CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-228

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:	August 31, 2009
To:	Wiley Chambers, M.D., Acting Director Division of Anti-Infective & Ophthalmology Products
Through:	Laura Pincock, Pharm.D., Acting Team Leader Denise Toyer, Pharm.D., Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
From:	Raichell S. Brown, Pharm.D., J.D., Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Bepreve (Bepotastine Besilate) Ophthalmic Solution 1.5%
Application Type/Number:	NDA 22-288
Applicant:	ISTA Pharmaceuticals
OSE RCM #:	2009-260

*** This document contains proprietary and confidential information that should not be released to the public.***

CONTENTS

1 INTRODUCTION

This review is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Bepreve, acceptable in OSE Review #2008-1987, dated February 9, 2009. Since that review, none of Bepreve's product characteristics have been altered. Additionally, the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective on June 16, 2009. Furthermore, the Review Division did not have any concerns with the proposed name, Bepreve, during our initial review.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources (see Section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. Because none of the proposed product characteristics were altered, we did not re-evaluate previous names of concern. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN update. DMEPA bases the overall risk assessment on the findings of a Failure Mode Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases yielded three new names, Agenerase, Hepsera, and Hiprex, thought to look similar to Bepreve and represent a potential source of drug name confusion. These names were evaluated using FMEA. The findings of the FMEA indicate that the proposed name, Bepreve, is not likely to result in name confusion with Agenerase, Hepsera, and Hiprex for the reasons presented in Appendices A and B.

3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Bepreve, is not vulnerable to name confusion that could lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Bepreve, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Anti-Infective and Ophthalmology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. OSE Review # 2008-1987. Proprietary Name Review of Bepreve, Raichell S. Brown. February 5, 2009.

2. Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

3. Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

4. USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)

USAN Stems List contains all the recognized USAN stems.

APPENDICES

Appendix A: Products that lack convincing orthographic or phonetic similarity to Bepreve.

Product Name Identified to have Potential for Confusion	**Similarity to Bepreve.**
Agenerase	orthographic

Appendix B: Single strength products with multiple differentiating product characteristics.

Product name with potential for confusion	**Similarity to Bepreve**	**Strength**	**Indication for Use**	**Usual Dose (if applicable)**	**Differentiating Product Characteristics (Bepreve vs. Product)**
Bepreve (Bepotastine) Ophthalmic Solution	**N/A**	**1.5%**	**Itching associated with allergic conjunctivitis**	**One drop in affected eye(s) twice a day**	**N/A**
Hiprex (Methenamine) Tablet	orthographic	1 gram	Prophylactic or suppressive treatment or frequently recurring urinary tract infections	1 gram by mouth twice daily	DOSAGE FORM: **Bepreve**- Ophthalmic Drop **Hiprex**- Oral Tablet ROUTE OF ADMINISTRATION: **Bepreve**- Topical to the eye(s) **Hiprex**- Oral
Hepsera (Adefovir) Tablet	orthographic	10 mg	Treatment of chronic Hepatitis B in patients 12 years of age or older	10 mg by mouth once daily	DOSAGE FORM: **Bepreve**- Ophthalmic Drop **Hepsera**- Oral Tablet ROUTE OF ADMINISTRATION: **Bepreve**- Topical to the eye(s) **Hepsera**- Oral FREQUENCY OF ADMINISTRATION: **Bepreve**- Twice daily **Hepsera**- Once daily

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