DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-258/S-014

Ecolab, Inc.
Attention: Ms. Rhonda Schulz
Senior Manager, Regulatory Affairs
370 North Wabasha Street
St. Paul, MN 55102

Dear Ms. Schulz:

Please refer to your supplemental new drug application dated August 10, 2004, received August 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Endure® 420 (2% chlorhexidine gluconate) solution and Endure® 400 (4% chlorhexidine gluconate) solution.

Your submission of September 27, 2005 constituted a complete response to our September 9, 2005 action letter.

We also acknowledge receipt of your submissions dated December 7, 2005, January 19, 2006, March 6, and 20, 2006.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new container and closure system for your 750-mL bottle.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. Under the ***Questions?*** heading in the Drug Facts label for Endure® 400 and Endure® 420, change the first letter in the word "call" to lower case and bold the toll free phone number using a 6-point bold type as the minimum font size.

2. In the Drug Facts label for Endure® 400, remove "(continued)" from the **Drug Facts** title on the first page.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container labels submitted March 20, 2006) including the revisions listed above, and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

We also recommend that you revise the phrase "Peel here for full drug labeling information" to "Peel here for ***Drug Facts***" on the Principal Display Panel For the Endure® 400 and Endure® 420.

We remind you to submit the specification for full strokes including test acceptance criteria and test method under the Drug Product Specification section in your next annual report.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submissions "**FPL for approved supplement NDA 19-258/S-014**." Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Laura Shay, Regulatory Project Manager, at (301) 796-0994.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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

/s/

Andrea Segal

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