DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018300/S018

SUPPLEMENT APPROVAL

Molnlycke Health Care
Attention: Caitlin Senter
Regulatory Affairs Specialist
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092

Dear Ms. Senter:

Please refer to your Supplemental New Drug Application (sNDA) dated December 1, 2011, received, December 2, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hibistat (0.5% chlorhexidine gluconate solution and 70% isopropyl alcohol w/w).

We acknowledge receipt of your amendments dated January 31, May 2, and May 6, 2012.

This "Changes Being Effected" supplemental new drug application provides for changes in the Drug Facts labeling to add directions for use in infants.

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 following minor editorial revision:

- Remove the periods from the end of the second and third bulleted statements under ***Directions*** in ***Drug Facts***.

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 (FPL) must be identical to the enclosed 5-mL immediate container (foil pouch) and 50-count carton labels submitted on May 2, 2012, and the 15-count carton label submitted on May 6, 2012

This FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.
The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications

(June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 018300/S018**." 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 Celia Peacock, Regulatory Project Manager at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES
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/

JOEL SCHIFFENBAUER
05/24/2012