DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208288

NDA APPROVAL

3M Health Care (Infection Prevention Division)
Attention: Dianne Gibbs
Regulatory Affairs Director, IPD Division
Building 275-5W-06
St. Paul, MN 55144-1000

Dear Ms. Gibbs:

Please refer to your new drug application (NDA) dated and received July 6, 2015, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for SoluPrep™ (2% chlorhexidine gluconate and 70% isopropyl alcohol), solution.

We acknowledge receipt of your amendment dated February 9, 2018, which constituted a complete response to our September 1, 2017 action letter.

This new drug application provides for the use of SoluPrep™ (2% chlorhexidine gluconate and 70% isopropyl alcohol) solution for patient preoperative skin preparation:

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

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 following:

Labeling submitted July 5, 2018:

- 10.5 mL Brite Green outer container (pouch with *Drug Facts*)
- 10.5 mL Brite Green immediate container (handle)
- 10.5 mL Brite Green consumer information leaflet
- 10.5 mL Clear outer container (pouch with *Drug Facts*)
- 10.5 mL Clear immediate container (handle)
- 10.5 mL Clear consumer information leaflet
- 26 mL Brite Green outer container (pouch with *Drug Facts*)
- 26 mL Brite Green immediate container (handle)
- 26 mL Brite Green consumer information leaflet

Labeling submitted August 1, 2018

- Target Product Information

Submit in "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 (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 208288**." 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, Senior 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:

- Carton and Container Labeling
- Target Product Information

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
08/08/2018