CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-555

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-555

Beckloff Associates, Inc. [U.S. Agent for Medi-Flex Hospital Products, Inc.]
Attention: Michael C. Beckloff
President and Chief Executive Officer
7400 West 110th Street, Suite 750
Overland Park, Kansas 66210

Dear Mr. Beckloff:

Please refer to your new drug application (NDA) dated December 10, 2001, received December 12, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep® One-Step Sepp® Applicators (2% chlorhexidine gluconate solution).

We acknowledge receipt of your submissions dated April 19, May 6, September 12 and 30, and October 2 and 3, 2002.

This new drug application provides for the use of Chloraprep® One-Step Sepp® Applicators (2% chlorhexidine gluconate solution) for the following indications:

- Patient preoperative skin preparation
- Patient pre-injection preparation

We have completed the review of this application, as amended, and it 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 draft labeling (carton and immediate container labels submitted October 3, 2002), and must be in the *Drug Facts* format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and *Drug Facts* format may render the product misbranded, and an unapproved new drug.

Submit copies of 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, but no more than 30 days after it is printed. Individually mount 10 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-555.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55). Based on the information submitted, we conclude that you have fulfilled the

pediatric study requirement at this time for children 2 months of age and older. Additionally, the pediatric study requirement has been waived for children under 2 months of age because of safety concerns with the use of ChloraPrep® in this age group.

In addition, we request that you submit four copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Infective Drug Products and one to the Division of Over-the-Counter Drug Products, and two copies of both the promotional materials directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product to the Division of Over-the-Counter Drug Products, when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

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

Sincerely,

/S/

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research

/S/

{See appended electronic signature page}

Janice Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Center for Drug Evaluation and Research

Attachment

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth
10/4/02 03:59:38 PM

Charles Ganley
10/7/02 11:03:01 AM