



NDA 017768/S-044

**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 April 13, 2017, received April 17, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Hibiclens<sup>®</sup> (chlorhexidine gluconate) solution, 4%.

This “Prior Approval” supplemental new drug application provides for the following changes:

- Adds an “Allergy alert” warning to labeling in accordance with the Agency’s “Changes Being Effected” (CBE-0) Request Letter dated February 2, 2017
- Modifies labeling to incorporate various other revisions in accordance with Agency requests dated May 16, August 31, and October 3, 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 minor editorial revision listed below:

For the Hibiclens<sup>®</sup> 15 mL packette 50-count outer carton, under “Directions”, *patient preoperative skin preparation*, after the word “Repeat”, remove the last sentence: (b) (4)

(b) (4)

**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 labeling listed in the following table, must incorporate the change specified above, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<b>Submitted Labeling</b>	<b>Date of Submission</b>
15 mL packette (pouch) Principal Display Panel (PDP)	September 29, 2017
4 fl oz bottle immediate container PDP and Drug Facts Labeling (DFL) carton	September 29, 2017
4 fl oz wide neck bottle immediate container PDP and DFL carton	September 29, 2017
8 fl oz bottle carton PDP and DFL	September 29, 2017
8 fl oz bottle immediate container PDP and DFL	September 29, 2017
32 fl oz bottle immediate container PDP and DFL	September 29, 2017
1 gallon bottle immediate container PDP and DFL	September 29, 2017
15 mL packette 50-count carton PDP and DFL	October 5, 2017
4 fl oz bottle carton PDP and DFL	October 5, 2017

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 017768/S-044.**” 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 Laurie Buonaccorsi, Regulatory Project Manager,  
at (240) 402-6297.

Sincerely,

*{See appended electronic signature page}*

Karen Murry Mahoney, MD, FACE  
Deputy Director  
Division of Nonprescription Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

ENCLOSURE(S):

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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KAREN M MAHONEY  
10/17/2017