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APPLICATION NUMBER:

22-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-004

ALTANA Pharma
210 Park Avenue
Florham Park, NJ 07932

Attention: Cheryl Czachorowski
Senior Manager, 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 (2), July 21 and 25, August 2, 4, 10, 11, 14, 17, 18, 21, 22, and 29, September 13, 15, 18, 22, 26, and 29, and October 6, 10, 13, 16, 17, and 19 (3), 2006.

This new drug application provides for the use of OMNARIS (ciclesonide) Nasal Spray for the treatment of seasonal and allergic rhinitis 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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert [copy enclosed], patient package insert [copy enclosed], and immediate container and carton labels submitted October 19, 2006, and foil pouch label submitted October 16, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 22-004**." Approval of this submission by FDA is not required before the labeling is used.

Submit an updated version of 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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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 studies for ages birth to less than 2 years of age and deferring pediatric studies for ages 2 through 16 years of age until December 31, 2007.

Your deferred pediatric study required under section 2 of the Pediatric Research Equity Act (PREA) is considered a required postmarketing study commitment. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. A deferred pediatric study under PREA for assessment of the effects of ciclesonide nasal spray on growth velocity in children.

   The study will be conducted in prepubescent children with allergic rhinitis and will be of adequate size to meet the objective. A dose of ciclesonide nasal spray that is relevant to the proposed ciclesonide nasal spray dose in children with allergic rhinitis will be used. Provided the systemic exposure from another formulation is higher than the systemic exposure from the nasal formulation, a linear growth study conducted with a formulation of ciclesonide other than the nasal formulation may be adequate.

Protocol Submission:	by January 2007
Study Start:	by April 2007
Final Report Submission:	by December 2007

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment should be clearly designated "**Required Pediatric Study Commitments**".

We remind you of your postmarketing study commitment in your submission dated October 19, 2006. This commitment is listed below.

2. A safety study to evaluate the effects of ciclesonide nasal spray on the HPA axis.

   The study will be conducted using the labeled dose and at least one higher dose of ciclesonide nasal spray. The study will include one or more 24-hour measurements of cortisol and be of adequate size and duration to meet the objective. The study will include efficacy assessments, PK measurements, or both to ensure compliance with study medication and will include a positive control arm.

Protocol Submission:	by March 2007
Study Start:	by June 2007
Final Report Submission:	by May 2008

Submit clinical protocols to your IND for this product. Submit study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, number of patients entered into each study. All submissions, including supplements, relating to this postmarketing study commitment should be prominently labeled "**Postmarketing**

Study Commitment Protocol", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Pulmonary and Allergy Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Colette Jackson, Regulatory Project Manager, at (301) 796-1230.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Office of Drug Evaluation II
Office of New Drugs

Enclosure: Approved Labeling