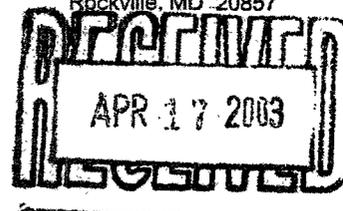




DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857



NDA 20-832/S-005

Beckloff Associates, Inc.
Attention: Diane Beatty, Ph.D.
Director, Scientific and Technical Services
7400 West 110th Street, Suite 720
Overland Park, KS 66210

Dear Dr. Beatty:

We have received your supplemental new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: chlorhexidine gluconate 2% (w/v) solution
Date of Application: March 11, 2003
Date of Receipt: March 12, 2003
Our Reference Number: NDA 20-832/S-005

This supplement proposes a new 26-mL applicator for pre-operative skin preparation. Clinical data is required to support the safety of this product in perioperative environments.

We have not received the appropriate user fee for this application. An application is considered incomplete and cannot be accepted for filing until all fees owed have been paid. Therefore, this application is not accepted for filing. We will not begin a review of this application's adequacy for filing until FDA has been notified that the appropriate fee has been paid. Payment should be submitted to the following address:

Food and Drug Administration
P.O. Box 360909
Pittsburgh, PA 15251-6909

Checks sent by a courier should be addressed to:

Food and Drug Administration (360909)
Mellon Client Service Center, Room 670
500 Ross Street
Pittsburgh, PA 15262-0001

NOTE: This address is for courier delivery only. Make sure the FDA Post Office Box Number (P.O. Box 360909) and user fee identification number are on the enclosed check.

The receipt date for this submission (which begins the review for filability) will be the date the review division is notified that payment has been received by the bank.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Products, HFD-560
Attention: Division Document Room, N115
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Products, HFD-560
Attention: Division Document Room, N115
9201 Corporate Blvd.
Rockville, Maryland 20850

You are encouraged to contact us prior to notification that you have paid the appropriate user fee, so that we can discuss what clinical studies will be necessary to support approval of this 26-mL applicator.

If you have any questions, call Tia Frazier, Project Manager, at 301-827-2271.

Sincerely yours,

{See appended electronic signature page}

David Hilfiker
Chief, Project Management Staff
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/

David Hilfiker
4/9/03 03:36:26 PM