DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018300/S-019

SUPPLEMENT APPROVAL

Mölnlycke Health Care
Attention: Megan Bevill
Manager, Regulatory Affairs
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092

Dear Ms. Bevill:

Please refer to your Supplemental New Drug Application (sNDA) dated November 16, 2017, received November 16, 2017, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hibistat® (chlorhexidine gluconate 0.5% and isopropyl alcohol 70%) cloth.

This "Changes Being Effected" supplemental new drug application provides to add an "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 change noted below:

For the following products:

- Hibistat® 15-count outer carton
- Hibistat® 50-count outer carton

Under the "**Warnings**" heading, include a period after the word "flame" to read: "**For external use only. Flammable, keep away from fire or flame.**"

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 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 on January 11, 2018

- 15-count outer carton
- 50-count outer carton
- 5 mL immediate container film

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 018300/S-019**." 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 Daniel Reed, Regulatory Project Manager, at (301) 796-2220.

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

ENCLOSURE(S):
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/

DANIEL H REED
04/19/2018

VALERIE S PRATT
04/19/2018