



NDA 18-469/S-036 & S-037

Alcon Laboratories, Inc.
c/o Alcon Research, Ltd.
Attention: Sarah Cantrell
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Cantrell:

Please refer to your supplemental new drug applications dated August 23, 2002, and received August 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BSS Plus Sterile Intraocular Irrigating Solution (balanced salt solution enriched with bicarbonate, dextrose and glutathione).

We acknowledge receipt of your March 14, 2003, submission which constituted a complete response to our December 23, 2003, action letter. We also acknowledge receipt of your submissions dated February 21, 2003.

These supplemental new drug applications provide for an alternate stopper material for the 250 mL and 500 mL drug product sizes and changes to the labeling.

We completed our review of these supplemental new drug applications as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 14, 2003.

In addition, if a future labeling supplement is submitted please incorporate the following changes:

1. The **HOW SUPPLIED** section of the package insert should include the container size, the target fill volume for each container size and the type of material utilized for the bottle stopper and cap.
2. Revise the Storage statement to read, "Store Part I and Part II at 2°-25°C (36°-77°F)."

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:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lori M. Gorski, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team Leader, for the
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

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/s/

Linda Ng
7/16/03 10:29:20 AM