CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-702

APPROVAL LETTER

ANDA 75-702

JUL 3 2001

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

Dear Sir:

This is in reference to your abbreviated new drug application dated September 13, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Cromolyn Sodium Nasal Solution USP, 5.2 mg cromolyn sodium delivered/spray, (40 mg/mL), packaged in 26 mL (200 metered spray) bottles.

Reference is also made to your amendments dated October 14, and October 25, 1999; April 28, 2000; and March 29, May 1, June 8, and June 12, 2001.

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 Over-The-Counter (OTC) labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Cromolyn Sodium Nasal Solution USP, 5.2 mg/spray, to be bioequivalent to the listed drug (NasalCrom® Nasal Spray, 5.2 mg cromolyn sodium/spray, of Pharmacia and Upjohn Consumer Healthcare).

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.

Sincerely yours,

Gary Buehler 7/3/01
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research