



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-660/S-017

Aventis Pharmaceuticals
200 Crossing Boulevard
Bridgewater, NJ 08807-0890

Attention: Kerry Rothschild, J.D.
Directory, Regulatory Analyst

Dear Dr. Rothschild:

Please refer to your supplemental new drug application dated August 8, 2003, received August 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tilade (nedocromil sodium) Inhaler.

This supplemental new drug application provides for the addition of a Geriatric Use subsection to the PRECAUTIONS section of the package insert. 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 submitted labeling (package insert submitted August 8, 2003).

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 19-660/S-017." 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).

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If you have any questions, call Colette Jackson, Regulatory Project Manager, at (301) 827-9984.

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

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Badrul Chowdhury
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