



NDA 21-114/S-002

Alcon Research, Ltd.  
Attention: Angela C. Kothe, OD, PhD  
Director, Regulatory Affairs  
6201 South Freeway  
Fort Worth, TX 76134-2099

Dear Dr. Kothe:

Please refer to your supplemental new drug application dated March 27, 2006, received March 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BETAXON™ (levobetaxolol hydrochloride ophthalmic suspension), 0.5%.

We acknowledge receipt of your submissions dated May 23, June 21, August 30, and September 12, 2006.

This supplemental new drug application provides for changes to the **PRECAUTIONS** section, **Pediatric Use** subsection to include additional pediatric information on BETAXON™ for the treatment of elevated intraocular pressure. It also provides for an additional sentence in the **ADVERSE REACTIONS** section.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted on September 12, 2006). These revisions are terms of the approval of this application.

Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at 301-796-1202.

Sincerely,

*{See appended electronic signature page}*

Janice Soreth, MD  
Director  
Division of Anti-Infective and Ophthalmology  
Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Janice Soreth  
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