DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-555/S-003

Cardinal Health
Attention: Michael Baltezor, Ph.D., Vice President
Research and Development
11400 Tomahawk Creek Parkway, Suite 310
Leawood, Kansas 66211

Dear Dr. Baltezor:

Please refer to your supplemental new drug application dated May 13, 2005, received May 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ChloraPrep (2%w/v chlorhexidine gluconate/70%v/v isopropyl alcohol) solution.

We acknowledge receipt of your submissions dated December 8, 2008, February 11, March 13 and 20, April 17, May 12, June 2, and June 10, 2009.

Your submission of December 8, 2008 constitutes a complete response to our action letter date November 16, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application provides revised labeling based on a final report for ChloraPrep Triple Swabsticks protocol MBT 371-121 entitled, "Test for Preoperative Skin Preparations".

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.

Submit final printed labeling (FPL) as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the enclosed labeling (inner carton, immediate container (foil pouch), and Drug Facts package insert submitted on June 10, 2009). These must be in the "Drug Facts" format (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 – Human Pharmaceutical Product Application and Related Submissions Using the eCTD Specifications (October 2005).* 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 "**Final Printed Labeling (FPL) for approved NDA 21-555/S-003**." 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

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