DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-014/S-022

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

Attention: Melissa J. Forth
Senior Regulatory Associate

Dear Ms. Forth:

Please refer to your supplemental new drug application dated December 2, 2005, received December 5, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Maxair™ Autohaler™(pirbuterol acetate inhalation aerosol), 200mcg.

This supplemental new drug application provides for revised container labels.

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 December 2, 2005.

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 Miranda Raggio, RN, BSN, MA, Regulatory Project Manager, at (301) - 796-2109.

Sincerely,

{See appended electronic signature page}

Badrul Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
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/

Lydia McClain
7/27/2006 12:16:33 PM
Acting Division Director