DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-503/S-022

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

Attention: Dina Clementson
Advanced Regulatory Associate

Dear Ms. Clementson:

Please refer to your supplemental new drug application dated May 13, 2002, received May 20, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Proventil HFA (albuterol sulfate) Inhalation Aerosol.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Carcinogensis, Mutagenesis, and Impairment of Fertility, Pregnancy subsections of the PRECAUTIONS section and to the OVERDOSAGE section of the package insert to revise the preclinical to clinical dose ratios for consistency with similar marketed products.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 13, 2002.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Akilah Green , Regulatory Project Manager, at (301) 827-5585.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division 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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