CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-371s000

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-371 **NDA APPROVAL**

MEDA Pharmaceuticals
265 Davidson Avenue, Suite 300
Somerset, NJ 08873-4120

Attention: Richard Fosko, RPh, MPH
Director, Regulatory Affairs

Dear Mr. Fosko:

Please refer to your new drug application (NDA) dated August 1, 2008, received August 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Astepro (azelastine hydrochloride 0.15% w/v) Nasal Spray.

We acknowledge receipt of your submissions dated September 5, 17, 18, and 19, and December 4, and 22 (2), 2008, and January 12, February 6, 18, and 20, April 3, 10, 20, and 29, July 15, 23, and 30, and August 11, 17, 25, and 27 (2) and 28 , 2009

This new drug application provides for the use of Astepro (azelastine hydrochloride 0.15% w/v) Nasal Spray for seasonal and perennial 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 content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on August 28, 2009.

CONTENT OF LABELING

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, text for the patient package insert, submitted August 28, 2009. 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 22-371**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted August 17, 2009, 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 22-371**." 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages zero to less than 2 years for seasonal allergic rhinitis and for ages zero to less than 6 months for perennial allergic rhinitis because necessary studies are impossible or highly impracticable. This is because the disease/condition does not exist in children in these age groups.

We are deferring submission of your pediatric studies for ages 2 years to less than 12 years for seasonal allergic rhinitis and 6 months to less than 12 years of age for perennial allergic rhinitis for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

1535-1. Deferred pediatric study under PREA for the treatment of perennial and/or seasonal allergic rhinitis in pediatric patients ages 6 years to less than 12 years of age. The study will include efficacy and safety assessments.

Protocol Submission:	November 2009
Study Completion:	June 2011
Final Report Submission:	December 2011

1535-2. Deferred pediatric study under PREA for the treatment of perennial and/or seasonal allergic rhinitis in pediatric patients ages 6 months to less than 6 years of age. The study will include safety assessments and PK measurements.

Protocol Submission:	April 2012
Study Completion:	March 2014
Final Report Submission:	September 2014

1535-3. Deferred pediatric study under PREA for the treatment of perennial and/or seasonal allergic rhinitis in pediatric patients ages 6 years to less than 12 years of age. The study will include efficacy and safety assessments.

Protocol Submission:	September 2012
Study Completion:	November 2013
Final Report Submission:	April 2014

1535-4. Deferred pediatric study under PREA for the treatment of perennial and/or seasonal allergic rhinitis in pediatric patients ages 6 years to less than 12 years of age. The study will include PK measurements.

Protocol Submission:	September 2012
Study Completion:	November 2013
Final Report Submission:	April 2014

Submit final study reports to the original NDA 22-203. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated "**Required Pediatric Assessment**".

We note that you have fulfilled the pediatric study requirement for ages 12 to 16 years for the seasonal and perennial allergic rhinitis indications for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product to this division.

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

LETTERS TO HEALTH CARE PROFESSIONALS

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 the original NDA 22-203 and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 22-203 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, Senior 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