



NDA 017768/S-039

## 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 Hibiclens (4% w/v chlorhexidine gluconate) solution.

We acknowledge receipt of your amendments dated April 23, 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 revisions:

1. For the 4-ounce outer carton, 8-ounce immediate container and outer carton, 16-ounce immediate container, and 32-ounce immediate container, add more space between the headings **Active ingredient** and **Purpose** to differentiate them as separate headings. Ensure that the heading **Purpose** and the word Antiseptic are right justified as required by 21 CFR 201.66(d)(6).
2. For the 4-ounce immediate container, add a period to the end of the last sentence under the first bullet under **Directions**.

### **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 labeling listed below:

Labeling submitted April 23, 2012

1. 50-count outer carton for 15-mL packettes

2. 15-mL immediate container (packet)
3. 4-ounce immediate container (bottle)
4. 8-ounce immediate container (bottle)
5. 16-ounce immediate container (bottle)
6. 32-ounce immediate container (bottle)
7. 1-gallon immediate container (bottle)

Labeling submitted May 6, 2012

8. 4-ounce outer carton
9. 8-ounce outer carton

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 017768/S-039.**” 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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JOEL SCHIFFENBAUER  
05/24/2012