



NDA 18-469/S-040 & S-041

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

Dear Ms. Cantrell:

Please refer to your supplemental new drug applications dated March 31, 2004, received April 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BSS Plus (balanced salt solution enriched with bicarbonate, dextrose and glutathione) Sterile Irrigating Solution.

We acknowledge receipt of your submissions dated July 21, August 20 and December 13, 2004. Your submission of August 20, 2004 constituted a complete response to our August 3, 2004, action letter.

These supplemental new drug applications provide for alternate packaging configuration for the 250 mL and 500 mL drug product sizes and a change to the labeling.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, submitted December 13, 2004.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format with proposed revisions clearly indicated, preferably in track changes. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Approval of this submission by FDA is not required before the labeling is used.

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

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 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

**This is a representation of an electronic record that was signed electronically and
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/s/

Linda Ng
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