DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22203/S-010
NDA 22203/S-011

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Meda Pharmaceuticals, Inc.
265 Davidson Avenue
Somerset, NJ 08873-4120

Attention: Cindy Yayac
Senior Manager, Regulatory Affairs

Dear Ms. Yayac:

Please refer to your Supplemental New Drug Applications (sNDA) dated September 24, 2014, received September 24, 2014, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Astepro (azelastine hydrochloride) Nasal Spray, 137 mcg (0.1%).

We acknowledge receipt of your amendments dated November 19, 2014, and January 20, February 6, 16, and 19, 2015.

Supplement 010 - This "Prior Approval" supplemental new drug application provides for the use of Astepro (azelastine hydrocholoride) 0.1% for the treatment of symptoms of seasonal allergic rhinitis in children 2 through 6 years of age.

Supplement 011 - This "Prior Approval" supplemental new drug application provides for the use of Astepro (azelastine hydrochloride) 0.1%for the treatment of symptoms of perennial allergic rhinitis in children 6 months through 6 years of age.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content

of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Instruction for Use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated September 24, 2014, containing the final report for the following postmarketing requirement listed in the August 31, 2009, approval letter, under NDA 22-371 for Astepro (azelastine hydrochloride) Nasal Spray 0.15%. We note the Agency request, in the August 31, 2009, approval letter, that you submit final study reports to the original NDA 22-203 for Astepro.

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.

We have reviewed your submission and conclude that the above requirement was fulfilled.

This completes your postmarketing requirements acknowledged in our August 31, 2009, approval letter, for Astepro under NDA 22-371, and NDA 22-203.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration

Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

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 Sadaf Nabavian, Regulatory Project Manager, at (301) 796-2777.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Deputy Director for Safety
Division of Pulmonary, Allergy, and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling (PI, PPI, IFU)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SALLY M SEYMOUR
02/20/2015