NDA 208288/S-004

SUPPLEMENT APPROVAL

3M Health Care – Medical Solutions Division
Attention: Ann Hupperts
Advanced Regulatory Affairs Specialist
2510 Conway Ave
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000

Dear Ms. Hupperts:

Please refer to your supplemental new drug application (sNDA) dated and received July 16, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SoluPrep S (chlorhexidine gluconate (2% w/v) and isopropyl alcohol (70% v/v)) solution.

We acknowledge receipt of your amendment dated November 23, 2022, which constituted a complete response to our November 3, 2022, action letter.

This "Prior Approval" sNDA provides for a modified formulation that includes removal of the polymer inactive ingredient from the 10.5 mL Brite Green, 10.5 mL Clear, and 26 mL Brite Green applicators, as well as associated labeling changes.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling, described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date Submitted
10.5 mL Brite Green outer container (pouch with *Drug Facts*)	January 6, 2023
10.5 mL Brite Green immediate container (handle)	January 12, 2023
10.5 mL Brite Green consumer information leaflet	January 6, 2023
10.5 mL Clear outer container (pouch with *Drug Facts*)	January 6, 2023
10.5 mL Clear immediate container (handle)	January 12, 2023
10.5 mL Clear consumer information leaflet	January 6, 2023
26 mL Brite Green outer container (pouch with *Drug Facts*)	January 6, 2023
26 mL Brite Green immediate container (handle)	January 6, 2023
26 mL Brite Green consumer information leaflet	January 6, 2023
Target Product Information	January 6, 2023

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 208288/S-004**." 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[3]

If you have any questions, contact Xiaoxue Nehrbass, Regulatory Project Manager, at (301) 796-1486.

Sincerely,

{See appended electronic signature page}

Pamela Horn, MD
Director, Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling
- Target Product Information

[3] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products

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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/

PAMELA J HORN
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