DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021555/S-015 **SUPPLEMENT APPROVAL**

CareFusion
Attention: Cynthia Kirk, Ph.D.
Vice President, Regulatory Affairs
11400 Tomahawk Creek Parkway
Suite 310
Leawood, KS 66211

Dear Dr. Kirk:

Please refer to your Supplemental New Drug Application (sNDA) dated January 22, 2010, received January 26, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ChloraPrep® [chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)] solution.

We acknowledge receipt of your amendments dated March 17 and 19, 2010.

This "Prior Approval" supplemental new drug application proposes a labeling change to the "Drug Facts" box "Use" section to add the statement, "Helps to reduce bacteria that potentially can cause skin infection" ChloraPrep® One-Step Sepp® 0.67-mL, ChloraPrep® One-Step 1.75-mL single swabstick, and ChloraPrep® One-Step 5.25-mL triple swabstick drug products.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the submitted labeling (ChloraPrep® One-Step Sepp® 0.67-mL carton label and package insert, ChloraPrep® One-Step 1.75-mL single swabstick carton label and package insert, and ChloraPrep® One-Step 5.25-mL triple swabstick carton label submitted March 17, 2010 and the ChloraPrep® One-Step 5.25-mL triple swabstick package insert submitted March 19, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021555/S-015**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Larry Bauer, Regulatory Project Manager, at (301) 796-4842.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21555	SUPPL-15	ENTURIA INC	CHLORAPREP (CHLORHEXIDINE GLUCONATE)

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
07/20/2010