NDA 017768/S-059

SUPPLEMENT APPROVAL

Molnlycke Health Care
Attention: Megan Bevill
Regulatory Affairs Director, Americas and Antiseptics
5445 Triangle Parkway
Suite 400
Peachtree Corners, GA 30092

Dear Megan Bevill:

Please refer to your supplemental new drug application (sNDA) dated and received February 2, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hibiclens (chlorhexidine gluconate) solution, 4% w/v.

This "Prior Approval" supplemental new drug application provides for the following labeling changes to the Hibiclens product line: (1) addition of "Helps reduce bacteria that potentially can cause disease" to the Principal Display Panel, and (2) complete rebranding of the 4 fl oz IFP bottle, 32 fl oz bottle, 1 gallon bottle, 15 mL packette and 15 mL packette dispenser box according to the scheme approved under S-056.

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, with the minor editorial revision listed below:

> For the 15 mL packette, revise the statement "Please refer to outer packaging for directions for use and products warnings." to read: "Please refer to outer packaging for directions for use and product warnings." by removing the letter "s" in "products".

LABELING

Submit final printed labeling (FPL), with the revision listed above, 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
4 fl oz carton	July 13, 2023
4 fl oz immediate container (bottle)	June 30, 2023
4 fl oz IFP immediate container (bottle)	June 30, 2023
8 fl oz carton	July 13, 2023
8 fl oz immediate container (bottle)	June 30, 2023
16 fl oz carton	July 13, 2023
16 fl oz immediate container (bottle)	June 30, 2023
32 fl oz immediate container (bottle)	June 30, 2023
1 gallon immediate container (bottle)	June 30, 2023
15 mL immediate container (packette)	July 13, 2023
15 mL packette retail box (50-count carton)	July 13, 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 017768/S-059**." 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).

[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

If you have any questions, contact Xiaoxue Nehrbass, Regulatory Project Manager, at xiaoxue.nehrbass@fda.hhs.gov, or 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
07/26/2023 11:06:16 AM