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 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 also refer to our June 10, 2004, approval letter for this "Changes Being Effected" supplemental new drug application. We write to acknowledge that the labeling revisions apply only to the 10.5-mL container size, and not to the 3.0-mL container size. Therefore, the approval letter should have referenced only the 10.5-mL container size, and not the 3.0-mL container size.

You will receive a corrected action letter dated the same as the original action letter (June 10, 2004). If you have any questions, call Tia Frazier, Project Manager, at 301-827-2271.

Sincerely yours,

{See appended electronic signature page}

Charles Ganley, M.D.
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/

Charles Ganley
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