DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17-532/S-030 **APPROVAL LETTER**

sanofi-aventis U.S. LLC
Attention: Jo Beth Crimmins
Specialist, Heritage Product Support
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Crimmins:

Please refer to your supplemental new drug application dated October 28, 2008, received October 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diabeta (glyburide) Tablets.

We acknowledge receipt of your submission dated June 23, 2009.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the package insert.

1. Under CONTRAINDICATIONS, addition of patients with type 1 diabetes mellitus.

2. Under WARNINGS, addition of the statement, "Persons allergic to other sulfonamide derivatives may develop an allergic reaction to glyburide as well."

3. Under PRECAUTIONS, addition of "patients with autonomic neuropathy" to the list of people in whom hypoglycemia may be difficult to recognize.

4. Under PRECAUTIONS, addition of ACE inhibitors, disopyramide, and fluoxetine to the list of drugs that may potentiate the hypoglycemic action of sulfonylureas.

5. Under PRECAUTIONS, addition of the statement, "Rifampin may worsen glucose control of glyburide because rifampin can significantly induce metabolic isozymes of glyburide such as CYP2C9 and 3A4."

6. Under ADVERSE REACTIONS, addition of language that cholestatic jaundice and hepatitis may progress to liver failure.

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 June 23, 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 June 23, 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 17-532/S-030."

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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