



**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:

To: Lisa L. Mathis, M.D., OND Associate Director  
Pediatric and Maternal Health Team  
Office of New Drugs (OND), CDER  
and  
M. Dianne Murphy, M.D., Director  
Office of Pediatric Therapeutics (OPT), OC

Thru: Melissa Truffa, R.Ph., Team Leader  
for  
Mark Avigan, M.D., C.M., Director  
Division of Drug Risk Evaluation

From: Ronald Wassel, Pharm.D., Safety Evaluator  
Division of Drug Risk Evaluation

Subject: 1-year Post-Pediatric Exclusivity Postmarketing Adverse  
Event Review

Drug Name: Betaxon<sup>TM</sup> (levobetaxolol hydrochloride)

Pediatric Exclusivity  
Approval Date: June 28, 2006

Application  
Type/Numbers: NDA # 21-114

Applicant/sponsors: Alcon

OSE RCM #: 2007-385

## **EXECUTIVE SUMMARY**

Betaxon<sup>TM</sup> (levobetaxolol) has never been 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 no cases for any age group in the Adverse Event Reporting System as of August 30, 2007.

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/s/

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Ronald Wassel  
8/30/2007 11:42:22 AM  
DRUG SAFETY OFFICE REVIEWER

Melissa Truffa  
8/30/2007 12:01:22 PM  
DRUG SAFETY OFFICE REVIEWER