DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-117/S-042

Abbott Laboratories
Dept. RA76/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Attention: Steven F. Hoff, PhD
Associate Director, Global Pharmaceutical Regulatory Affairs

Dear Dr. Hoff:

Please refer to your supplemental new drug application dated July 25, 2007, received July 26, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azmacort® (triamcinolone acetonide) Inhalation Aerosol.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of decreased bone mineral density, osteoporosis, and fracture to the ADVERSE REACTIONS section of the product label.

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 content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on July 25, 2007.

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 Colette Jackson, Regulatory Health Project Manager, at (301) 796-1230.

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: Approved Labeling

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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