CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-832

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

NDA 20-832

Food and Drug Administration
Rockville MD 20857

JUL 14 2000

Beckloff Associates, Inc. [Agent for Medi-Flex Hospital Products, Inc.]
Attention: Michael C. Beckloff
President and Chief Executive Officer
Commerce Plaza II, Suite 720
West 110th Street
Overland Park, Kansas 66210

Dear Mr. Beckloff:

Please refer to your new drug application (NDA) dated January 13, 2000, received January 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep® (Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v) Topical Solution.

We acknowledge receipt of your submissions dated February 3, and 21, March 16, April 6, May 11 and 25, June 8, and July 7, 11, 12, (2 facsimiles) and 13, (facsimile) 2000. Your submission of January 14, 2000 constituted a complete response to our February 20, 1998 action letter.

This new drug application provides for the use of ChloraPrep® (Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v) One-Step as a patient preoperative skin preparation.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling and must be formatted in accordance with the requirements of 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.

Please 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 ten of the copies on heavy-weight paper or similar material. Alternately, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 20-832." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We note 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, please submit two copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Anti-Infective Drug Products and one copy to the Division of Over-the-Counter Drug Products. For administrative purposes, this submission should be sent to the NDA and should be identified as new correspondence to approved NDA 20-832.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, contact Thomas Parmelee, Pharm.D., Project Manager, at (301) 827-2222.

Sincerely,

/S/

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

/S/

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosures