DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-496/S-015

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 supplemental new drug application (sNDA) submitted on March 14, 2005, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amaryl (glimepiride) Tablets.

We acknowledge receipt of your submission dated October 31, 2005.

Your submission of October 31, 2005, constituted a complete response to our September 15, 2005, action letter.

This supplemental new application provides for changes to the following sections of the Amaryl (glimepiride) Tablets package insert: **CLINICAL PHARMACOLOGY-Special Populations-Pediatric; PRECAUTIONS-Pediatric Use; Adverse Reactions-Pediatric patients** and was submitted in response to the amended Written Request issued on April 14, 2004.

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted October 31, 2005, with a modification in the **PRECAUTIONS, Pediatric Use** section.) Marketing this product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-496/S-015**." Approval of this submission by FDA is not required before the labeling is used.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 301-796-1168.

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: Approved Package Insert (draft)

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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