



NDA 18-938/S-017

Aventis Pharmaceutical Products
Attention: Susan Witham
Director, Drug Regulatory Affairs
Route 202-206
Box 6800
Bridgewater, NJ 08807-0800

Dear Ms. Witham:

Please refer to your supplemental new drug application dated February 11, 2002, received February 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DDAVP® (desmopressin acetate) Injection, 4 µg/mL.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the carton label for the 10 X one mL ampules of 4 µg/mL DDVAP Injection.

1. Instruction regarding how to use the one point cut DDAVP ampules
2. Change in the company name from Rhone-Poulenc Rohrer to Aventis Pharmaceuticals Products Inc.
3. Minor graphic changes
4. Replacement of the caution statement: "**Caution:** Federal (U.S.A.) law prohibits dispensing without a prescription" with "R_x only"
5. Change in the address of Ferring AB, the manufacturer of the drug product
6. Addition of the following to the carton label:
 - a. **Dosage and Administration:** See package insert for dosage and administration.
 - b. **Warning:** Keep out of reach of children.
 - c. Store refrigerated 2 to 8°C (36 to 46°F).

We have completed the review of this supplemental application 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 final printed labeling submitted February 11, 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 Steve McCort, Regulatory Project Manager, at (301) 827-6415.

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/

Mary Parks
8/8/02 04:28:29 PM
for Dr. Orloff