DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18469
S-054
S-055

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 PLUS Sterile Irrigating Solution (balanced salt solution enriched with bicarbonate, dextrose, and glutathione).

Prior Approval Supplemental New Drug Application 054 provides for:

1. Revision to the following labeling to remove any overly broad statements regarding additives, and

   I. Labeling for BSS PLUS 500 mL (Part I) and 20 mL (Part II) Bottle kit
      a. BSS PLUS 500 mL (Part 1) /20 mL (Part II) package insert
      b. BSS PLUS 500 mL (Part 1) container label
      c. BSS PLUS 20 mL (Part II) container label
      d. BSS PLUS 20 mL (Part II) carton
   II. Labeling for BSS PLUS 250 mL (Part I) and 10 mL (Part II) Bottle kit
      a. BSS PLUS 500 mL (Part 1) /20 mL (Part II) package insert
      b. BSS PLUS 250 mL (Part 1) container label
      c. BSS PLUS 10 mL (Part II) container label
      d. BSS PLUS 10 mL (Part II) carton
   III. Labeling for BSS PLUS 500 mL bag presentation (Part I) + 20 mL bottle (Part II) kit
      a. BSS PLUS Bag Presentation package insert
      b. BSS PLUS 500 mL Bag Presentation Part I container label
      c. BSS PLUS Bag Presentation Part II (20 mL) container label

2. Revision to the storage statement in the labeling.

Prior Approval Supplemental New Drug Application 055 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 Effected" (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 18469/S-054 and NDA 18469/S-055**." 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