DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 74-686

Food and Drug Administration
Rockville MD 20857

APR 21 1999
Received

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Novopharm NC, Inc.
Attention: Dietrich Bartel
U.S. Agent for: Novopharm Limited
4700 Novopharm Boulevard
Wilson, NC 27893

Dear Sir:

This is in reference to your abbreviated new drug application dated June 5, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Glyburide Tablets USP (Micronized), 1.5 mg, 3 mg, 4.5 mg, and 6 mg.

Reference is also made to our Tentative Approval letter dated November 10, 1998, and to your amendments dated January 13, March 15, and March 24, 1999.

The listed drug product referenced in your application is subject to periods of patent protection which expire on April 5, 2005 (U.S. Patent No. 4,735,805 [the '805 patent]) and April 10, 2007 (U.S. Patent No. 4,916,163 [the '163 patent]), respectively. Your application contains certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents will not be infringed by your manufacture, use, or sale of Glyburide Tablets USP, (Micronized). Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent(s) which are the subject of the certifications before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received by the patent holders. You notified the Agency that Novopharm Limited (Novopharm) complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement regarding the '805 patent was brought against Novopharm within the statutory forty-five day period. However, you notified the Agency that Pharmacia & Upjohn Company initiated a patent infringement action against you in the United States District Court for the Northern District of Illinois Eastern Division involving the '163 patent (Pharmacia & Upjohn Company v. Novopharm Limited, Civil Action No. 97 C 3992). Subsequently on March 15, 1999, you notified the Agency that the court decided in favor of Novopharm and that the decision was not appealed by the plaintiff.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Glyburide Tablets USP, (Micronized), 1.5 mg, 3 mg, 4.5 mg, and 6 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Glynase® PresTab® Tablets, 1.5 mg, 3 mg, 4.5 mg, and 6 mg, respectively, of Pharmacia and Upjohn Co.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or 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.

Sincerely yours,

D. L. Sporn

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research