DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-258/S-011

Ecolab, Inc.
Attention: Rhonda Schultz
Senior Manager, Regulatory Affairs
370 Wabasha Street North
St. Paul, MN 55102-1390

Dear Ms. Schulz:

Please refer to your supplemental new drug application dated November 16, 2001, received November 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Endure® 420 Cida-Stat™ (2% and 4% chlorhexidine gluconate) solution.

We acknowledge receipt of your submissions dated May 7, July 25, and September 5, 2002; October 30 and December 18, 2003; May 28, September 20, October 4 and 13, 2004; and January 24 and February 8, 2005.

Your submission of October 13, 2004 constituted a complete response to our October 6, 2004 action letter.

This supplemental new drug application proposes a (b)(4)----------

(b)(4)----------

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.

The final printed labeling (FPL) must be identical to the submitted labeling [immediate container (bag) labeling and dispenser sticker with expiration date submitted on January 24, 2005, and dispenser labeling submitted on October 13, 2004], and must be formatted in accordance with the requirements of 21 CFR 201.66.

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/these submission(s) "**FPL for approved supplement NDA 19-258/S-011**." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug 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/

Curtis Rosebraugh
2/15/05 08:25:51 AM