DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 20-496/S-021

sanofi-aventis U.S. LLC
Attention: Debra L. Kolb
Specialist, US Regulatory Affairs Marketed Products
Mailstop 55A-430A
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Kolb:

Please refer to your supplemental new drug application dated October 14, 2008, received October 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amaryl (glimepiride) Tablets.

We acknowledge receipt of your submissions dated February 27, and May 27, 2009.

This "Changes Being Effected" supplemental new drug application provides for the following additions to the package insert: (1) addition of disopyramide, fluoxetine, and quinolones to the list of drugs that may potentiate the hypoglycemic action of sulfonylureas, under the Drug Interactions subsection of the CLINICAL PHARMACOLOGY section; (2) addition of a statement that persons allergic to other sulfonamide derivatives may develop an allergic reaction to glimepiride, under the WARNINGS section; (3) addition of a statement that hypoglycemia may be difficult to recognize in patients with autonomic neuropathy, under the PRECAUTIONS section; and (4) addition of dyspnea, fall in blood pressure, and shock as examples of hypersensitivity reactions worsening, under the ADVERSE REACTIONS section.

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 (package insert submitted on May 27, 2009).

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the enclosed labeling (text for package insert submitted on May 27, 2009). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-496/S-021."

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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