DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-555/S-001

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

Dear Ms. McBride:

Please refer to your supplemental new drug application dated November 9, 2004, received November 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep Single Swabstick (2% w/v chlorhexidine gluconate swab).

We acknowledge receipt of your submission dated May 5, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new 1.75-mL packaging configuration.

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 submitted May 5, 2005, immediate container (pouch) and carton labels submitted May 5, 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 21-555/S-001**." 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 you propose to use for this product to the Division of Over-the-Counter Drug Products. Submit all proposed materials in draft or mock-up form, not final print.

We have recently become aware of additional packaging configurations and associated labeling proposed for this drug product. We remind you to submit any new packaging configurations to FDA for review prior to marketing.

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}
Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Charles Ganley
5/10/05 04:54:29 PM