



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

FACSIMILE TRANSMITTAL SHEET

DATE: May 28, 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: 3

Comments:

Document to be mailed: YES xNO

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If you are not the addressee, or a person authorized to deliver this document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone at (301) 796-2300. Thank you.

NDA 22-203

_____, (azelastine hydrochloride) Nasal Spray, 137 mcg.

b(4)

Please refer to your July 30, 2007, new drug application (NDA) for _____ (azelastine hydrochloride) Nasal Spray. We acknowledge your submission dated May 20, 2008. We have the following labeling comments. These comments are not all inclusive and we may have additional comments. Submit revised draft labeling incorporating these changes by COB May 29, 2008.

1.

b(4)

2.

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

b(4)

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

/s/

Colette Jackson
5/28/2008 02:56:25 PM
CSO

Jackson, Colette

Sax Cary [csax@medapharma.us]

Sent: Wednesday, May 14, 2008 12:59 PM

To: Jackson, Colette; Fosko Richard

Subject: RE: April 14, 2008, Tcon Meeting Minutes

Colette,

I received these minutes. For some reason I did not receive the email you sent last evening; odd.

Thank you. Cary

Did you receive my secure email certificate earlier this week?

Cary Sax

MEDA Pharmaceuticals

265 Davidson Avenue

Somerset, NJ 08873

732-564-2369 (office)

732-564-2377 (fax)

908-229-6317 (cell)

From: Jackson, Colette [mailto:colette.jackson@fda.hhs.gov]

Sent: Wednesday, May 14, 2008 12:36 PM

To: Fosko Richard; Sax Cary

Subject: April 14, 2008, Tcon Meeting Minutes

Rick,

Here are final meeting minutes for the April 14, 2008, teleconference for NDA 22-203. Please confirm receipt of the meeting minutes.

Let me know if you have any questions.

<<April 14 2008 Labeling Tcom MM for Sponsor.pdf>>

Colette Jackson

Regulatory Health Project Manager

Division of Pulmonary and Allergy Products

U.S. Food and Drug Administration

Center for Drug Evaluation and Research

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

PH 301-796-1230

F 1-796-9718/9728

E-mail: colette.jackson@fda.hhs.gov

This email and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you are not the addressee you are prohibited from disseminating, distributing or copying this e-mail. The company accepts no liability for any damage caused by any virus transmitted in this email. If you received this in error, please contact the sender and delete the material from any computer.

**APPEARS THIS WAY
ON ORIGINAL**



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

FACSIMILE TRANSMITTAL SHEET

DATE: May 14, 2008

To: Richard Fosko	From: Colette Jackson
Company: MEDA	Division of Pulmonary and Allergy Products
Fax number: 732-564-2377	Fax number: 301-796-9718
Phone number: 732-564-2358	Phone number: 301-796-1230

Subject: NDA 22-203 April 14, 2008 Labeling Teleconference Meeting Minutes

Total no. of pages including cover: 6

Comments:

Document to be mailed: YES xNO

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If you are not the addressee, or a person authorized to deliver this document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone at (301) 796-2300. Thank you.

MEMORANDUM OF TELECON

DATE: April 14, 2008

APPLICATION NUMBER: NDA 22-203

BETWEEN:

Name: MEDA Pharmaceuticals Representatives:

Richard Spivey, PharmD., Ph.D., Vice President, Development
Harry Sacks, M.D., Vice President, Medical and Scientific Affairs
Louis Sanquini, Director, Marketing
Richard Fosko, Director, Regulatory Affairs
Cary Sax, Associate Director, Regulatory Affairs
Preena Modi, Manager, Regulatory Affairs

Phone: 1-866-742-1857

Representing: MEDA Pharmaceuticals

AND

Name: FDA Representatives:

Division of Pulmonary and Allergy Products:

Badrul A. Chowdhury, M.D., Ph.D., Division Director
Sally Seymour, M.D., Clinical Team Leader
Prasad Peri, Ph.D., Pharmaceutical Assessment Lead, ONDQA
Partha Roy, Ph.D., Clinical Pharmacology Reviewer
Wei Qiu, Ph.D., Acting Clinical Pharmacology Team Leader
Timothy McGovern, Ph.D., Pharmacology/Toxicology Team Leader
Ted Guo, Ph.D., Statistical Reviewer
Qian Li, Ph.D., Statistical Team Leader
Colette Jackson, Regulatory Health Project Manager

Division of Drug Marketing, Advertising, and Communications:

Michelle Safarik, PA-C, Regulatory Review Officer

Division of Medication Errors and Prevention:

Loretta Holmes, PharmD, Safety Evaluator
Denise Toyer, PharmD, Deputy Division Director

SUBJECT: Labeling for NDA 22-203

BACKGROUND:

MEDA (formerly MedPointe Pharmaceuticals) submitted a new drug application (NDA) on July 30, 2007, for _____, which is a sweetened formulation of azelastine hydrochloride nasal spray. The formulation contains two excipients, sucralose and sorbitol to mask the bitter taste. MEDA is seeking approval of this application in patients 5 years of age and older for the treatment of symptoms of seasonal allergic rhinitis and for the treatment of symptoms of vasomotor rhinitis in patients 12 years of age and older. On April 4, 2008, the Agency sent proposed labeling revisions and labeling comments to MEDA. This labeling teleconference discussed the revisions outlined in the April 4, 2008, facsimile.

b(4)

DISCUSSION:

MEDA referred to lines 507 to 510 in the Full Prescribing Information (FPI) of the FDA proposed label. _____

b(4)

_____. The Agency stated that we can consider inclusion of the language in the label for the 2 spray dose, but _____

MEDA referred to lines 120 to 122 of the FPI, and the statement _____

b(4)

_____. MEDA stated that this statement is misleading and should be deleted. MEDA explained that the grading used in the study protocol only defined Grade 3 lesions as nasal ulcerations. The majority of the reported cases were Grade 2 lesions which are not ulcerations. MEDA stated that the statement regarding mild epistaxis is not used in its proper context and should be modified to reflect the baseline reports. The Agency acknowledged MEDA's concern with the proposed language and agreed that the language does not take into account the baseline findings of nasal ulcerations and epistaxis. However, the Agency noted that there were more ulcerations during the trial compared to baseline; therefore, the information cannot be completely removed from the label. The Agency recommended that MEDA propose some alternative language for the Agency to consider.

MEDA referred to lines 92, 119, and 537 which refer to "dysguesia". MEDA stated that a 2-week study described the taste as "different" or "unusual" and MEDA would like to replace "dysguesia" with "unusual taste". The Agency agreed that the term is open to interpretation and noted that the currently marketed Astelin product uses the term "bitter taste". The term "bitter taste" is well understood and it is preferred over "unusual taste". MEDA stated that the sweetened formulation contains sucralose and the term "bitter taste" does not capture the spectrum of reports, such as sweet, bad, or strange taste. The Agency suggested MEDA propose language in their revised label, and we will take it under consideration, but "bitter taste" is the preferred term for consistency with Astelin.

MEDA asked the Agency for an update on the review of their proposed tradenames ' _____ and " _____ . The Agency stated that the use of modifiers are not acceptable unless they communicate a clinical difference to the medical practitioner in order to choose a particular drug. MEDA has proposed names for which the modifiers are ambiguous or have no meaning and the Agency is concerned this could cause significant medication errors. MEDA stated that there are other currently marketed products that use modifiers and the Agency's rationale is unclear as to why MEDA's proposed names are unacceptable. The Agency stated that we are concerned that the " _____ does not communicate a clinical difference to the clinician and therefore should not be used. MEDA stated that they will provide education to the healthcare community to explain the differences in the original Astelin and the sweetened azelastine hydrochloride formulations. The _____ is to express the sorbitol and sucralose used in the sweetened formulation and was not picked arbitrarily. The Agency did not agree with MEDA's proposed tradenames and suggested MEDA submit a different name for review.

b(4)

MEDA referred to the deletion of the vasomotor rhinitis (VMR) and pediatric indications. MEDA stated that there were previous discussions during development and MEDA conducted their program as agreed with the Agency. MEDA was surprised to see that the indications were no longer in the label and would like an explanation from the Agency. The Agency stated that for VMR, we acknowledge the earlier communications. _____

b(4)

_____ MEDA stated that the Agency's concerns regarding the triggers for VMR are conceptual and theoretical. MEDA stated that they had multiple discussions with the Agency and submitted a Special Protocol Assessment and they are very disappointed that they are being told 8 months into the review that they have a lack of data for their VMR indication. The Agency stated that information was relayed in the filing letter dated October 12, 2007, that the adequacy of the application to support a VMR indication would be a review issue. Review of the application has determined that without supporting data, a VMR indication cannot be obtained.

Regarding the pediatric SAR indication, MEDA stated that prior discussions with the Agency concluded that studies for the _____ years of age could be deferred until after action. MEDA is surprised that there is no support for the pediatric population in their current application. The Agency referred to comment #2 of our November 4, 2005, Special Protocol Assessment Response letter which states:

b(4)

b(4)

b(4)

b(4)

This issue has been discussed at the Office and Center levels of the Agency.

MEDA stated that they intend to submit a Formal Dispute Resolution (FDR) with the Center within the next few days. MEDA would like the application to have a favorable action on the agreed items of the label and dispute the VMR and pediatric indications. The Agency noted that an FDR is submitted after an action has been taken and it is not likely that 2 separate actions will be taken. MEDA is looking for an approval for indications in which there are no studies or data to support the VMR and pediatric indications. MEDA stated that they will discuss their options internally and get back with the Agency.

Colette Jackson
Regulatory Health Project Manager

Drafted: CCJ/ May 7, 2008

Initialed:

Seymour/ May 9, 2008

Peri/ May 8, 2008

Li/ May 8, 2008

Guo/ May 8, 2008

Safarik/ May 7, 2008

Seymour for Chowdhury/ May 14, 2008

Finalized: CCJ/ May 14, 2008

Filename: 22203 April 14 2008 labeling tcon MM.doc

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

/s/

Colette Jackson
5/14/2008 12:31:07 PM
CSO