DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-051/S-013

Pharmacia & Upjohn Company
Attention: Kathleen Collins
Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Collins:

Please refer to your supplemental new drug application dated February 11, 2008, received February 11, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Glynase PresTab (micronized glyburide) Tablets.

We acknowledge receipt of your submission dated September 17, 2008.

This supplemental new drug application provides for the following changes to the Package Insert, which were requested in a supplement request letter dated November 21, 2007.

1. The INDICATIONS AND USAGE section was changed to "GLYNASE PresTab Tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

2. The following statement was added to the PRECAUTIONS section: "There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with GLYNASE PresTab or any other anti-diabetic drug."

3. Text previously located in the INDICATIONS AND USAGE section was moved to the PRECAUTIONS section, under a new heading "Physician Counseling Information for Patients".

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, submitted September 17, 2008.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks

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