DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020832/S-031
NDA 021555/S-018

SUPPLEMENT APPROVAL

CareFusion
Attention: Carolyn E. Lindsey, RAC
Manager, Regulatory Affairs
11400 Tomahawk Creek Parkway, Suite 310
Leawood, KS 66211

Dear Ms. Lindsey:

Please refer to your Supplemental New Drug Applications (sNDAs) dated May 8, 2013, received May 10, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following products:

> **NDA 020832** ChloraPrep® [chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)] solution
>
> **NDA 021555** ChloraPrep® [chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)] solution

We acknowledge receipt of your amendments dated July 8, August 2, 5, and 13, 2013.

These "Prior Approval" supplemental new drug applications provide for labeling modifications of the following products: ChloraPrep single and triple swabsticks, and ChloraPrep SEPP, FREPP, and 1-mL applicators to include

- a "do not use with electrocautery procedures" statement
- modification of the 3-mL applicators to include a revised statement "if using an ignition source, allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)."
- modification of the 3-mL applicators (clear, teal, and yellow) to include the statement "Applicator is sterile if package is intact"
- and other minor editorial changes.

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 with the following minor editorial revision:

> Revise the statement "1-mL FREPP APPLICATOR" to read
> "1-mL APPLICATOR" on the 1-mL applicator lidding.

You also have the option of implementing the minor editorial revisions noted below:

1. Acceptable optional minor editorial revisions:
    a. The warning statement "WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME." that currently appears in red in the draft labeling may be changed to black (i.e., single color labeling).

    b. You have the option to completely remove the warning statement "WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME." located outside the ***Drug Facts*** box for the 0.67-mL SEPP, 1.5-mL FREPP, Single Swabstick, and Triple Swabstick.

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 following labels submitted on August 2, 2013: outer carton, secondary packaging, and package inserts for the 1-mL applicator, 1.5-mL Frepp and 3-mL applicators (clear, teal, and orange) under NDA 020832 (S-031) and 0.67-mL Sepp under NDA 021555 (S-018), and for the outer carton, immediate container label, and package inserts for the Single Swabstick and Triple Swabstick under NDA 021555 (S-018), 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 (June 2008)." 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 020832/S-031 and NDA 021555/S-018".** Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 Celia Peacock, Regulatory Project Manager at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:
Carton and Container Labeling

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
10/10/2013