DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-012

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 dated February 8, 2006, received February 9, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep® (2% chlorhexidine gluconate (w/v) topical solution).

We acknowledge receipt of your submissions dated June 15, August 8, 9, and 10, October 12 and 13, and November 8, 2006.

This supplemental application proposes to revise the warning statement "Do not use with electrocautery procedures" to "Do not use with electrocautery procedures until dry" for the ChloraPrep® One-Step Frepp® 1.5-mL, 3-mL and 10.5-mL applicators and the ChloraPrep® with Tint [redacted] 10.5-mL and [redacted] applicator. Due to distinct safety issues related to the [redacted]. This letter only pertains only to the ChloraPrep® One-Step Frepp® 1.5-mL, 3-mL and 10-mL applicators and the ChloraPrep® with Tint [redacted])10.5-mL applicator.

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 agreed upon labeling text (the lidding, outer carton, Drug Facts, and package insert submitted on November 8, 2006) and must be formatted in accordance with the requirements of 21 CFR 201.66.

In addition, within 180 days or at the time of next printing, separate the statement of identity from the promotional statement on the ChloraPrep® One-Step Frepp® 1.5-mL carton label.

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-012**." 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

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

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy 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/

Joel Schiffenbauer

12/8/2006 12:13:20 PM