DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-722/S-029 and NDA 12-546/S-032

Aventis Pharmaceuticals, Inc.
Attention: Kerry Rothschild, J.D.
Director, Regulatory Affairs
200 Crossing Boulevard
Bridgewater, NJ 08807-0890

Dear Dr. Rothschild:

Please refer to your supplemental new drug applications dated March 5, 2004, received March 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TENUATE® (diethylpropion hydrochloride USP) TENUATE DOSPAN® (diethylpropion hydrochloride USP).

These supplemental new drug applications provide for changes in the product labeling to provide geriatric use information consistent with the requirements of 21 CFR 20157(f)(10).

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

According to the "Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997-Elimination of Certain Labeling Requirements", the inclusion of "Rx Only" statement is not required for package insert labeling. However, if a manufacturer chooses to include the statement, the Agency prefers that it be placed in the TITLE section of the package insert.

In your next printing, please revise your package insert to include "Rx Only" such that it is placed in the TITLE section of the labeling, to conform to "Guidance for Industry. Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997-Elimination of Certain Labeling Requirements"

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert) and/or submitted labeling (package insert submitted March 5, 2004. These revisions are terms of the approval of these applications.

As of June 8, 2004 all submissions containing labeling must be submitted electronically. Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. All electronic submission should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research

Central Document Room
5901 B Ammendale Road
Beltsville, MD 20705-1266

For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 11-722/S-029, NDA 12-546/S-032." Approval of these submissions 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, HFD-410
FDA
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 Oluchi Elekwachi, PharmD, MPH , Regulatory Project Manager, at (301) 827-6381.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Labeling

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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