



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

FACSIMILE TRANSMITTAL SHEET

DATE: October 1, 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

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NDA 22-203

Astepro® (azelastine hydrochloride) Nasal Spray, 137 mcg.

Please refer to your July 30, 2007, new drug application (NDA) for _____ (azelastine hydrochloride) Nasal Spray. We acknowledge your submissions dated August 14, and September 17, 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 October 6, 2008.

b(4)

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

Enclosure: FDA Proposed Labeling

14 Page(s) Withheld

 Trade Secret / Confidential (b4)

 Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

Withheld Track Number: Administrative-2

Drafted: CCJ/ September 30, 2008

Initialed:

Barnes/ September 29, 2008

Limb/ October 1, 2008

Seymour / October 1, 2008

Chowdhury/ October 1, 2008

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/s/

Colette Jackson
10/1/2008 12:53:24 PM
CSO



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-203

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

Attention: Richard Fosko
Director, Regulatory Affairs

Dear Mr. Fosko:

We acknowledge receipt on August 15, 2008, of your August 14, 2008, resubmission to your new drug application for (azelastine hydrochloride) Nasal Spray, 137 mcg.

We consider this a complete, class 1 response to our May 30, 2008, action letter. Therefore, the user fee goal date is October 15, 2008.

Please cite the NDA number listed above at the top of the page for any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service/ Courier/Overnight Mail:
FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Division of Pulmonary and Allergy Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Sincerely,

{See appended electronic signature page}

Colette Jackson
Regulatory Health Project Manager
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Colette Jackson
9/15/2008 06:04:35 PM

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		REQUEST FOR CONSULTATION		
TO (Division/Office): CDER OSE CONSULTS		FROM: Colette Jackson Project Manager Division of Pulmonary and Allergy Products, HFD-570		
DATE September 10, 2008	IND NO.	NDA NO. 22-203	TYPE OF DOCUMENT N	DATE OF DOCUMENT August 14, 2008
NAME OF DRUG Astepro	PRIORITY CONSIDERATION Priority	CLASSIFICATION OF DRUG Antihistamine Nasal Spray	DESIRED COMPLETION DATE October 3, 2008	
NAME OF FIRM: MEDA Pharmaceuticals				
REASON FOR REQUEST				
I. GENERAL				
<input type="checkbox"/> NEW PROTOCOL <input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> NEW CORRESPONDENCE <input type="checkbox"/> DRUG ADVERTISING <input type="checkbox"/> ADVERSE REACTION REPORT <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION <input type="checkbox"/> MEETING PLANNED BY				
<input type="checkbox"/> PRE-NDA MEETING <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> SAFETY/EFFICACY <input type="checkbox"/> PAPER NDA <input type="checkbox"/> CONTROL SUPPLEMENT				
<input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> LABELING REVISION <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE <input type="checkbox"/> FORMULATIVE REVIEW <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW):				
II. BIOMETRICS				
STATISTICAL EVALUATION BRANCH		STATISTICAL APPLICATION BRANCH		
<input type="checkbox"/> TYPE A OR B NDA REVIEW <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW OTHER (SPECIFY BELOW):		<input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER (SPECIFY BELOW):		
III. BIOPHARMACEUTICS				
<input type="checkbox"/> DISSOLUTION <input type="checkbox"/> BIOAVAILABILITY STUDIES <input type="checkbox"/> PHASE IV STUDIES		<input type="checkbox"/> DEFICIENCY LETTER RESPONSE <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS <input type="checkbox"/> IN-VIVO WAIVER REQUEST		
IV. DRUG EXPERIENCE				
<input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP		<input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE <input type="checkbox"/> POISON RISK ANALYSIS		
V. SCIENTIFIC INVESTIGATIONS				
<input type="checkbox"/> CLINICAL		<input type="checkbox"/> PRECLINICAL		
COMMENTS, CONCERNS, and/or SPECIAL INSTRUCTIONS:				
<p>This is a request for a consult on the labeling for MEDA's NDA 22-203. This submission is a Class 1 resubmission to our May 23, 2008, NA letter. The labeling is in both paper and electronic. It is located in the EDR in the submission dated August 14, 2008, and in volume 1 of the paper submission.</p> <p>PDUFA DATE: October 15, 2008</p> <p>ATTACHMENTS:</p> <p>CC: Archival NDA 22-203 HFD-570/Division File HFD-570/Jackson</p>				
SIGNATURE OF REQUESTER Colette Jackson 6-1230		METHOD OF DELIVERY (Check one) <input checked="" type="checkbox"/> MAIL <input type="checkbox"/> HAND		
SIGNATURE OF RECEIVER		SIGNATURE OF DELIVERER		

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/s/

Colette Jackson
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5/28/05

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