CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

22-124s000

Trade Name: **Omnaris Nasal Spray**

Generic Name: ciclesonide

Sponsor: Nycomed US Inc.

Approval Date: 11/21/07

Indications: Treatment of seasonal allergic rhinitis in patients 6 through less than 12 years of age.

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-124 **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 21, 2005, received December 22, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omnaris (ciclesonide) Nasal Spray.

We acknowledge receipt of your submissions dated March 2, 17, 21, 24, and 30, April 7, 14, and 21, May 4, June 2, 6, and 21, July 21 and 25, August 2, 4, 10, 11, 14, 17, 18, 21, 22, and 29, September 13, 15, 18, 22, 26, and 29, October 6, 10, 13, 19 (3) and 27, November 3, and December 1 (2), 2006 , and May 24, June 14, July 24, October 17, 22, 23, and 26, and November 5, 9, and 20, 2007.

The May 24, 2007, submission constituted a complete response to our October 20, 2006, action letter.

This new drug application provides for the use of OMNARIS (ciclesonide) Nasal Spray for the treatment of seasonal allergic rhinitis in patients 6 through less than 12 years of age.

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 enclosed labeling (text for the package insert and the patient package insert). 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 22-124."

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 2 years of age. We note that you have fulfilled the pediatric study requirement for this application.

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).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 22-004 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

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

11/21/2007 03:37:52 PM