DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-832/S-014

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 24, 2006, received April 25, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep® (chlorhexadine gluconate 2% w/v and isopropyl alcohol 70% w/v) topical solution.

We acknowledge receipt of your submission dated December 4, 2007, received December 5, 2007.

Your submission of December 4, 2007 constituted a complete response to our October 24, 2006 action letter.

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days," proposes ChloraPrep® With Tint 3-mL, 10.5-mL, and 26-mL applicators containing a pledget impregnated with FD&C Yellow # 6 dye for nonprescription marketing for the currently approved indication of patient preoperative skin preparation.

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 revision listed below.

> On the 26 mL applicator lidding under the ***Drug Facts Warnings*** heading, "**Stop use and ask a doctor if**" subheading, the word "irritation" should not be in bold-face type. This revision should be made at the time of next printing or within 180 days, whichever comes first.

The final printed labeling (FPL) must be identical to, and include the revision listed, the submitted labeling (package insert submitted December 4, 2007, applicator lidding for the 3 mL, 10.5 mL, and 26 mL applicators submitted December 4, 2008, the carton labels for the 3 mL and 10.5 mL applicators submitted December 4, 2007, and the barrel labels for the 10.5 mL and 26 mL applicators), and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable. The 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-014**." Approval of this submission by FDA is not required before the labeling is used.

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

Please also note the following:

1. Due to the discrepancy in surface area between the approved treatment area for the 26 mL applicator and the study template sizes, we recommend that you use a smaller applicator (e.g., 10.5 mL) in any future efficacy studies that will be used to demonstrate equivalence.

2. For any future studies, we recommend that you recruit subjects of a broad variety of races and ages to better reflect the intended patient population for these products.

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 Robin Anderson Duer, Regulatory Project Manager, at (301) 796-0534.

Sincerely,

{See appended electronic signature page}

Andrea Leonard Segal, M.D.
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

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