



NDA 019258/S-023

**SUPPLEMENT APPROVAL**

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

Dear Mr. Carlson:

Please refer to your Supplemental New Drug Application (sNDA) dated July 16, 2015, received July 17, 2015, and your amendments, 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.

This “Changes Being Effected” sNDA proposes 750 mL and 1250 mL container closure systems and 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 labels: Scrub-Stat™ 2% 750 mL and 1250 mL immediate containers and Scrub-Stat™ 4% 750 mL and 1250 mL immediate containers dated January 12, 2016 and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The FPL should be submitted 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-023.**” 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 final printed labeling (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 Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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THERESA M MICHELE  
01/14/2016