CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-702

ADMINISTRATIVE DOCUMENTS

APPROVAL SUMMARY PACKAGE

ANDA NUMBER: 75-702

FIRM: Bausch & Lomb Pharmaceuticals
Attention: Joseph B. Hawkins
8500 Hidden River Parkway
Tampa, FL 33637
Tel# (813) 975-7700 ext 7102
FAX# (813) 975-7757

DOSAGE FORM: Nasal Spray

STREGHTH: 40 mg/mL; 5.2 mg/actuation; 26 mL bottle

DRUG: Cromolyn Sodium

CGMP STATEMENT/EIR UPDATED STATUS: The EER is acceptable for all firms listed as per the EER Summary report dated 12/1/99 as per S. Ferguson of HFD-322.

Manufacturing, processing, packaging, labeling and testing of the referenced drug product will be performed at:

Bausch & Lomb Pharmaceuticals
Hidden River Manufacturing Facility
8500 Hidden River Parkway
Tampa, FL 33637

Manufacturer of the bulk Drug Substance (BDS) DMF #8164:

The following contract laboratories are utilized:

Performs Chemical and Microbiological compendial testing.

Performs Chemical compendial testng.

Performs Chemical and Microbiological compendial testng.

Bausch & Lomb does not use any contract laboratories in the manufacturing, processing, or labeling of the referenced drug product.

BIOEQUIVALENCY STATUS: A Bioequivalence Review was completed on 5/31/00, and the Division of Bioequivalence had no further questions at this time. Bio was found acceptable for the 26 mL container. The 13 mL container has been withdrawn although it was also acceptable in a 7/00 review.

METHODS VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S): Method validation by the District Laboratory is not required for the approval of the application. The drug substance and drug product are USP.

STABILITY - ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION? The Drug Product (Cromolyn Sodium Nasal Spray 40 mg/mL; 5.2 mg/actuation; 26 mL bottle) will be packaged in 26 mL fill, white, HDPE. The c/c components are acceptable for use.

The Division of Bioequivalence has determined Bausch & Lomb's delivery device to be comparable to the innovator's pump. The pumps are deemed equivalent (same manufacturer, operating principle and materials of construction. The actuators and inserts are the same. Refer to the 3/16/00 Bioequivalence review.

LABELING: SATISFACTORY. Labeling was found satisfactory as per the labeling approval summary of Angela Payne.

STERILIZATION VALIDATION (IF APPLICABLE): N/A.

SIZE OF BIO BATCH - (FIRM'S SOURCE OF NDS O.K.?): B&L manufactured a exhibit batch (Lot #12588) on 12/17/98 and filled into 26 mL package sizes utilizing various HDPE bottle/resin manufacturers. B&L has proposed production batch sizes. The for the DS is adequate.

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH WERE THEY MANUFACTURED VIA SAME PROCESS The exhibit batch manufactured to support this application was made from the same process as the proposed production batches. exhibit batch was utilized for the stability studies. er proposed production batch sizes will be utilized.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?: The proposed production batches will be manufactured utilizing the same manufacturing process as the exhibit batch.

REVIEW OF PROFESSIONAL LABELING #2
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-702 **Date of Submission: June 19 and 26, 2000**
Applicant's Name: Bausch & Lomb
Established Name: Cromolyn Sodium Nasal Solution USP, 40 mg/mL

Labeling Deficiencies:

1. GENERAL COMMENTS

   Identify your product as a "Nasal spray" some where on the main panels.

2. CONTAINER (13 mL and 26 mL [200 metered sprays]) – Add "Nasal Spray".

3. CARTON (1x13 mL and 1 x 26 mL [200 metered sprays])

   See GENERAL COMMENTS.

4. PATIENT LEAFLET

   See GENERAL COMMENTS.

Please revise your labels and labeling, as instructed above, and submit 12 copies of final print labeling.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes- http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Wm. Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-702 **Date of Submission: September 13, 1999**
Applicant's Name: Bausch & Lomb
Established Name: Cromolyn Sodium Nasal Solution USP, 40 mg/mL

Labeling Deficiencies:

1. GENERAL COMMENTS

   a. 21 CFR 314.94(8)(iii) requires that the applicant's labels/labeling be the same as the labels/labeling for the reference listed drug. Revise your labels/labeling to be in accord with the enclosed copy of the reference listed drug's labels/labeling.

   b. In addition, please note that the "DRUG FACTS" labeling format has not yet been approved. Until the reference listed drug receives approval for this formatting change, you must provide labels/labeling that is the same as the approved labeling for the reference listed drug.

2. CONTAINER (26 mL [200 metered sprays])

   a. We note that you state you have chosen to not to use the extended content label at this time, however, the reference listed drug's container label contains DIRECTIONS FOR USE and WARNINGS which are important for the safe use of this medication. Revise to be in accord with the container labels for the reference listed drug. See GENERAL COMMENTS.

2. CARTON (1 x 26 mL [200 metered sprays])

   a. See GENERAL COMMENTS.

3. PATIENT LEAFLET

   a. See GENERAL COMMENTS.

   b. We note that you have omitted some material from the patient leaflet, citing the information is a marketing educational piece. However, the entire leaflet is part of the approved labeling for the reference listed drug and therefore, your leaflet must be the same as the reference listed drug's leaflet.

Please revise your labels and labeling, as instructed above, and submit 4 copies of draft labeling or 12 copies of final print labeling if you wish.

You may request a copy of the most recent labels and labeling from Freedom of Information at FDA/Freedom of Information Staff (HFI-35), 5600 Fishers Lane, Rockville, MD 20857.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes- http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research