ANDA 74-805 February 20, 2002

Bausch & Lomb Pharmaceuticals
Attention: Joseph B. Hawkins
8500 Hidden River Parkway
Tampa, FL 33637

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 13, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Flunisolide Nasal Solution USP, 0.025% (25 mcg flunisolide/ spray), packaged in a 200 metered spray container.

Reference is also made to your amendments dated April 9, 1996; January 25, January 28, March 6, April 4, August 3, August 22, 2000; March 9, June 4, September 27, October 23, November 30, 2001; and January 3, 2002.

The listed drug referenced in your application, Nasalide Nasal Solution of Dura Trading Company, Ltd., is subject to a period of patent protection which will expire on June 12, 2007 [U.S. Patent No. 4,933,168 (the '168 patent)]. Your application contains a patent certification to the '168 patent 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 the patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Bausch & Lomb Pharmaceuticals, Inc. (Bausch & Lomb) 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 & Lomb within the statutory forty-five day period.

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 Flunisolide Nasal Solution USP, 0.025%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug Nasalide Nasal Solution, 0.025%, of Dura Trading Company, Ltd.).

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.

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,

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