DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-008

Medi-Flex, Inc.
Attention: Linda McBride, R.Ph.
Director, Regulatory Affairs
11400 Tomahawk Creek Parkway, Suite 310
Leawood, Kansas 66211

Dear Ms. McBride:

Please refer to your supplemental new drug application dated July 6, 2004, received July 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep with Tint (2% chlorhexidine gluconate w/v and 70% isopropyl alcohol v/v solution).

We acknowledge receipt of your submissions dated December 31, 2004, and January 25, May 2 and May 3, 2005.

Your submission of December 31, 2004 constituted a complete response to our November 5, 2004 action letter.

This supplemental new drug application proposes a newly-designed applicator with a sponge tip (pledget) impregnated with FD&C Green #3 dye for preoperative 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 (package insert dated May 3, 2005, immediate container (lidding) labeling dated May 2, 2005, and Applicator Barrel labeling dated May 2, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-832/S-008**." 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, call Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription 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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