DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-911/S-008

3M Pharmaceuticals
3M Center
270-3A-08
St. Paul, MN 55144-1000

Attention: Amy E. Fowler
Senior Regulatory Associate

Dear Ms. Fowler:

Please refer to your supplemental new drug application dated January 31, 2003, received February 3, 2003, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for QVAR (beclomethasone dipropionate HFA) Inhalation Aerosol.

This "Changes Being Effected" supplemental new drug application provides for revisions to the carton and container label for QVAR to indicate IVAX Corporation as the new distributor of this drug product.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) of the container and canister must be identical to, immediate container and carton labels submitted January 31, 2003.

Provide the following changes to the proposed labeling before marketing drug product with the proposed labeling.

1. This pertains to the carton labeling. Either include the "100" into the same line as "Metered Inhalations" at the top of the carton, without the b)(4)---------- or delete this from the carton labeling. We note that this information is duplicated at the bottom of the labeling.

2. This pertains to the immediate container labeling. Improve the prominence of the established name so it is commensurate with the prominence of the proprietary name, in accordance with 21 CFR 201.10(g)(2).

If you have any questions about the above comments, please contact us to discuss this further.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-911/S-008." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ms. Ladan Jafari, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury
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