

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 our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Validation of the regulatory methods has not been completed. It is the policy of the office not to withhold approval until the validation is complete. We acknowledge your commitment to cooperate to satisfactorily resolve any deficiencies that may be identified.

As noted above, your Fenofibrate Capsules (Micronized), 67 mg, are 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.

In order to provide for final approval of the 67 mg strength, please submit a supplemental application. This supplemental application should be submitted 60 to 90 days prior to the date you believe the 67 mg strength is eligible for final approval. The supplemental application should provide a detailed summary of the circumstances impacting upon the date of final approval. The supplemental application should also provide 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. Alternatively, a statement that no such changes have been made to the application since the date of this tentative approval should be submitted.

With respect to the 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.

The 67 mg strength of the drug product may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of the 67 mg strength of the drug product before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, the 67 mg strength of this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The supplemental application providing for final approval of the 67 mg strength should be designated as EXPEDITED REVIEW REQUESTED in your cover letter. Before you submit this or any additional supplements to this application, please contact Ruby Wu, R.Ph., Project Manager, at 301-827-5848, for further instructions.

Sincerely yours,

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

APPROVAL – 134 AND 200 MG STRENGTHS only;

TENTATIVE APPROVAL – 200 mg strength.