



NDA 13-422/S-035

Alcon Laboratories, Inc.  
Attn: Norma J. Schafer  
Regulatory Affairs Analyst  
6201 South Freeway  
Fort Worth, Texas 76134-2099

Dear Ms. Schafer:

Please refer to your supplemental new drug application dated October 25, 2002, received October 29, 2002, submitted under of the Federal Food, Drug, and Cosmetic Act for Maxidex (dexamethasone ophthalmic suspension) 0.1%.

This "Changes Being Effected" supplemental new drug application provides for a Geriatric Use subsection under the **PRECAUTIONS** section of the product package insert.

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

Please note that if a future supplement is submitted it should include:

The **HOW SUPPLIED** section of the package insert should include the target fill volume for each container size and the color and type of plastic for the bottle container, dropper tip, and cap. Cap color should be consistent with those assigned by the American Academy of Ophthalmology.

The **DESCRIPTION** section of the package insert should include the pH, osmolality, molecular formula and molecular weight of the product.

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, HF-2  
FDA  
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).

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If you have any questions, call Raphael Rodriguez, Regulatory Project Manager, at (301) 827-2090

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.  
Deputy Director  
Division of Anti-Inflammatory, Analgesic, and  
Ophthalmic Drug Products, HFD-550  
Office of Drug Evaluation V  
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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Wiley Chambers  
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