



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

FACSIMILE TRANSMITTAL SHEET

DATE: April 4, 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: 25

Comments:

Document to be mailed: YES xNO

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NDA 22-203

_____ (azelastine hydrochloride) Nasal Spray, 137 mcg.

Please refer to your July 30, 2007, new drug application (NDA) for _____ (azelastine hydrochloride) Nasal Spray. Please refer to the enclosed labeling with our preliminary labeling comments and/or recommendations. The FDA-proposed revisions to your draft labeling for _____ have been made using the clean copy of the Word version of the label submitted on July 30, 2007. 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. General labeling comments

- a. Remove the header.
- b. Change _____ to TRADENAME throughout the label as _____ was not found to be acceptable. When you refer to your product in the label, make sure to use the full name TRADENAME Nasal Spray.
- c. The indication for seasonal allergic rhinitis has been revised from the "_____" to the "relief of symptoms of seasonal allergic rhinitis". This indication reflects a distinction between the relief of symptoms with antihistamines and the treatment of SAR for corticosteroids because corticosteroids are thought to affect the underlying inflammation. This indication is consistent with recently approved antihistamines (e.g. Xyzal).
- d. The indication of vasomotor rhinitis was deleted throughout the label because your program does not provide adequate support for this indication.

e. _____

b(4)

2. The following comment pertains to the Highlights section of the product label.

The initial US approval date refers to the year that FDA initially approved the new molecular entity, azelastine. Confirm the date to reflect the initial approval date for azelastine.

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

- a. Update the Table of Contents to reflect changes in package insert.

- b. In Section 1, we have removed the individual symptoms from the indication for consistency across products in the PLR format.
- c. A new Administration Information subsection was included in Section 2.2.
- d. In Section 5.1, the language was revised for consistency with the label for other approved antihistamines (e.g. Xyzal).
- e. In Section 6.1, please provide the demographic profile for the entire population exposed to TRADENAME Nasal Spray.
- f. In Section 6.1, the pediatric information was deleted as we cannot extrapolate safety data with Astelin Nasal Spray for this product because of the new excipients (one of which is novel for a nasal spray).
- g. Standard PLR language was added to Section 6.2.
- h. Section 7 was reorganized for clarity.
- i. Section 8.1 was reorganized for the PLR format with detailed information provided in Section 13.2 (Animal Toxicology and/or Pharmacology).
- j. Section 8.4 was revised to reflect the lack of safety information in patients 5 to 11 years of age.
- k. In Section 14.1, the efficacy results for all treatment groups were included. The pooled placebo post hoc analysis you proposed is not acceptable.

l.

[Redacted text]

b(4)

m.

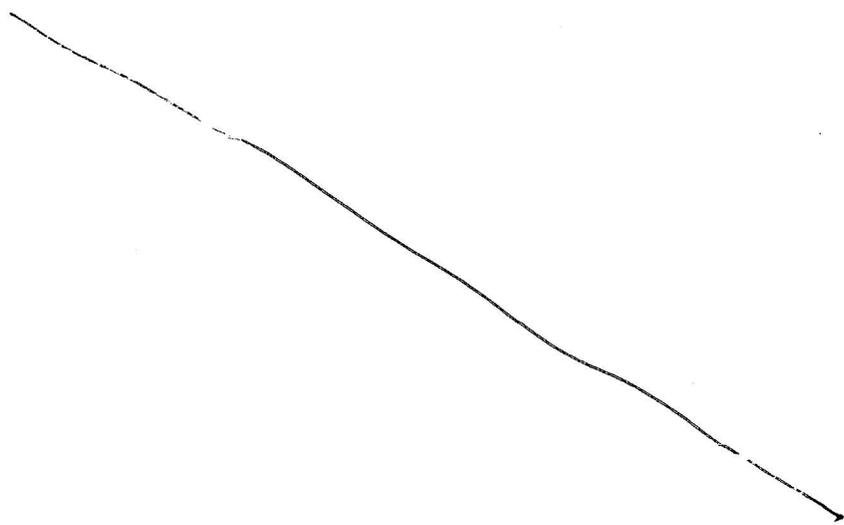
[Redacted text]

b(4)

[Redacted text]

- 4. The following comments pertain to the Patient Package Insert. We are awaiting an internal consult from the Division of Risk Management for the Patient Package Insert and the Patient Instructions for Use, so additional comments will follow.

- a. In the Patient Package Insert, step 2 of the "To Clean" section instructs the user to "Squirt several times while holding under water." The user is later instructed to "Reinsert the pump into the open bottle and tighten by turning clockwise" and to follow the instructions for priming. It is not clear whether the priming process will clear all of the water from the tubing that may have collected during the "squirt several times while holding under water" process. If the priming process is not adequate to clear out the residual water, please include instructions for how to clear the tubing of water before reinserting the pump into the bottle.
 - b. Please ensure that the diagram used in the Patient Package Insert that identifies the different parts of the spray bottle can be easily read. Additionally, label the diagrams (e.g., Figure 1, Figure 2) and refer to these diagrams, as appropriate, in the text portion of the instructions.
 - c. Include storage instructions for the nasal spray in the Patient Package Insert.
5. The following comments pertain to the carton and container labeling.



b(4)

6. The following comments pertain to the Carton Label.



b(4)

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

Enclosure: Recommendations to the Proposed Labeling

20 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Colette Jackson
4/4/2008 05:53:13 PM
CSO



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

FACSIMILE TRANSMITTAL SHEET

DATE: December 4, 2007

To: Richard Fosko	From: Colette Jackson
Company: MedPointe Pharmaceuticals	Division of Pulmonary and Allergy Products
Fax number: 732-564-2361	Fax number: 301-796-9718
Phone number: 732-564-2358	Phone number: 301-796-1230
Subject: NDA 22-203 IR Letter	

Total no. of pages including cover: 4

Comments:

Document to be mailed: YES NO

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NDA 22-203

INFORMATION REQUEST LETTER

MedPointe Pharmaceuticals, MedPointe Healthcare, Inc.
265 Davidson Avenue
Suite 300
Somerset, NJ 08873-4120

Attention: Richard Fosko, RPh
Associate Director

Dear Mr. Fosko:

Please refer to your July 30, 2007 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ——— (azelastine hydrochloride) Nasal Spray. b(4)

We also refer to your submissions dated August 16, September 13, and October 26, 2007.

We are reviewing the Clinical section of your submission and have the following comments and information requests. We request a written response by COB December 14, 2007, in order to continue our evaluation of your NDA.

1. The patient disposition for Study MP430 (Volume 21, Section 10.1, Text Table 1) notes that a total of 6 patients were discontinued from the study due to adverse events. However, a later section (Volume 22, Table 14.3.2.3) notes that a total of 8 patients were discontinued prematurely due to adverse events. Clarify this discrepancy and provide the reason for the discontinuation for each of these patients.
2. We remind you of the 74-day filing letter, dated October 12, 2007, in which we requested a breakdown of the patients who had VMR versus PAR in the long-term safety study, MP432, including a tabulation of adverse events and Mini-RQLQ by this categorization.

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

Sincerely,

{See appended electronic signature page}

Sandy Barnes
Supervisory CSO
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Sandra Barnes
12/3/2007 06:37:48 PM



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

FACSIMILE TRANSMITTAL SHEET

DATE: October 18, 2007

To: Dr. Mike Bernhardt	From: Colette Jackson
Company: MedPointe	Division of Pulmonary and Allergy Products
Fax number: 732-564-2377	Fax number: 301-796-9718
Phone number: 732-564-2353	Phone number: 301-796-1230
Subject: NDA 22-203 Acknowledgement Letter	

Total no. of pages including cover: 4

Comments:

Document to be mailed: YES NO

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NDA 22-203

NDA ACKNOWLEDGMENT

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

Attention: Michael I. Bernhard, PhD.
Senior Director, Regulatory Affairs

Dear Dr. Bernhard:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: _____ (azelastine hydrochloride) Nasal Spray, 137 mcg **b(4)**

Review Priority Classification: Standard

Date of Application: July 30, 2007

Date of Receipt: July 31, 2007

Our Reference Number: NDA 22-203

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on September 28, 2007, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be May 30, 2008.

Please cite the NDA number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary and Allergy Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

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obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see <http://www.fda.gov/cder/ddms/binders.htm>

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

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., PhD
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Badrul Chowdhury
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