DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019258/S-021 **SUPPLEMENT APPROVAL**

Ecolab Inc.
Attention: Pete Carlson
Principal Regulatory Specialist - Healthcare
370 Wabasha St. North
St. Paul, MN 55102-1390

Dear Mr. Carlson:

Please refer to your Supplemental New Drug Application (sNDA) dated February 2, 2015, received February 4, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Scrub-Stat 2%™ and Scrub-Stat 4%™ (chlorhexidine gluconate 2% and 4%) solutions.

We acknowledge receipt of your amendments dated June 5 and July 16, 2015.

This "Changes Being Effected" sNDA proposes an additional size/shape container/closure system with associated labeling.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the following submitted labeling: Scrub-Stat 2%™ 750-mL immediate container and dispenser, Scrub-Stat 2%™ 1250-mL immediate container and dispenser, Scrub-Stat 4%™ 750-mL immediate container and dispenser, and Scrub-Stat 4%™ 1250-mL immediate container and dispenser dated July 16, 2015, and must be in the "***Drug Facts***" format (21 CFR 201.66), where applicable.

Submit the FPL electronically according to the guidance for industry titled "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 Labeling for approved NDA 019258/S-021**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your FPL, the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 Celia Peacock, Senior Regulatory Project Manager at (301) 796-4154.

Sincerely,

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Immediate Container and Dispenser Labeling

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

/s/

THERESA M MICHELE
08/05/2015