



NDA 17-922/S-031
18-938/S-019
19-955/S-005

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

Dear Mr. Rothschild

Please refer to your supplemental new drug applications submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act:

- 1) NDA 17-922/S-031
submitted May 21, 2003, DDAVP® Nasal Spray (desmopressin acetate) and DDAVP Rhinal Tube (desmopressin acetate),
- 2) NDA 18-938/S-019
submitted May 20, 2003, DDAVP® Injection (desmopressin acetate) 4 µg/mL,
- 3) NDA 19-955/S-005
submitted May 20, 2003, DDAVP® Tablets (desmopressin acetate).

These supplemental new drug applications, submitted as “Special Supplement – Changes Being Effected”, provide for the following revisions to the package insert:

- 1) **WARNINGS** section to include signs and symptoms of water intoxication and hyponatremia;
- 2) **PRECAUTIONS** section for reports of anaphylaxis associated with the intravenous and intranasal formulations.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling submitted on May 20, 2003 (**NDA 18-938/S-019 and NDA 19-955/S-005**) and May 21, 2003 (**NDA 17-922/S-031**). However, to comply with the “Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 – Elimination of Certain Labeling Requirements,” at the next printing of the package insert, please move “Rx Only” to the title section.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>. To expedite review of this patent declaration form, we request you submit an additional copy of the form to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

If you have any questions, please call Lina AlJuburi, Regulatory Project Manager, at (301) 827-6414.

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
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/s/

David Orloff
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