DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020832/ S-034
NDA 021555/ S-019

SUPPLEMENT APPROVAL

CareFusion
Attention: Erica Sethi, M.S.
Manager, Regulatory Affairs
75 North Fairway Drive
Vernon Hills, IL 60061

Dear Ms. Sethi:

Please refer to your Supplemental New Drug Applications (sNDA) dated January 8, 2014, received January 10, 2014, submitted under section 505(b)(2) 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 January 27 and 31, 2014.

These "Changes Being Effected" supplemental new drug applications provide for the revision of product labels to indicate the non-sterility of your drug product, as per the November 14, 2013, FDA Changes Being Effected (CBE) Supplement Request letter requesting labeling changes for topical antiseptic drug products indicated for patient preoperative skin preparation and preinjection skin preparation.

We have completed our review of these applications, as amended. They are 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 following:

Labeling submitted January 8, 2014

NDA 20-832

- ChloraPrep® One-Step 1-mL: 20-count outer carton, secondary packaging (applicator lidding), and package insert for 20-count outer carton
- ChloraPrep® One-Step 1.5-mL: secondary packaging (applicator lidding) and package insert (front and back) for 20-count outer carton
- ChloraPrep® One-Step 3-mL: 25-count outer carton and secondary packaging (applicator lidding)

- ChloraPrep® With Tint (Teal and Orange) 3-mL: 25-count outer carton and secondary packaging (applicator lidding)
- ChloraPrep® One-Step and ChloraPrep® With Tint 3-mL package insert for 25-count outer carton
- ChloraPrep® One-Step 10.5-mL: 25-count outer carton and secondary packaging (applicator lidding)
- ChloraPrep® With Tint (Teal and Orange) 10.5-mL: 25-count outer carton and secondary packaging (applicator lidding)
- ChloraPrep® One-Step and ChloraPrep® With Tint 10.5-mL package insert for 25-count outer carton
- ChloraPrep® One-Step 26-mL: secondary packaging (applicator lidding)
- ChloraPrep® With Tint (Teal and Orange) 26-mL: secondary packaging (applicator lidding)
- ChloraPrep® One-Step and ChloraPrep® With Tint 26-mL package insert

NDA 21-555

- ChloraPrep® One-Step Sepp 0.67-mL: 200-count outer carton and package insert for 200-count outer carton
- ChloraPrep® One-Step Single Swabstick 1.75-mL: 48-count outer carton and immediate container (foil pouch)
- ChloraPrep® One-Step Single Swabstick 1.75-mL and ChloraPrep® One-Step Triple Swabstick 5.25-mL package insert
- ChloraPrep® One-Step Triple Swabstick 5.25-mL: 40-count outer carton and immediate container (foil pouch)

Labeling submitted January 27, 2014

NDA 20-832

- ChloraPrep® One-Step 10.5-mL: immediate container (applicator handle)
- ChloraPrep® With Tint (Teal and Orange) 10.5-mL: immediate container (applicator handle)
- ChloraPrep® One-Step 26-mL: immediate container (applicator handle) right and left
- ChloraPrep® With Tint (Teal and Orange) 26-mL: immediate container (applicator handle) right and left

Labeling submitted January 31, 2014

NDA 20-832

- ChloraPrep® One-Step Frepp 1.5-mL: 20-count outer carton
  NDA 21-555
- ChloraPrep® One-Step Sepp 0.67-mL: secondary packaging (applicator lidding)

Submit these labels 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-034" and "NDA 021555 / S-019".** 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}

Theresa Michele, M.D.,
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/

DANIEL BRUM
06/30/2014
Signed on behalf of Dr. Theresa Michele