DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-845/S-021

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

Dear Dr. Son:

Please refer to your supplemental new drug application dated November 9, 2007, received November 13, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Betoptic S (betaxolol hydrochloride ophthalmic suspension) 0.25%.

This supplemental new drug application provides for changes to the DOSAGE AND ADMINISTRATION, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, DESCRIPTION, HOW SUPPLIED, and PATIENT COUNSELING INFORMATION sections of the package insert labeling.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on November 9, 2007.

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed draft labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 19-845/S-021."

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
Suite 12B05
5600 Fishers Lane
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

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

/s/

Wiley Chambers

5/8/2008 01:07:17 PM