DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-022

Cardinal Health
Attention: Michael Baltezor, Ph.D.
Chief Scientific Officer
11400 Tomahawk Creek Parkway
Suite 310
Leawood, KS 66211

Dear Dr. Baltezor:

Please refer to your supplemental new drug application dated April 17, 2008, received April 18, 2008, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep® (chlorhexidine gluconate 2% (w/v) and isopropyl alcohol 70% (v/v)) topical solution.

This supplemental new drug application proposes to add a 1.0 mL applicator, with associated labeling, to the current line of applicators.

We have completed our review of this application. 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 revision that you committed to in your October 15, 2008 email listed below:

- Remove the terminal zero where it appears in "1.0-mL" on the lidding and carton label.

Also, your request for a 36 month expiry period based on the analysis of the statistical data comparing the three year stability of the 0.67 mL Sepp and 1.5 mL Frepp application is granted.

The final printed labeling (FPL) must be identical to, and include the revision listed, the enclosed labels (carton label with ***Drug Facts*** and applicator lidding label) along with the agreed upon minor revision, and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable. This revision is a term 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-022**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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
Suite 12B05
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 Mary Lewis, Regulatory Project Manager, at (301) 796-0941.

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

10/23/2008 06:15:17 AM