

NDA 207964/S-003

SUPPLEMENT APPROVAL

Medline Industries, LP
Attention: Alannah Minarcik
Senior Regulatory Affairs Specialist
Three Lakes Drive
Northfield, IL 60093

Dear Ms. Minarcik:

Please refer to your supplemental new drug application (sNDA) dated and received December 14, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ReadyPrep CHG (chlorhexidine gluconate) cloth, 2%.

This “Changes Being Effected” supplemental new drug application provides for the addition of a new packaging configuration containing six cloths per pack.

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
6-count immediate container	January 20, 2023
32-count carton (shipping carton)	January 20, 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 207964/S-003.**” 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 product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.³

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>

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

If you have any questions, contact Xiaoxue Nehrbass, Regulatory Project Manager, at (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

ENCLOSURE(S):

- Carton and Container Labeling

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
05/24/2023 02:12:17 PM