DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-911/S-015

3M Drug Delivery Systems
3M Center, Building 270-3A-08
St. Paul, MN 55144-1000

Attention: Dina M. Clementson
Advanced Regulatory Associate

Dear Ms. Clementson:

Please refer to your supplemental new drug application dated July 19, 2006, received July 20, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for QVAR (beclomethasone dipropionate HFA) Inhalation Aerosol.

We acknowledge receipt of your submissions dated September 25, October 10, and 25, and November 9, 2006.

Your submission of October 25, 2006, constituted a complete response to our October 16, 2006, action letter.

This supplemental new drug application proposes changes to the labeling for QVAR to include information from the in-vitro drug delivery studies.

We completed our review of this application, as amended. 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) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert) submitted on November 9, 2006.

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 20-911/S-015**." Approval of this submission by FDA is not required before the labeling is used.

Within 30 days of the date of this letter, submit the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the labeling text submitted on November 9, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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) 796-1231.

Sincerely,

{See appended electronic signature page}

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

Enclosure: PKG Insert

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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