CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-371s000

PROPRIETARY NAME REVIEW(S)

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 08, 2009
To:	Badrul Chowdhury, MD, Director Division of Pulmonary and Allergy Products
Through:	Kellie Taylor, PharmD, MPH, Team Leader Denise P. Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
From:	Zachary Oleszczuk, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Astepro (b) (4) (Azelastine Hydrochloride) Nasal Spray 205.5 mcg/actuation
Application Type/Number:	NDA 22-371
Applicant:	MEDA Pharmaceuticals, Inc.
OSE RCM #:	2009-304

1 INTRODUCTION

This 505(b)(1) NDA for Astepro (b) (4) (NDA #22-371), proposes a new strength to the currently marketed Astepro nasal spray (NDA #22-203). Astepro (b) (4) will be available as 0.15 % while the currently marketed Astepro is available as 0.1 %. The Applicant proposes the same indication of seasonal allergic rhinitis in adults and adolescents 12 years of age or older for both products. The Applicant is also proposing an additional indication of perennial allergic rhinitis for adults and adolescents 12 years of age or older for Astepro (b) (4) S. The usual dose of the currently marketed Astepro is 1 or 2 sprays per nostril twice daily. The usual dose of Astepro (b) (4) is 2 sprays per nostril once or twice daily.

1.1 REGULATORY HISTORY

The Applicant initially submitted the proposed name (b) (4), for review and comment. However, the Division of Pulmonary and Allergy Products (DPAP) and the Division of Medication Error Prevention and Analysis (DMEPA) had concerns that the use of two different proprietary names could lead to concomitant therapy and result in excess sedation. As such, DPAP and DMEPA held a teleconference with the Applicant on January 5, 2009, to discuss these concerns. In response to the teleconference, the Applicant withdrew the name (b) (4) in a submission dated February 09, 2009. Additionally, in the same submission the Applicant submitted the name Astepro (b) (4) and two alternate names (b) (4)) for NDA #22-371 for assessment regarding potential name confusion with other proprietary or established drug names.

2 MATERIAL REVIEWED

On February 09, 2009 the Applicant submitted the name Astepro (b) (4) for review and comments. Additionally, the Applicant submitted two alternate names (b) (4) .

Since the root name 'Astepro" is currently marketed, DMEPA conducted a search of the Adverse Event Reporting System (AERS) database to determine if there are any medication errors associated with name confusion with the currently marketed Astepro that may be indicative of potential name confusion with Astepro (b) (4). Additionally, DMEPA evaluated the effect the modifier (b) (4), would have on any reported name confusion that is occurring with the root name Astepro.

3 DISCUSSION

DMEPA had concerns when evaluating this name from a safety and clinical perspective with the proposal to add the modifier (b) (4) to Astepro. This concern was based on the following. The modifier (b) (4) does not have an established meaning in currently marketed drug products. Additionally, DMEPA believes that this product and the currently marketed Astepro can be appropriately managed under the proprietary name 'Astepro' and that the two products can be differentiated by their respective strengths (0.1% and 0.15%).

Since the name Astepro is currently on the market, DMEPA evaluated the modifier (b) (4) and how the resulting product line extension would affect currently marketed Astepro and other drug products that are currently marketed. Additionally, the modifier (b) (4) is evaluated for a consistent meaning and to see if the modifier could act as a source of error or confusion independently of the name.

1 Page has been Withheld in Full immediately following this page as B4 (TS)

3.1.1 Comments From the Division of Pulmonary and Allergy Products (DPAP)

In an email dated February 2, 2009, DPAP did not recommend the use of Astepro (b) (4) because the (b) (4) does not have a standard meaning. Additionally, including a modifier solely to designate a higher strength of the same active ingredient is inconsistent with similar products that are already on the market (e.g. Atrovent Nasal Spray 0.03% vs. Atrovent Nasal Spray 0.06% and Flovent Diskus 50 mcg vs. Flovent Diskus 100 mcg). DPAP feels that managing the two products under the same name Astepro designating the strengths (0.1% vs. 0.15%) would provide clearer differentiation to patients and healthcare practitioners.

3.2 ASTEPRO ROOT NAME

DMEPA found that the proposed product and the currently marketed Astepro product could be successfully managed under the name Astepro and the two products could be differentiated by the strengths of the products. Since DMEPA found the name Astepro acceptable for this product and Astepro is currently marketed, DMEPA preformed an AERS search to identify any name confusion that may be occurring with the currently marketed Astepro. The MedRA High Level Group Term (HLGT) "Medication Errors" and Preferred Term (PT) "Pharmaceutical product complaint" were used as search criteria for Reactions. The search criteria used for Products were active ingredients "Aze%", trade names "Aste%" and verbatim substance search "Aze%" and "Aste%". Date limitations were set from October 15, 2008, through February 25, 2009, since Astepro was first approved on October 15, 2008.

The AERS search preformed on February 25, 2009 yielded 3 cases. These cases were manually reviewed for medication errors related to name confusion with Astepro. None of the cases involved name confusion with Astepro. The cases that were identified either involved another azelastine product (Astelin) or Astepro was a concomitant medication in those cases. A negative AERS search can not guarantee that name confusion is not occurring with Astepro, since it is known that medication errors are under reported. Additionally, Astepro has only been on the market for five months and errors may have not been reported due to the limited time the product has been on the market.

4 CONCLUSIONS AND RECOMMENDATIONS

DMEPA concurs with DPAP and objects to the use of the proposed proprietary name, Astepro (b) (4) for this product. The Proprietary Name Risk Assessment findings indicate that the (b) (4) is ambiguous and does not have a consistent recognized meaning among healthcare professionals.

Furthermore, using a modifier for the sole purpose of identifying a greater amount of active drug is inconsistent with similar products that are currently marketed. As such, we believe the product can be managed under the existing product name, Astepro, with an educational program to make practitioners aware of the new product strength.

In addition, we acknowledge that the Applicant submitted two alternate proprietary names, (b) (4) However, DMEPA does not recommend the use of these two names for the same reasons outlined above for Astepro (b) (4)

If you have any questions or need clarifications, please contact Sean Bradley, OSE Project Manager, at 301-796-1332.

4.1 COMMENTS TO THE APPLICANT

We have completed our review of this proposed proprietary name and have concluded that this name is unacceptable because the proposed modifier (b) (4)' is ambiguous and does not have a consistent recognized meaning among healthcare professionals.

Although, you state that the modifier (b) (4) is used to express the greater amount of active drug in Astepro (b) (4) compared to Astepro, you have not submitted any data to support your claim that "the modifier (b) (4) is well established and understood by healthcare professionals as a designation of a product containing a greater amount of active drug than the product with the same root name." Additionally, the modifier (b) (4)' may not have a consistent meaning when compared with the currently marketed products that use this modifier in their proprietary name.

(b) (4)

Additionally, including a modifier solely to designate a higher strength of the same active ingredient is inconsistent with similar products that are already on the market (e.g. Atrovent Nasal Spray 0.03% vs. Atrovent Nasal Spray 0.06% and Flovent Diskus 50 mcg vs. Flovent Diskus 100 mcg). Managing the two products under the one proprietary name, Astepro, and designating the strengths (0.1% vs. 0.15%) provides clearer differentiation and a more readily discernable meaning to patients and healthcare practitioners. Although you have submitted two alternate proprietary names, (b) (4) we do not recommend the use of either of these two names for the sole purpose of designating a higher strength of the same active ingredient

REFERENCES

1. Adverse Events Reporting System (AERS)

AERS is a database application in CDER FDA that contains adverse event reports for approved drugs and therapeutic biologics. These reports are submitted to the FDA mostly from the manufactures that have approved products in the U.S. The main utility of a spontaneous reporting system that captures reports from health care professionals and consumers, such as AERS, is to identify potential postmarketing safety issues. There are inherent limitations to the voluntary or spontaneous reporting system, such as underreporting and duplicate reporting; for any given report, there is no certainty that the reported suspect product(s) caused the reported adverse event(s); and raw counts from AERS cannot be used to calculate incidence rates or estimates of drug risk for a particular product or used for comparing risk between products.

APPENDIX

(b) (4)

[3] Medilexicom, http://www.medilexicon.com/medicalabbreviations.php. May 28, 2008

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

/s/

Zachary A Oleszczuk
5/8/2009 09:33:27 AM
DRUG SAFETY OFFICE REVIEWER

Kellie Taylor
5/8/2009 10:36:03 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
5/8/2009 11:00:43 AM
DRUG SAFETY OFFICE REVIEWER