DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-016

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, 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 submissions dated June 15, August 10, October 4 (2), and October 5, 2006.

This supplemental application proposes to revise the warning statement on all of the labeling "Do not use with electrocautery procedures" to "Do not use with electrocautery procedures until dry" for the ChloraPrep® with Tint 26-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 and with the minor editorial revisions listed below:

1. Revise the statements on the boxed warnings on the package insert which reads as follows:
   - avoid getting solution into hairy areas.
   - Solution may take much longer to dry or may not dry completely

   Revise these statements to read as:
   - avoid getting solution into hairy areas. Solution may take much longer to dry or may not dry completely.

2. Revise the letter "S" in "Solution" in the second and fourth bulleted statements to a lowercase letter on the boxed warnings on the barrel label.

3. Print the telephone number in bold face type in the ***Drug Facts*** label in accordance with 21 CFR 201.66(c) (9).

The final printed labeling (FPL) must be identical to, and include the revisions listed, the submitted labeling (package insert submitted October 5, 2006, and the barrel label and lidding (with Drug Facts) submitted October 4, 2006), must be formatted in accordance with the requirements of 21 CFR 201.66 where applicable. These revisions are terms of the approval of this application.

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-016**." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated October 4, 2006. This commitment is listed below.

1. Demonstrate the drying time and vapor dissipation of the 6-mL and 26-mL solution in hair, at least shoulder length, under normal surgical suite conditions.

Protocol Submission:	by December 28, 2006
Study Start:	by March 28, 2007
Final Report Submission:	by June 28, 2008

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

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}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
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/

Joel Schiffenbauer

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