DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-470

Food and Drug Administration
Rockville MD 20857

JUL 1 2005

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
Senior Director, Regulatory Affairs
2 Quaker Road
P.O. Box 2900
Pomona, NY 10970

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated July 31, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Desmopressin Acetate Tablets, 0.1 mg and 0.2 mg.

Reference is also made to your amendments dated January 24, May 2, and July 10, 2003; May 25 and July 23, 2004; and January 21, March 11, March 14, March 21, March 23, May 9, and May 27, 2005. In addition, we acknowledge receipt of your amendments dated December 10, and December 20, 2002; and February 11, 2005 addressing the patent issues noted below.

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 Tablets, 0.1 mg and 0.2 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (DDAVP® Tablets, 0.1 mg and 0.2 mg, respectively, of Aventis Pharmaceutical Products, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The listed drug product (RLD) referenced in your application, DDAVP® Tablets, 0.1 mg and 0.2 mg of Aventis Pharmaceutical Products Inc. (Aventis), is subject to periods of patent protection. The following patents and expiration dates for DDAVP® Tablets are currently listed in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

| U.S. Patent Number | Expiration Date |
|---|---|
| 5,047,398 (the '398 patent) | September 10, 2008 |
| 5,500,413 | June 29, 2013 |
| 5,674,850 | December 23, 2013 |
| 5,763,407 | June 29, 2013 |

Your ANDA contains paragraph IV patent certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Desmopressin Acetate Tablets, 0.1 mg and 0.2 mg under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action was brought against Barr Laboratories, Inc. (Barr) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. This action must have been brought against Barr prior to the expiration of 45 days from the date the notices you provided under section 505(j)(2)(B)(i) were received by the NDA/patent holder(s). You have notified the agency that Barr complied with the requirements of section 505(j)(2)(B) of the Act. As a result, Aventis initiated a patent infringement action against you in United States District Court for [redacted] involving a challenge to the '398 patent [redacted]. No action was intitated within the statutory 45-day period by either the NDA or patent holder with respect to the other patents. You have notified us that the district court granted summary judgment in your favor with respect to the '398 patent on the bases of inequitable conduct and non-infringement. Following this decision, [redacted] announced its intent to appeal.

With regard to 180-day generic drug exclusivity and Desmopressin Acetate Tablets, 0.1 mg and 0.2 mg, Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the patents listed above. Therefore, with this approval, Barr is eligible for 180 days of market exclusivity. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, runs from the earlier

of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).[1] Please submit correspondence to this application informing the agency of the date the exclusivity begins to run.

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 you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and
Communications (HFD-42)
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

FDA's field staff has not completed the validation of the regulatory methods submitted in your application. It is the policy of the Office of Generic Drugs to proceed with approval

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[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1). "Decision of a court" as used in clause (iv) of section 505(j)(5)(B) of the Act means a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken. See MMA § 1102(b)(3).

of your application while this process continues. We acknowledge receipt of your commitment to cooperate with the agency to resolve any methods validation related deficiencies which may be identified.

Sincerely yours,

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