DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-703

JAN 27 2005

Apotex Corp.
Attention: Marcy Macdonald
U.S. Agent for: Apotex Inc.
616 Heathrow Drive
Lincolnshire, IL 60069

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 26, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act(Act) for Desmopressin Acetate Nasal Solution, 0.01% (Nasal Spray), 10 mcg/0.1 mL packaged in 5 mL bottles with a nasal pump dispenser.

Reference is also made to our Tentative Approval letter issued on November 30, 2004, and your amendments dated December 29, 2004, and January 24, 2005.

The listed drug product (RLD) referenced in your application, DDAVP Nasal Spray of Aventis Pharmaceutical Products Inc. (Aventis), is subject to periods of patent protection. The following U.S. patents for DDAVP Nasal Spray and their expiration dates are currently listed in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent	Expiration Date
5,482,931 (the '931 patent)	June 29, 2013
5,550,413 (the '413 patent)	June 29, 2013
5,674,850 (the '850 patent)	December 23, 2013
5,763,407 (the '407 patent)	June 29, 2013

As noted in your November 30, 2004, tentative approval letter, no legal action was brought against Apotex Inc. (Apotex) for infringement of the '413, '850, or '407 patents within the statutory 45 day period. However, litgation was brought Apotex in the United States District Court for the District of New

Jersey involving your challenge to the '931 patent (Ferring BV and Aventis Pharmaceuticals, Inc. v. Apotex Inc., Civil Action No. 03-3860 (MLC)(JJH). (b)(4)

(b)(4)

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Desmopressin Acetate Nasal Solution, 0.01%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (DDAVP Nasal Spray, 0.01%, of Aventis Pharmaceutical Products Inc.). This drug product is approved for storage at controlled room temperature.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend that you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and
Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20957

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6)

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research