CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202236Orig1s000

PHARMACOLOGY REVIEW(S)

INTEROFFICE MEMO

TO: NDA 202,236 (DYMISTA; Azelastine Hydrochloride 0.1% and Fluticasone Propionate 0.37% Nasal Spray)
Submissions dated April 1 and July 1, 2011, respectively

FROM: Timothy W. Robison, Ph.D., D.A.B.T.
Pharmacology/Toxicology Team Leader
Division of Pulmonary, Allergy, and Rheumatology Products

DATE: December 7, 2011

I concur with the conclusions and recommendations of Dr. Marcie Wood's Review dated September 23, 2011. The review recommended approval of the application from the nonclinical perspective.

The applicant has developed a fixed dose combination of azelastine and fluticasone propionate administered as a nasal spray for the treatment of allergic rhinitis in children and adults 12 years of age and older. This is the first combination product of an anti-histamine and corticosteroid.

The nonclinical safety program for the fixed dose combination of azelastine and fluticasone propionate administered as a nasal spray is based upon the complete toxicology programs conducted with each of the monoproducts. The applicant also conducted 14-day intranasal toxicology studies in rats and dogs and a 3-month intranasal toxicology study in rats with the combination of azelastine hydrochloride and fluticasone propionate to assess for potential additive or synergistic toxic effects of the combination. There was no evidence of additive or synergistic toxic effects of the combination with particular reference to local toxicity in the nasal cavity and sinuses. See Dr. Wood's review for further details.

Dr. Wood's Review makes recommendations for changes in the product labeling in Sections 8.1, 8.3, 10, 12.1, 13.1, and 13.2.

There are no outstanding PharmTox issues.

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

/s/

TIMOTHY W ROBISON
12/07/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY NDA REVIEW AND EVALUATION

Application number:	NDA 202236
Supporting document/s:	SDN 1, SDN 4
Applicant's letter date:	SDN 1: April 1, 2011
	SDN 4: July 1, 2011
CDER stamp date:	SDN 1: April 1, 2011
	SDN 4: July 1, 2011
Product:	Azelastine Hydrochloride 0.1% and Fluticasone Propionate 0.37% Nasal Spray
Indication:	Seasonal allergic rhinitis
Applicant:	Meda Pharmaceuticals, Inc.
Review Division:	Division of Pulmonary, Allergy, and Rheumatology Products
Reviewer:	Marcie Wood, Ph.D.
Supervisor/Team Leader:	Timothy Robison, Ph.D., DABT
Division Director:	Badrul Chowdhury, M.D., Ph.D.
Project Manager:	Philantha Bowen

Template Version: September 1, 2010

Disclaimer

Except as specifically identified, all data and information discussed below and necessary for approval of NDA 202236 are owned by Meda Pharmaceuticals, Inc. or are data for which Meda Pharmaceuticals, Inc. has obtained a written right of reference. Any information or data necessary for approval of NDA 202236 that Meda Pharmaceuticals, Inc. does not own or have a written right to reference constitutes one of the following: (1) published literature, or (2) a prior FDA finding of safety or effectiveness for a listed drug, as reflected in the drug's approved labeling. Any data or information described or referenced below from reviews or publicly available summaries of a previously approved application is for descriptive purposes only and is not relied upon for approval of NDA 202236.

TABLE OF CONTENTS

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.