DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020832/S-042

SUPPLEMENT APPROVAL

Becton, Dickinson, and Company
Attention: Erica Sethi, MS
Manager, Regulatory Affairs
75 North Fairway Drive
Vernon Hills, IL 60061

Dear Ms. Sethi:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 15, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act (FDCA) for ChloraPrep® (chlorhexidine gluconate 2% (w/v) isopropyl alcohol 70% (v/v)) topical solution.

This "Changes Being Effected "sNDA proposes the addition of the "Allergy alert" warning and related changes in accordance with the "Changes Being Effected" (CBE-0) Request Letter from the Agency dated February 2, 2017.

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 incorporation of the minor editorial changes noted below:

> Under the Drug Facts labeling "**Warnings**" heading, reformat the allergic reaction warning subheading by changing the first letter in "Alert" to lower case and inserting a colon after the "t" to appear as "**Allergy alert:**" as required under 21 CFR 201.66(c)(5)(ii)(B) and (d)(1).

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 listed labeling, after incorporating the changes specified above, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Labeling submitted March 15, 2017

- ChloraPrep® One-Step 1 mL applicator secondary packaging
- ChloraPrep® One-Step FREPP® 1.5 mL applicator secondary packaging version 1
- ChloraPrep® One-Step FREPP® 1.5 mL applicator secondary packaging version 2
- ChloraPrep® One-Step 10.5 mL Clear applicator handle label
- ChloraPrep® One-Step 10.5 mL Hi-Lite Orange® applicator handle label

- ChloraPrep® One-Step 10.5 mL Teal® applicator handle label
- ChloraPrep® One-Step 26 mL Clear applicator handle right label
- ChloraPrep® One-Step 26 mL Clear applicator handle left label
- ChloraPrep® One-Step 26 mL Hi-Lite Orange® applicator handle right label
- ChloraPrep® One-Step 26 mL Hi-Lite Orange® applicator handle left label
- ChloraPrep® One-Step 26 mL Teal® applicator handle right label
- ChloraPrep® One-Step 26 mL Teal® applicator handle left label

Labeling submitted June 29, 2017

- ChloraPrep® One-Step 1 mL applicator 60-count carton
- ChloraPrep® One-Step 1 mL applicator package insert
- ChloraPrep® One-Step FREPP® 1.5 mL applicator 20-count carton
- ChloraPrep® One-Step FREPP® 1.5 mL applicator package insert
- ChloraPrep® One-Step 3 mL Clear applicator 25-count carton
- ChloraPrep® One-Step 3 mL Clear applicator secondary packaging
- ChloraPrep® With Tint 3 mL Hi-Lite Orange® applicator 25-count carton
- ChloraPrep® With Tint 3 mL Hi-Lite Orange® applicator secondary packaging
- ChloraPrep® One-Step & ChloraPrep® With Tint 3 mL applicator package insert
- ChloraPrep® One-Step 10.5 mL Clear applicator 25-count carton
- ChloraPrep® One-Step 10.5 mL Clear applicator secondary packaging
- ChloraPrep® One-Step 10.5 mL Hi-Lite Orange® applicator 25-count carton
- ChloraPrep® One-Step 10.5 mL Hi-Lite Orange® applicator secondary packaging
- ChloraPrep® One-Step 10.5 mL Teal® applicator 25-count carton
- ChloraPrep® One-Step 10.5 mL Teal® applicator secondary packaging
- ChloraPrep® One-Step & ChloraPrep® With Tint 10.5 mL applicator package insert
- ChloraPrep® One-Step 26 mL Clear applicator secondary packaging
- ChloraPrep® One-Step 26 mL Hi-Lite Orange® applicator secondary packaging
- ChloraPrep® One-Step 26 mL Teal® applicator secondary packaging
- ChloraPrep® One-Step & ChloraPrep® With Tint 26 mL applicator package insert

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020832/S-042**." 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 CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,
{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
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/

VALERIE S PRATT
09/12/2017