ANDA 75-890 February 8, 2002

West-ward Pharmaceutical Corp.
Attention: Elizabeth A. Marro
U.S. Agent for Al-Hikma Pharmaceuticals
435/465 Industrial Way West
Eatontown, NJ 07724

Dear Madam:

This is in reference to your abbreviated new drug application dated June 2, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Glyburide Tablets USP (Micronized), 1.5 mg, 3 mg, and 6 mg.

Reference is also made to your amendment dated November 30, 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.

The reference listed drug product (RLD) upon which you have based your application, Glynase PresTab Tablets of Pharmacia & Upjohn Co., is currently subject to periods of patent protection (U.S. Patent Nos. 4,735,805 and 4,916,163 expiring April 5, 2005 and April 10, 2007, respectively). Your application contains a Paragraph III Certification to each patent under Section 505(j)(2) (A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of both of these patents. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii)

of the Act until both patents have expired, i.e., April 10, 2007.

Because the Agency is granting a tentative approval for this application, please submit an amendment between 60 to 90 days prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

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

Please note that this 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 this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to April 10, 2007, you should amend your application accordingly.

Please note that significant changes to your application should not be included in the request for final approval. Amendments for these changes should be submitted separately and will be classified by the office based upon established practice.

Please contact Ruby Wu, R.Ph. Project Manager, at 301-827-5848, if you have questions concerning the status of this application.

Sincerely yours,

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

cc: ANDA 75-890
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205

Endorsements:
HFD-623/R.Trimmer/2/6/02
HFD-623/D.Gill/2/6/02
HFD-617/R.Wu/2/5/02
HFD-613/A.Payne/2/6/02
HFD-613/J.Grace/2/6/02

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F/T by: gp/2/6/02

TENTATIVE APPROVAL