



NDA 20-496/S-018 and S-019

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

Dear Ms. Kolb:

Please refer to your supplemental new drug applications dated April 16, 2008, received April 17, 2008 (S-018) and May 15, 2008, received May 16, 2008 (S-019), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amaryl (glimepiride) Tablets.

We acknowledge receipt of your submissions dated November 10, 2008, and January 15, 2009, to S-018, and dated June 18, and December 4, 2008, to S-019.

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

S-018: (1) The INDICATIONS AND USAGE section was changed to "AMARYL is 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 AMARYL or any other anti-diabetic drug." These changes were requested in a supplement request letter dated November 21, 2007.

S-019: (1) Clarithromycin was added under the Drug Interactions subsection of the CLINICAL PHARMACOLOGY section. (2) Hemolytic anemia was added to the PRECAUTIONS section.

We 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 December 4, 2008, to S-019 and on January 15, 2009, to S-018.

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(1)] 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 December 4, 2008, and January 15, 2009, with the additional language proposed for S-021, submitted on October 15, 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 20-946/S-018 and S-019."

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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