DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-007

Beckloff Associates, Inc.
Attention: Wayne Vallee, R.Ph., RAC
Director, Regulatory Affairs
7400 West 110th Street, Suite 720
Overland Park, KS 66210

Dear Mr. Vallee:

Please refer to your supplemental new drug application dated January 6, 2004, received January 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep One-Step 10.5-mL Applicators (2% chlorhexidine gluconate solution).

We acknowledge receipt of your submissions dated April 19 and June 8, 2004.

This supplemental new drug application provides for a new information sheet for inclusion inside the immediate containers (lidding) of ChloraPrep One-Step 10.5-mL Applicators. The insert contains additional warnings and directions for the use of ChloraPrep One-Step 10.5-mL Applicators.

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 (package insert submitted June 8, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-832/S-007." 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
Office of Drug Evaluation V
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
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