DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-496/S-016

Aventis Pharmaceuticals Inc.
Attention: Steve Caffé, M.D.
Head, Regulatory Development
200 Crossing Boulevard, P.O. Box 6890
Bridgewater, NJ 08807-0890

Dear Dr. Caffé:

Please refer to your May 5, 2005, supplemental new drug application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amaryl (glimepiride) Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the text of the **ADVERSE REACTIONS** section of the package insert to reflect post-marketing reports of some dermatologic, hematologic and metabolic reactions observed in patients being treated with Amaryl.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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
FDA
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Lina AlJuburi, Regulatory Project Manager, at 301-827-6414.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Final printed labeling submitted May 5, 2005, for Amaryl (glimepiride) Tablets

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/s/

David Orloff

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