DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-006

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 December 10, 2003, received December 11, 2003, 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 December 19, 2003, March 1, 2004, April 19, 2004, and May 20, 2004.

This "Changes Being Effected" supplemental new drug application proposes additional warnings and other editorial changes to the labeling for ChloraPrep One-Step 10.5-mL Applicators (2% chlorhexidine gluconate solution).

We 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 approved draft labeling [immediate container (lidding), applicator barrel and carton labels submitted on May 20, 2004], and must be formatted in accordance with the requirements of 21 CFR 201.66.

We note that these changes have not been applied to the 3.0-mL Applicator, also marketed under this NDA.

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-006." 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}

Charles Ganley, M.D.
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/

Charles Ganley
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