DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-532/S-027 and S-028

sanofi-aventis U.S. LLC
Attention: Jo Beth Crimmins
U.S. Regulatory Affairs Marketed Products
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Crimmins:

Please refer to your supplemental new drug applications dated April 16, 2008, received April 17, 2008 (S-027) and dated May 28, 2008, received May 29, 2008 (S-028), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diabeta (glyburide) Tablets.

We acknowledge receipt of your submissions dated October 29, 2008, and February 17, 2009, to S-027, and dated February 17, 2009, to S-028.

These supplemental new drug applications provide for the following changes to the Package Insert:

S-027: (1) The INDICATIONS AND USAGE section was changed to "Diabeta is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabtes 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 Diabeta or any other anti-diabetic drug." These changes were requested in a supplement request letter dated November 21, 2007.

S-028: (1) Revision to the CONTRAINDICATIONS section to include hypersensitivity to any of the drug's excipients and patients treated with bosentan. (2) Hemolytic anemia was added to the PRECAUTIONS section. (3) Clarithromycin was added to the list of drugs with which the hypoglycemic action of sulfonylureas may be potentiated, in the Drug Interactions subsection of the PRECAUTIONS section. (4) Information regarding bosentan and cyclosporine were added to the Drug Interactions subsection of the PRECAUTIONS section.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, submitted on February 17, 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 February 17, 2009, with the additional language **(b) (4)** , submitted on October 28, 2008). 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-027 and S-028."

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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