



NDA 21-114/S-003

SUPPLEMENT APPROVAL

Alcon, Inc.
c/o Alcon Research, Ltd.
Attention: Michael C. Son, Ph.D., RAC
Senior Manager, Regulatory Affairs
6201 South Freeway, R3-52
Fort Worth, Texas 76134-2099

Dear Dr. Son:

Please refer to your supplemental new drug application dated February 12, 2009, received February 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Betaxon (levobetaxolol HCl ophthalmic suspension) 0.5%.

We acknowledge receipt of your submissions dated September 2 and October 7, 2009.

This "Prior Approval" supplemental new drug application provides for revised labeling in the PLR format.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on October 7, 2009.

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-114/S-003.**"

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Michael Puglisi, Project Manager, at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective
and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21114	SUPPL-3	ALCON INC	BETAXON

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

/s/

WILEY A CHAMBERS
03/09/2010