DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-832/S-025 **SUPPLEMENT APPROVAL**

CareFusion 213 LLC
Attention: Mike Baltezor, Ph.D.,
V.P., Research and Development
11400 Tomahawk Creek Parkway, Suite 310
Leawood, KS 66211

Dear Dr. Baltezor:

Please refer to your supplemental new drug application dated September 3, 2009, received September 4, 2009, 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 submissions dated January 15, 29, and February 26, 2010.

This "Changes Being Effected" supplemental new drug application provides for revised flammability warning statements to the labeling for the ChloraPrep® One-Step 1.0-mL applicator, ChloraPrep® One-Step 1.5-mL Frepp® applicator, ChloraPrep® One-Step 3-mL applicator, ChloraPrep® One-Step 10.5-mL applicator, ChloraPrep® One-Step 26-mL applicator, ChloraPrep® With Tint (FD&C Green #3) 3-mL applicator, ChloraPrep® With Tint (FD&C Green #3) 10.5-mL applicator, ChloraPrep® With Tint (FD&C Green #3) 26-mL applicator, ChloraPrep® With Tint (FD&C Yellow #6) 3-mL applicator, ChloraPrep® With Tint (FD&C Yellow #6) 10.5-mL applicator, ChloraPrep® With Tint (FD&C Yellow #6) 26-mL applicator products in response to the August 4, 2009 supplemental labeling request letter.

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 (FPL) 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 as follows, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

**Labeling submitted February 26, 2010**

Clear Solution

- ChloraPrep® One-Step 1.0-mL carton label
- ChloraPrep® One-Step 1.5-mL Frepp® carton label

- ChloraPrep® One-Step 3-mL immediate container (lidding) and carton label
- ChloraPrep® One-Step 10.5-mL immediate container (lidding) and carton label
- ChloraPrep® One-Step 26-mL immediate container (lidding)

Green Tint Solution

- ChloraPrep® With Tint (Green) 3-mL immediate container (lidding) and carton label
- ChloraPrep® With Tint (Green) 10.5-mL immediate container (lidding) and carton label
- ChloraPrep® With Tint (Green) 26-mL immediate container (lidding)

Yellow Tint Solution

- ChloraPrep® With Tint (Yellow) 3-mL immediate container (lidding) and carton label
- ChloraPrep® With Tint (Yellow) 10.5-mL immediate container (lidding) and carton label
- ChloraPrep® With Tint (Yellow) 26-mL immediate container (lidding)

**Labeling submitted September 3, 2009**

Clear Solution

- ChloraPrep® One-Step 1.5-mL Frepp® immediate container (lidding)
- ChloraPrep® One-Step 3-mL package insert
- ChloraPrep® One-Step 10.5-mL package insert and immediate container (handle)
- ChloraPrep® One-Step 26-mL package insert and immediate container (handle)

Green Tint Solution

- ChloraPrep® With Tint (Green) 10.5-mL immediate container (handle)
- ChloraPrep® With Tint (Green) 26-mL immediate container (handle)

Yellow Tint Solution

- ChloraPrep® With Tint (Yellow) 10.5-mL immediate container (handle)
- ChloraPrep® With Tint (Yellow) 26-mL immediate container (handle)

Package inserts for all tinted products

- ChloraPrep® With Tint 3-mL
- ChloraPrep® With Tint 10.5-mL
- ChloraPrep® With Tint 26-mL

**Labeling Submitted January 29, 2010**

- ChloraPrep® One-Step 1.0-mL Applicator immediate container (lidding)

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 20-832/S-025**." Approval of this submission by FDA is not required before the labeling is used.

## LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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 Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-20832 | SUPPL-25 | ENTURIA INC | CHLORAPREP |

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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JOEL SCHIFFENBAUER
03/03/2010