DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020832/ S-027
NDA 020832/ S-028
NDA 021555/ S-016

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 Application (sNDA) dated February 21, 2012, received February 22, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

> 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 amendment dated August 8, 2012.

The February 21, 2012 submission constituted a complete response to our December 29, 2011 action letter.

This "Changes Being Effected" labeling supplemental new drug application provides for a class labeling change requested by the FDA for alcohol-based topical antiseptic products, to include a more specific warning regarding the length of time required for the hair to dry prior to use.

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 and with the minor editorial revisions listed below/indicated in the enclosed labeling.

1. For the 3-mL package insert, move the hairline from below the "Do not use" subheader to be relocated above the "Do not use" subheader in accordance with 21 CFR 201.66 (d)(8).

2. For the 3-mL, 10.5-mL, and 26-mL package inserts, we recommend that the letter "t" in the word "the" be in lower case after the third bullet under *Other*

information so that it reads "■ the tint will slowly fade from the skin. Soap and water or alcohol may be used to remove the tint if desired."

3. For all *Drug Facts* labeling under *Use*, remove the colon and replace it with a period to separate the following statements to read "for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection."

LABELING

Submit final printed labeling, with the revisions listed above, 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 labeling listed below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Labeling submitted February 21, 2012

1. ChloraPrep® One-Step 1-mL 20-count outer carton
2. ChloraPrep® One-Step 1-mL Secondary packaging (applicator lidding)
3. ChloraPrep® One-Step Frepp 1.5-mL Secondary Packaging (applicator lidding)
4. ChloraPrep® One-Step Frepp 1.5-mL Package insert (front and back) for 20-count outer carton
5. ChloraPrep® One-Step 3-mL 25-count outer carton
6. ChloraPrep® One-Step 3-mL Secondary packaging (applicator lidding)
7. ChloraPrep® With Tint (Green) 3-mL 25-count outer carton
8. ChloraPrep® With Tint (Green) 3-mL Secondary packaging (applicator lidding)
9. ChloraPrep® With Tint (Yellow) 3-mL 25-count outer carton
10. ChloraPrep® With Tint (Yellow) 3-mL Secondary packaging (applicator lidding)
11. ChloraPrep® One-Step 10.5-mL 25-count outer carton
12. ChloraPrep® One-Step 10.5-mL immediate container (applicator handle)
13. ChloraPrep® One-Step 10.5-mL Secondary packaging (applicator lidding)
14. ChloraPrep® With Tint (Green) 10.5-mL immediate container (applicator handle)
15. ChloraPrep® With Tint (Green) 10.5-mL Secondary packaging (applicator lidding)
16. ChloraPrep® With Tint (Yellow) 10.5-mL 25-count outer carton
17. ChloraPrep® With Tint (Yellow) 10.5-mL immediate container (applicator handle)
18. ChloraPrep® With Tint (Yellow) 10.5-mL Secondary packaging (applicator lidding)
19. ChloraPrep® One-Step Sepp 0.67-mL 200-count outer carton
20. ChloraPrep® One-Step Sepp 0.67-mL Secondary packaging (applicator lidding)
21. ChloraPrep® One-Step Sepp 0.67-mL Package insert for 200-count outer carton
22. ChloraPrep® One-Step Single Swabstick 1.75-mL Immediate container (foil pouch)
23. ChloraPrep® Triple Swabstick 5.25-mL Immediate container (foil pouch)

Labeling submitted August 8, 2012

24. ChloraPrep® One-Step 1-mL Package insert for 20-count outer carton
25. ChloraPrep® One-Step Frepp 1.5-mL 20-count outer carton
26. ChloraPrep® One-Step & ChloraPrep® With Tint 3-mL Package insert for 25-count outer carton
27. ChloraPrep® One-Step & ChloraPrep® With Tint 10.5-mL Package insert for 25-count outer carton
28. ChloraPrep® With Tint (Green) 10.5-mL 25-count outer carton
29. ChloraPrep® One-Step 26-mL Immediate container (applicator handle)
30. ChloraPrep® One-Step 26-mL Secondary packaging (applicator lidding)
31. ChloraPrep® One-Step & ChloraPrep® With Tint 26-mL Package insert
32. ChloraPrep® With Tint (Green) 26-mL Immediate container (applicator handle)
33. ChloraPrep® With Tint (Green) 26-mL Secondary packaging (applicator lidding)
34. ChloraPrep® With Tint (Yellow) 26-mL Immediate container (applicator handle)
35. ChloraPrep® With Tint (Yellow) 26-mL Secondary packaging (applicator lidding)
36. ChloraPrep® Single Swabstick 1.75-mL & Triple Swabstick 5.25-mL Package insert for 48-count outer carton (Single Swabstick) and 40-count outer carton (Triple Swabstick)
37. ChloraPrep® One-Step Single Swabstick 1.75-mL 48-count outer carton
38. ChloraPrep® Triple Swabstick 5.25-mL 40-count outer carton

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-027, NDA 020832/ S-028, and NDA 021555/ S-016**."

Approval of this submission by FDA is not required before the labeling is used.

Please note that the attached labeling also includes the changes found in the NDA 020832/S-030 and NDA 021555/S-017 approval letter which provided for the addition of warnings regarding use of CHG products in infants.

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.

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 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
08/16/2012