ANDA 74-830 JAN 25, 1999

Bausch & Lomb Pharmaceuticals, Inc.
Attention: Donald H. Chmielewski
8500 Hidden River Parkway
Tampa, Fl 33637

Dear Sir:

This is in reference to your abbreviated new drug application dated December 31, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Desmopressin Acetate Nasal Solution, 0.01%.

Reference is also made to your amendments dated November 4, 1997; January 26, February 4, April 21, June 17, June 23, July 16, August 28, September 22, October 6, December 1, December 2, December 3, December 15, December 22, and December 30, 1998; and January 4, 1999.

The listed drug product referenced in your application is subject to periods of patent protection which expire on June 29, 2013 (patents 5,482,931 [the '931 patent], 5,498,598 [the '598 patent], and 5,500,413 [the '413 patent]) and on December 23, 2013 (patents 5,674,850 [the '850 patent], and 5,763,407 [the '407 patent]), respectively. Your application contains patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on the '407 patent or the '850 patent, or that these two patents are invalid or unenforceable. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patents which are the subject of the certifications before expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received. You have notified the Agency that Bausch and Lomb Pharmaceuticals, Inc. has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Bausch and Lomb Pharmaceuticals, Inc. within the statutory forty-five day period. In accord with 21 CFR 314.94(a)(12)(vi), Bausch and Lomb Pharmaceuticals, Inc. is not required to submit a patent certification for the '413, '598, and '931 patents.

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, 0.1 mg/mL (0.01%), of Rhone-Poulenc Rorer Pharmaceuticals, Inc.).

Under 21 CFR 314.70, 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

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 FD-2253 at the time of their initial use.

Sincerely yours,

Roger L. Williams, M.D.
Deputy Center Director for
Pharmaceutical Science
Center for Drug Evaluation and Research