DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-922/S-034
NDA 18-938/S-023
NDA 19-955/S-010

Aventis Pharmaceuticals Inc.
Attention: Sanjukta Bhaduri
Senior Manager, Regulatory Affairs
300 Somerset Corporate Blvd., Mail stop SC3-605A
Bridgewater, NJ 088007-0977

Dear Ms. Bhaduri:

Please refer to your supplemental new drug applications dated May 11, 2005, received May 12, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DDAVP® Intranasal (desmopressin acetate), DDAVP® Injection (desmopressin acetate) and DDAVP® Tablets (desmopressin acetate).

These supplemental new drug applications provide for revisions to the text of the **CLINICAL PHARMACOLOGY: Human Pharmacokinetics**, **CONTRAINDICATIONS**, **WARNINGS**, **PRECAUTIONS: Geriatric Use**, **DOSAGE AND ADMINISTRATION**, and **HOW SUPPLIED** (Rhinal Tube only) sections of the package insert.

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.

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 these submissions "**FPL for approved supplement NDA 17-922/S-034, NDA 18-938/S-023 and NDA 19-955/S-010**." 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 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 inserts for DDAVP® Intranasal (desmopressin acetate), DDAVP® Injection (desmopressin acetate) and DDAVP® Tablets (desmopressin acetate) as submitted by the sponsor on May 11, 2005.

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
11/10/2005 11:57:20 AM
for Dr. Orloff