NDA 021555/S-028

SUPPLEMENT APPROVAL

Becton, Dickinson and Company
Attention: Shelley Wilcox
Staff Specialist, Regulatory Affairs
75 North Fairway Drive
Vernon Hills, IL 60061

Dear Shelley Wilcox:

Please refer to your supplemental new drug application (sNDA) dated and received March 8, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ChloraPrep Single Swabstick and Triple Swabsticks [chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)], swab.

We acknowledge receipt of your amendment dated May 4, 2023, which constituted a complete response to our September 8, 2021, action letter.

This "Prior Approval" supplemental new drug application provides for the following:

- Addition of a new sterile drug product solution for the 1.75 mL Single Swabstick and 5.25 mL Triple Swabsticks
- Labeling changes including removal of the pre-injection indication for use and addition of sterile verbiage
- Change to the foil pouch materials and manufacturer
- Change to the swabstick materials and dimension

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling, described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date of Submission
1.75 mL Single Swabstick applicator 48-count outer carton	July 28, 2023
1.75 mL Single Swabstick applicator secondary packaging (foil pouch)	July 28, 2023
5.25 mL Triple Swabsticks applicator 40-count outer carton	July 28, 2023
5.25 mL Triple Swabsticks applicator secondary packaging (foil pouch)	July 28, 2023
1.75 mL Single Swabstick and 5.25 mL Triple Swabsticks package insert	July 28, 2023

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021555/S-028**." 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[3]

If you have any questions, contact Xiaoxue Nehrbass, Regulatory Project Manager, at xiaoxue.nehrbass@fda.hhs.gov or (301) 796-1486.

Sincerely,

{See appended electronic signature page}

Pamela Horn, MD
Director, Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Outer Carton and Secondary Packaging Labeling
- Package Insert

[3] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PAMELA J HORN
08/30/2023 11:36:52 AM