



NDA 20742
S-025
S-026

SUPPLEMENT APPROVAL

Alcon Laboratories, Inc.
Attention: Suzanne Cadden MSc
Head of Regulatory Affairs - USA
6201 South Freeway
Fort Worth, TX 76134

Dear Ms. Cadden:

Please refer to your two Supplemental New Drug Applications (sNDAs) dated October 14, 2015, received October 15, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BSS Sterile Irrigating Solution (balanced salt solution).

Prior Approval Supplemental New Drug Application 025 provides for:

- 1) revision to the following labeling to remove any overly broad statements regarding additives, and
 - I. Package Insert for the 250 mL and 500 mL glass bottles
 - II. Container label for 250 mL glass bottle
 - III. Container label for 500 mL glass bottle
 - IV. Package Insert for 500 mL flexible plastic container
 - V. Container label for 500 mL flexible plastic container
 - VI. Bag Overwrap for 500 mL flexible plastic container
 - VII. Package Insert for the 15 mL and 30 mL DROPTAINER dispenser bottles
 - VIII. Backing Paper for 15 mL DROPTAINER dispenser bottles
 - IX. Backing Paper for 30 mL DROPTAINER dispenser bottles
 - X. 15 mL DROPTAINER dispenser bottles packer – 3 dozen 15 mL single dose bottles
 - XI. 30 mL DROPTAINER dispenser bottles packer – 3 dozen 30 mL single dose bottles
- 2) revision to the storage statement in the labeling.

Prior Approval Supplemental New Drug Application 026 provides for removal of the “DO NOT FREEZE” statement from the labeling and directions for use with support for this revision

provided in the form of stability data from freeze-thaw studies conducted on each package configuration of the drug product.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling text for the package insert, with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 20742/S-025 and NDA 20742/S-026.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REPORTING REQUIREMENTS

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 Ms. Lois Almoza, Regulatory Health Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Deputy Director
Division of Transplant and Ophthalmology
Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):

Package Insert
Carton and Container Labeling

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

/s/

WILEY A CHAMBERS
11/06/2015