CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-658

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-658

NDA APPROVAL

Nycomed US Inc.
220 Park Avenue
Florham Park, New Jersey 07932

Attention: Cheryl Czachorowski
Director, Regulatory Affairs

Dear Ms. Czachorowski:

Please refer to your new drug application (NDA) dated December 22, 2003, received December 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alvesco® (ciclesonide) Inhalation Aerosol 80 mcg and 160 mcg.

We acknowledge receipt of your submissions dated February 5(2), 11, 16, and 26, March 2, 4, 10, and 22, April 2, 26(2), and 29, May 27, July 7, 8, and 26, August 2(2), 4(2), 9, and 16, September 16, 22, 27, and 30, October 6, 15(2), and 25, and December 2, and 13, 2004, January 19, February 1, June 20, and July 28, 2005, February 2, and 7, 2006, and March 15, July 10, October 31, November 30, and December 3, 14, 19(2), 21, and 28, 2007, and January 3, 4, and 7, 2008.

The July 10, 2007, submission constituted a complete response to our October 21, 2004, action letter.

This new drug application provides for the use of Alvesco® (ciclesonide) Inhalation Aerosol for the treatment of asthma in patients 12 years of age and older.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling, copy enclosed (text for the package insert and the patient package insert submitted January 7, 2008). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-658."

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on January 4, 2008, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission **"Final Printed Carton and Container Labels for approved NDA 21-658."** Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for ages zero to less than 6 months of age and deferring pediatric studies for ages 6 months to 4 years of age until December 31, 2010.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
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 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
1/10/2008 02:07:19 PM