

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**207964Orig1s000**

*Trade Name:* ReadyPrep CHG (chlorhexidine gluconate)

*Generic or Proper Name:* Chlorhexidine Gluconate Cloth

*Sponsor:* Medline Industries, Inc.

*Approval Date:* November 20, 2018

*Indication:* For patient preoperative skin preparation. Helps to reduce bacteria that can potentially cause skin infection.

# CENTER FOR DRUG EVALUATION AND RESEARCH

## 207964Orig1s000

### CONTENTS

#### Reviews / Information Included in this NDA Review.

<b>Approval Letter</b>	<b>X</b>
<b>Other Action Letters</b>	
<b>Labeling</b>	<b>X</b>
<b>REMS</b>	
<b>Summary Review</b>	<b>X</b>
<b>Officer/Employee List</b>	<b>X</b>
<b>Office Director Memo</b>	
<b>Cross Discipline Team Leader Review</b>	<b>X</b>
<b>Clinical Review(s)</b>	<b>X</b>
<b>Product Quality Review(s)</b>	<b>X</b>
<b>Non-Clinical Review(s)</b>	<b>X</b>
<b>Statistical Review(s)</b>	<b>X</b>
<b>Clinical Microbiology / Virology Review(s)</b>	<b>X</b>
<b>Clinical Pharmacology Review(s)</b>	<b>X</b>
<b>Other Reviews</b>	<b>X</b>
<b>Risk Assessment and Risk Mitigation Review(s)</b>	
<b>Proprietary Name Review(s)</b>	<b>X</b>
<b>Administrative/Correspondence Document(s)</b>	<b>X</b>

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**207964Orig1s000**

**APPROVAL LETTER**



NDA 207964

## NDA APPROVAL

Medline Industries, Inc.  
Attention: Bill Parthun  
Director, Research and Development  
One Medline Place  
Mundelein, IL 60060

Dear Mr. Parthun:

Please refer to your New Drug Application (NDA) dated and received February 9, 2016, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for ReadyPrep™ CHG (chlorhexidine gluconate) cloth, 2%.

We acknowledge receipt of your major amendment dated June 13, 2018, which extended the goal date by three months.

This new drug application provides for the use of ReadyPrep™ CHG (chlorhexidine gluconate) cloth, 2% as a patient preoperative skin preparation:

- helps reduce bacteria that can potentially cause skin infection
- for preparation of skin prior to surgery

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.

### **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 submitted on October 30, 2018:

- ReadyPrep™ CHG immediate container (2-count)
- ReadyPrep™ CHG outer container (24-count carton)

Submit 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 — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4)*. For administrative purposes, designate this submission “**Final Printed**”

**Labeling for approved NDA 207964.”** 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.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **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}*

Theresa Michele, MD  
Director  
Division of Nonprescription Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

ENCLOSURES:  
Immediate and Outer Container Labeling

-----  
**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/  
-----

THERESA M MICHELE  
11/20/2018