



NDA 20-496/S-007

Aventis Pharmaceuticals
Attention: Kimberly A. Davis
Senior Regulatory Analyst
300 Somerset Corporate Boulevard
PO Box 6977
Bridgewater, NJ 08807-0977

Dear Ms. Davis:

Please refer to your supplemental new drug application dated March 3, 2000, received March 6, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amaryl[®] (glimepiride) Tablets, 1, 2, and 4 mg.

This supplemental new drug application provides for revisions to the **Gastrointestinal Reactions** and **Dermatologic Reactions** subsections of the **ADVERSE REACTIONS** section of the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted March 22, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call James Cross, Regulatory Project Manager, at 301-827-6381.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

David Orloff

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