



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-514/S-009

Alcon Laboratories, Inc.
c/o Alcon Research, Ltd.
Attn: Norma J. Schafer
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Schafer:

Please refer to your supplemental new drug application dated July 16, 2001, received July 17, 2001, submitted under the Federal Food, Drug, and Cosmetic Act for Natacyn (natamycin ophthalmic suspension) Ophthalmic Suspension, 5%.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated April 20, 2007, April 17, and May 23, 2008. Your submission of April 20, 2007, constituted a complete response to our May 30, 2003, action letter.

This "Changes Being Effected" supplemental new drug application provides for changes to the product package insert.

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 content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format with the enclosed label.

Per our conversation on June 27, 2008, it was agreed that the following citation at the end of your May 23, 2008, package insert will be removed: *Laupen, J.O.; McLellan, W.L.; El Nakeeb, M.A.: "Antibiotics and Fungal Physiology," Antimicrobial Agents and Chemotherapy, 1965: 1006, 1965.

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

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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 Lori Gorski, Regulatory Project Manager, at (301) 796-0722.

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
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/s/

Wiley Chambers
7/18/2008 11:59:53 AM