DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-004

Beckloff Associates
U.S. Agent for Medi-Flex, Inc.
Attention: Diane Beatty, Ph.D.
Senior Director, Pharmaceutical Development
Commerce Plaza II, Suite 720
7400 West 110th Street
Overland Park, Kansas 66210

Dear Dr. Beatty:

Please refer to your supplemental new drug application dated August 7, 2002, received August 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 2% chlorhexidine gluconate solution packaged in a 10.5 mL applicator.

We also acknowledge receipt of your submissions dated September 4, 2002, October 11 and 25, 2002, January 23 and 31, 2003, and February 20 and 24, 2003.

Your submission of February 20, 2003, constituted a complete response to our February 6, 2003, action letter.

This supplemental new drug application provides for a 10.5 mL applicator for pre-operative skin preparation.

We have 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 enclosed labeling [immediate container (lidding) and carton labels submitted February 20, 2003], and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry entitled 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 ten 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-004." 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, please 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

Enclosure

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

/s/

Curtis Rosebraugh
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