



**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: September 25, 2007

To: M. Dianne Murphy, MD
Director, Office of Pediatric Therapeutics (OPT), OIASI
Office of the Commissioner

CDR Lisa L. Mathis, USPHS, MD
Pediatric and Maternal Health Team
Office of New Drugs

Felicia Collins, MD
Medical Officer
Pediatric and Maternal Health Team
Office of New Drugs

Thru: Solomon Iyasu, M.D., M.P.H., Director
Division of Surveillance, Research and Communication Support
Office of Surveillance and Epidemiology

From: Vicky Borders-Hemphill, Pharm.D./ Drug Use Data Specialist
Division of Surveillance, Research and Communication Support
Office of Surveillance and Epidemiology

Subject: BetaxonTM (levobetaxolol hydrochloride) BPCA
Drug Name(s): BetaxonTM (levobetaxolol hydrochloride)

Application Type/Number: NDA # 21-114

Applicant/sponsor: Alcon Research, Ltd.

OSE RCM #: 2007-385

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CONTENTS

EXECUTIVE SUMMARY	1
1 Introduction.....	1
1.1 Regulatory history.....	1
2 Conclusion	1
CONCURRENCE	1

EXECUTIVE SUMMARY

This consult examines the drug utilization patterns for Betaxon™ (levobetaxolol), a cardioselective beta-adrenergic receptor blocking agent, in the pediatric population, patients aged 0-16 years, with a primary focus on patterns of use two years before and one year following the granting of Pediatric Exclusivity on June 28, 2006.

Betaxon™ is no longer marketed in the United States, and it is not currently being studied under an IND. There has been no U.S. distribution per the annual report. There are not any utilization data to provide.

1 INTRODUCTION

1.1 REGULATORY HISTORY

On January 4, 2002, Congress enacted the Best Pharmaceuticals for Children Act (BPCA) to improve the safety and efficacy of pharmaceuticals for children. Section 17 of that Act requires the review of adverse events associated with the use of a drug in children during the one year following the date on which the drug received marketing exclusivity. In support of this mandate, the FDA is required to provide a report to the Pediatric Advisory Committee on the drug utilization patterns and adverse events associated with the use of the drug soon after the one-year anniversary of granting exclusivity. This review is in addition to the routine post-marketing safety surveillance activities the FDA performs for all marketed drugs.

In October of 1999, FDA issued a Pediatric Written Request for studies in pediatric patients with a clinical diagnosis of glaucoma or elevated intraocular pressure to evaluate the safety and clinical response on elevated intraocular pressure.

On February 23, 2000, under NDA 21-114, Betaxon™ was approved for lowering intraocular pressure in patients with chronic open angle glaucoma or ocular hypertension.

Alcon Research, Ltd. conducted studies and gained approval for the use of Betaxon™ in pediatric patients for the treatment of elevated intraocular pressure on September 28, 2006, under NDA 21-114/S-002. Pediatric Exclusivity was granted on June 28, 2006.

2 CONCLUSION

Betaxon™ is no longer marketed in the United States, and it is not currently being studied under an IND. There has been no U.S. distribution per the annual report. There are not any utilization data to provide.

CONCURRENCE

Laura Governale, Pharm D., MBA.
Team Leader
Division of Surveillance, Research, and
Communication Support (DSRCS)
Solomon Iyasu, M D, MPH
Director
Division of Surveillance, Research, and

Communication Support (DSRCS)

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/s/

Vicky Borders-Hemphill
10/2/2007 03:27:03 PM
DRUG SAFETY OFFICE REVIEWER

Solomon Iyasu
10/2/2007 05:47:04 PM
MEDICAL OFFICER