NDA 20-463/S-002

Pharmacia Consumer Healthcare
Attention: Raymond E. Dann, Ph.D.
Director, Regulatory Affairs
100 Route 206 North
Peapack, NJ 07977

27 MAR 2001

Dear Dr. Dann:

Please refer to your new drug application (NDA) dated August 19, 1999, received August 31, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NasalCrom Nasal Solution (cromolyn sodium nasal solution) nasal spray.

We acknowledge receipt of your submissions dated October 27, 1999; January 31, February 9, April 4, April 6, April 26 and 27, June 26 and 27, November 22, and December 14, 2000; and February 28, and March 2, 2001. Your submission of March 2, 2001 constituted a complete response to our June 30, 2000 action letter.

This new drug application provides for the use of NasalCrom Nasal Solution (cromolyn sodium nasal solution) nasal spray for use in children down to 2 years of age.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container, carton labels and patient package insert submitted February 28, 2001) and must be formatted in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and "Drug Facts" format may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-463." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have fulfilled the pediatric study requirement at this time.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Babette Merritt, Project Manager, at (301) 827-2222.

Sincerely,

Charles Ganley, M.D.
Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
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