



NDA 17-922/S-038  
NDA 18-938/S-027  
NDA 19-955/S-013

sanofi-aventis U.S. LLC  
Attention: Jo Beth Crimmins  
Specialist, Heritage Product Support U.S. Regulatory Affairs Marketed Products  
55 Corporate Drive, Mail code 55A-430A  
Bridgewater, NJ 08807

Dear Ms. Crimmins:

Please refer to your supplemental new drug applications dated October 4 and 5, 2006, received October 5 and 6, 2006, 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).

We acknowledge receipt of your submissions dated October 6, 2006, and September 13, 14 and 17, 2007.

These supplemental new drug applications provide for proposed revisions to the Contraindications, Warnings, and Dosage and Administration sections of the Tablet and Injection labels, and to the Indications and Usage, Contraindications, Warnings, Precautions, Dosage and Administration and How Supplied sections of the Intranasal label, including the Patient Instruction Guide.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling (text for package insert submitted on September 13, 2007 for NDA 19-955/S-013, text for package insert submitted on September 14, 2007 for NDA 18-938/S-027 and text for package insert and patient instruction guide submitted on September 14, 2007 for NDA 17-922/S-038).

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, “**SPL for approved supplement NDA 17-922/S-038, NDA 18-938/S-027 and NDA 19-955/S-013.**”

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:

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MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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 Jennifer Johnson, Regulatory Project Manager, at (301) 796-2194.

Sincerely,

*{See appended electronic signature page}*

Mary H. Parks, M.D.  
Director  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: Package Inserts and Patient Instruction Guide for DDAVP Intranasal, Package Inserts for DDAVP Injection and DDAVP Tablets

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/s/

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Mary Parks  
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