Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation II

FACSIMILE TRANSMITTAL SHEET

DATE: October 9, 2008

To: Richard Fosko	**From:** Colette Jackson
Company: MEDA Pharmaceuticals	Division of Pulmonary and Allergy Products
Fax number: 973-564-2377	**Fax number:** 301-796-9718
Phone number: 973-564-2358	**Phone number:** 301-796-1230
Subject: NDA 22-203	
Total no. of pages including cover:	

Comments:

Document to be mailed: YES xNO

NDA 22-203
Astepro® (azelastine hydrochloride) Nasal Spray, 137 mcg.

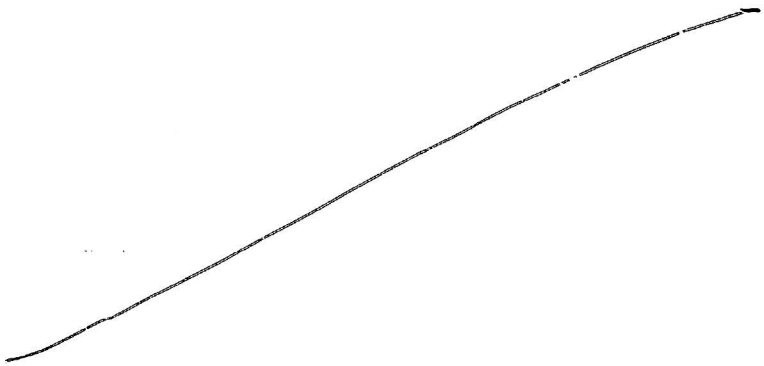
Please refer to your July 30, 2007, new drug application (NDA) for Astepro® (azelastine hydrochloride) Nasal Spray. We acknowledge your submissions dated August 14, and October 6, 2008. We have the following labeling comments. These comments are not all inclusive and we may have additional comments. Submit revised draft labeling incorporating theses changes by COB October 10, 2008.

The following comments pertain to the proposed package insert:

1. Minor wording edits regarding the presentation of racial/ethnic data are included in the attached, marked draft label to ensure consistency with other labels for similar drug products.

2. Minor additions in the Patient Information section have been made to ensure consistency with other portions of the package insert and to improve readability.

The following comments pertain to the carton/container labels:



b(5)

If there are any questions, please contact Ms. Colette Jackson, Project Manager, at 301-796-1230.

Enclosure: FDA Proposed Labeling

16 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Administrative- 1

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/s/

Colette Jackson
10/9/2008 11:32:44 AM
CSO

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date: October 8, 2008

To: Badrul Chowdhury, M.D., Director
Division of Pulmonary and Allergy Products

Through: Jodi Duckhorn, M.A., Team Leader
Patient Labeling and Education Team
Division of Risk Management (DRISK)

From: Nancy Carothers, RN, BA
Patient Product Information Specialist
Patient Labeling and Education Team
Division of Risk Management (DRISK)

Subject: Review of Patient Labeling (Patient Package Insert and Patient Instructions for Use) #2

Drug Name(s): ASTEPRO™ (azelastine hydrochloride) Nasal Spray

Application Type/Number: NDA 22-203

Applicant/sponsor: MEDA Pharmaceuticals

OSE RCM #: 2008-584

1 INTRODUCTION

Meda Pharmaceuticals submitted a New Drug Application (NDA) for Astelin (azelastine hydrochloride) on July 30, 2007. This submission was not approved and under a dispute resolution, the sponsor resubmitted the NDA under a new drug name (ASTEPRO) on May 23, 2008. The first submission had an indication for children under age 12 and this submission has an indication for children, age 12 and over, and adults. The Patient Package Insert (PPI) was reviewed in the previous submission (May 8, 2008) and the sponsor has included those suggested changes in this PPI. The submitted labeling includes Professional Information in PLR format with patient labeling in the form of a Patient Package Insert and Patient Instructions for Use as part of section 17 Patient Counseling Information.
This review is written in response to a request by the review division for the Patient Labeling and Education Team to review the submitted patient labeling.

2 MATERIAL REVIEWED

- ASTEPRO Patient Package Insert (PPI) submitted August 14, 2008
- ASTEPRO Patient Instructions for Use (PIFU) submitted August 14, 2008
- ASTEPRO ME Professional Information (PI) submitted August 14, 2008

3 DISCUSSION

The purpose of patient directed labeling is to enhance appropriate use and provide important risk information about medications. Our recommended changes are consistent with current research to improve risk communication to a broad audience, including those with lower literacy.
The draft PPI submitted by the sponsor has a Flesch Kinkaid grade level of 7.0, and a Flesch Reading Ease score of 65.2. To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60% (60% corresponds to an 8th grade reading level). The reading scores as submitted by the sponsor are acceptable.

In our review of the PPI, we have:

- simplified wording and clarified concepts where possible,
- made it consistent with the PI,
- removed unnecessary or redundant information
- ensured that it meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006).

In 2008, The American Society of Consultant Pharmacists Foundation in collaboration with The American Foundation for the Blind published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. They recommend using fonts such as Arial, Verdana, or APHont to make medical information more accessible for patients with low vision. We have reformatted the PPI document

using the font APHont, which was developed by the American Printing House for the Blind specifically for low vision readers.
See the attached document for our recommended revisions to the PPI. Comments to the review division are ***bolded, underlined and italicized***.
We are providing the review division a marked-up and clean copy of the revised PPI. We recommend using the clean copy as the working document.
All future relevant changes to the PI should also be reflected in the PPI.

4 CONCLUSIONS AND RECOMMENDATIONS

- The PPI includes a warning, not to allow ASTEPRO Nasal Spray to get into the eyes and mouth. The PI warns about the eyes (17.5), but does not warn about the mouth. This warning should be added to the PI, or removed from the PPI. In addition, there should be advice on what to do if the spray gets into the eyes or mouth, especially if the spray causes any serious consequences. This advice should be added to the PI and PPI. The PI and PPI must be consistent.

- The PI states that oral ingestion of antihistamines in "[redacted]children" can potentially cause serious side effects, however, the PPI says that "children" should seek help if they swallow ASTEPRO. In our previous review (dated May 5, 2008), we recommended that the sponsor remove '[redacted]' from the PPI. For consistency, '[redacted]' should be removed from the PI as well. The PI and PPI must be consistent. b(4)

- The side effect of the spray having a "sweet taste" does not appear in the PI but does appear in the PPI. If it is a side effect and if it is used in the PPI, it should be added to the PI so that the PI and PPI are consistent. b(4)

- [redacted]

- The section, "How should I use ASTEPRO Nasal Spray?" says to breathe gently to keep the medicine from running down the back of your throat. The instruction should include, "do not tip your head back" because this is the primary action to take to keep the medicine from going down the back of the throat. This instruction should be added to the Patient Counseling Section of the PI for consistency.

Please let us know if you have any questions.

15 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓
_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Proprietary Name Review- 1

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/s/

Nancy B Carothers
10/8/2008 11:59:47 AM
DRUG SAFETY OFFICE REVIEWER

Jodi Duckhorn
10/8/2008 12:10:20 PM
DRUG SAFETY OFFICE REVIEWER