DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-010

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

Dear Ms. McBride:

Please refer to your supplemental new drug application submitted May 6, 2005 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep® (2% chlorhexidine gluconate (w/v) and isopropyl alcohol 70% v/v) topical solution.

Your submission of November 17, 2005 constituted a complete response to our November 7, 2005 action letter.

This supplemental new drug application proposes a 10.5-mL applicator for preoperative skin preparation with a sponge tip (pledget) impregnated with FD&C Green #3 dye and a new trade name, ChloraPrep with Tint 10.5-mL Applicator.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter. The labeling submitted on December 21, 2005 to your August 29, 2005 supplemental new drug application (S-011), approved December 27, 2005, supersedes the labeling submitted in this supplement. Therefore, this supplement is approved for use as recommended in the final printed labeling (FPL) submitted in your December 21, 2005 supplemental new drug application to Supplement 011.

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 submissions "**FPL for approved supplement NDA 20-832/S-010**." 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Laura Shay, Regulatory Project Manager, at (301) 796-0994.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Andrea Segal

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