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

FACSIMILE TRANSMITTAL SHEET

DATE: May 13, 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 FDA Proposed Labeling	
Total no. of pages including cover: 21	

Comments:

Document to be mailed: YES xNO

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

Please refer to your July 30, 2007, new drug application (NDA) for azelastine hydrochloride nasal spray. We also acknowledge your submission dated April 25, 2008. Please refer to the enclosed labeling with our preliminary labeling comments and/or recommendations. The FDA-proposed revisions to your draft labeling have been made using the clean copy of the Word version of the label submitted on April 25, 2008. FDA-proposed insertions are underlined and deletions are in strike-out. These comments are not all inclusive and we may have additional comments. Submit revised draft labeling incorporating the changes outlined in our enclosed labeling.

1. The following comments pertain to the Full Prescribing Information of the product label.

    a. In Section 14.1, the inclusion of Hispanic demographic information here and not in Section 6.1 may be confusing. If possible, revise Section 6.1 to include Hispanics.

    b. The efficacy information for one spray was moved to follow the clinical trial description as it is pertinent to the interpretation of the study results.

2. The following comment pertains to the Patient Package Insert and the Patient Instructions for Use.

    The Patient Package Insert and the Patient Instructions for Use have been extensively revised to make the language more consumer friendly. Included in the revisions are comments in brackets {}. Please address these comments.

3. The following comment pertains to the Structured Product Label.

    Revise your Drug Listing Data Elements (DLDE) to include water.

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

Enclosure: Recommendations to the Proposed Labeling

18 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Administrative- 3

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/s/

Colette Jackson
5/13/2008 05:16:19 PM
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:	May 5, 2008
To:	Badrul Chowdhury, M.D., Director Pulmonary and Allergy Products
Through:	Jodi Duckhorn, M.A., Team Leader Patient Labeling and Education Team Division of Risk Management (DRISK)
From:	Sharon R. Mills, BSN, RN, CCRP 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)
Drug Name(s):	TRADENAME (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 TRADENAME (azelastine hydrochloride) on July 30, 2007. 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

- TRADENAME Patient Package Insert (PPI) submitted April 25, 2008
- TRADENAME Patient Instructions for Use submitted April 25, 2008
- TRADENAME Professional Information submitted April 25, 2008

3 DISCUSSION

The purpose of patient information leaflets 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 7.7, and a Flesch Reading Ease score of 62.9. 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 where possible,
- made it consistent with the Professional Information,
- removed unnecessary or redundant information
- Although not required for Patient Information, we have put this PPI in the question–and-answer format specified in the Medication Guide Regulations (21 CFR 208.20) that we recommend for all FDA approved patient labeling.
- ensured that the PPI 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

1. The sponsor uses both the terms "doctor," and "health care provider" in the proposed PPI and Patient Instructions for Use. We recommend that one term be used consistently throughout the document.
2. We have moved the information about the expiration date to "How should I store TRADENAME?"
3. We moved the statement "TRADENAME can cause drowsiness" to a section called "What should I avoid while using TRADENAME Nasal Spray" and included information about avoiding driving, operating heavy machinery or doing other dangerous activities after using TRADENAME. We also added a bullet to avoid alcohol and other medicines that cause drowsiness while using TRADENAME.
4. We have added the statement, "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088." This verbatim statement is required for all Medication Guides effective January 2008 (see 21 CFR 208.20 (b)(7)(iii); also see Interim Final Rule, *Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products* in Federal Register Vol. 73, No. 2, p.402-404, 1/3/2008). Although not required for voluntary PPIs like TRADENAME, we recommend adding this language to all FDA-approved patient labeling for consistency.
5. We have added the section "General Information aboutTRADENAME."
6. In the Patient Instructions for Use, all of the figures should be enlarged. Also, the print in Figure 1 is too small to easily read.

Please let us know if you have any questions.

14 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Proprietary Name Review- 2

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/s/

Sharon Mills
5/5/2008 05:21:06 PM
DRUG SAFETY OFFICE REVIEWER

Jodi Duckhorn
5/5/2008 08:13:43 PM
CSO

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

FACSIMILE TRANSMITTAL SHEET

DATE: April 23, 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 Tradename Comments

Total no. of pages including cover: 3

Comments:

Document to be mailed: YES xNO

NDA 22-203
[redacted] (azelastine hydrochloride) Nasal Spray, 137 mcg.

Please refer to your July 30, 2007, new drug application (NDA) for [redacted] (azelastine hydrochloride) Nasal Spray. We have received the following comment regarding your proposed trade names. b(4)

> We do not recommend the use of the proprietary names, [redacted] or [redacted] for this product. The results of the Proprietary Name Risk Assessment found that the proposed names, [redacted] and [redacted], are confusing and misleading because the modifiers do not convey the differences between the proposed product and the currently available Astelin.
>
> We do not believe that a modifier used in conjunction with the root name "Astelin", would convey to practitioners that Astelin and [redacted], or [redacted] have different formulations, indications of use, and patient populations. We believe the safest way to market this new formulation is under a proprietary name that does not contain the root name "Astelin".

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

Drafted: CCJ/ April 22, 2008

Initialed:

Barnes/ April 22, 2008
Seymour/ April 23, 2008
Chowdhury/ April 23, 2008

Finalized: CCJ/ April 23, 2008

Filename: 22203 April 2008 DMETS Fax.doc

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/s/

Colette Jackson
4/23/2008 12:55:26 PM
CSO