**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-015

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 May 26, 2006, received May 30, 2006, 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 submission dated November 3, 2006.

This "Changes Being Effected in 30 days" supplemental application proposes the marketing of a ChloraPrep® One-Step 26-mL applicator without tint.

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 submitted labeling (package insert, barrel label and lidding (with Drug Facts) submitted November 3, 2006), must be formatted in accordance with the requirements of 21 CFR 201.66 where applicable.

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-015**." Approval of this submission by FDA is not required before the labeling is used.

In addition, we request that you submit one copy of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print.

Please submit one market package of the drug product when it is available.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Laura E. Shay, Regulatory Project Manager, at (301) 796-0994.

Sincerely,

*{See appended electronic signature page}*

Susan Johnson, PhD
Associate Director
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/

---

Susan Johnson
11/21/2006 04:11:59 PM