NDA 017768/S-063

SUPPLEMENT APPROVAL

Mölnlycke Health Care AB
Attention: Patcy Noella
Regulatory Affairs Manager
Entreprenörsstråket 21
Mölndal, 431 53
Sweden

Dear Patcy Noella:

Please refer to your supplemental new drug application (sNDA) dated and received July 7, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hibiclens (chlorhexidine gluconate) solution, 4% w/v.

This "Changes Being Effected" sNDA provides for minor modifications to the layout of the Drug Facts label for the 4 fl oz product.

APPROVAL & LABELING

We have completed our review of this application. 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 4 fl oz immediate container (NDC 0234-0575-04) labeling submitted July 7, 2025, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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-063**." Approval of this submission by FDA is not required before the labeling is used.

[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.

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).

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

Sincerely,

{See appended electronic signature page}

Melanie Blank, M.D., M.S.
Deputy Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Immediate Container Labeling

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

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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/

MELANIE J BLANK
10/29/2025 10:24:08 AM