DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019258/S-016 **SUPPLEMENT APPROVAL**

Ecolab Inc.
Attention: Pete Carlson
Senior Regulatory Affairs Specialist
Regulatory Affairs (EUC/9)
370 Wabasha Street N.
St. Paul, MN 55102-1390

Dear Mr. Carlson:

Please refer to your October 14, 2009 Supplemental New Drug Application (sNDA), received October 23, 2009, 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%) solution.

We acknowledge receipt of your submissions dated December 30, 2009, January 19, March 26, April 7, 9, 15 and 19, 2010.

This "Prior Approval" supplemental new drug application provides for a proprietary name change for these products and the associated labeling changes.

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 as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling submitted on April 15 and 19, 2010, as identified below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Labeling submitted April 15, 2010

Scrub-Stat™ 2%

- 18-oz. (540-mL) immediate container (bottle)
- 33.8-oz. (1,000-mL) immediate container (bottle)
- 33.8-oz. (1,000-mL) immediate container (nozzle bag)
- 3.78-L (1-gallon) immediate container (bottle)

- 55 gallon immediate container (drum)

Scrub-Stat™ 4%

- 18-oz. (540-mL) immediate container (bottle)
- 33.8-oz. (1,000-mL) immediate container (bottle)
- 3.78-L (1-gallon) immediate container (bottle)
- 55 gallon immediate container (drum)

Labeling submitted April 19, 2010

Scrub-Stat™ 2%

- 4-oz. immediate container (bottle)
- 27-oz. (750-mL) immediate container (bottle)

Scrub-Stat™ 4%

- 4-oz. immediate container (bottle)
- 27-oz. (750-mL) immediate container (bottle)

The final printed labeling 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 (October 2005).* 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-016**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Larry Bauer, Regulatory Project Manager, at (301) 796-4842.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure(s):
Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19258	SUPPL-16	ECOLAB INC	CHG SCRUB

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

/s/

JOEL SCHIFFENBAUER
04/23/2010