DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-011
NDA 21-555/S-005

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 [NDA 20-832/S-011] dated August 29, 2005, received August 30, 2005, 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 solution).

We acknowledge receipt of your submissions dated December 21 and 22, 2005.

We also refer to your supplemental new drug application [NDA 21-555/S-005] dated September 30, 2005, received October 3, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the ChloraPrep One-Step 0.67-mL Sepp Applicator (chlorhexidine gluconate 2% w/v and isopropyl alcohol 70% v/v solution).

We acknowledge receipt of your submissions dated December 21 and 22, 2005.

These supplemental new drug applications provide for a change of the labeled storage temperature conditions for the following topical antiseptic applicators approved under the above-referenced NDAs:

ChloraPrep One-Step Frepp 1.1-mL
ChloraPrep One-Step 3.0-mL and 10.5-mL
ChloraPrep with Tint 10.5-mL and 26-mL
ChloraPrep Sepp 0.67-mL

We have completed our review of these applications, as amended. These applications are 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 submitted labeling [0.67-mL Sepp carton (dispenser) labeling submitted December 22, 2005, 1.5-mL Frepp carton (dispenser) labeling submitted December 21, 2005, Chloraprep One-Step 3.0-mL carton (dispenser) labeling submitted December 21, 2005, Chloraprep One-Step 3.0-mL immediate container (lidding) labeling submitted December 22, 2005, Chloraprep One-Step 10.5-mL carton (dispenser) and immediate container (lidding) labeling submitted on December 21, 2005, Chloraprep with Tint 10.5-mL carton (dispenser) and immediate container (lidding) labeling submitted December 21, 2005, and Chloraprep with Tint

26.0-mL immediate container (lidding) labeling submitted December 21, 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 these submissions "**FPL for approved supplements NDA 20-832/S-011 and NDA 21-555/S-005**." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs 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 (21 CFR 314.80 and 314.81).

If you have any questions, call Tia Frazier, Regulatory Project Manager, at (301) 796-0890.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Acting 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

12/27/2005 02:04:52 PM