DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021074/S-012

SUPPLEMENT APPROVAL

3M Health Care
3M Infection Prevention Division
Attention: Nadia Battah
Regulatory Affairs
3M Center, 2510 Conway Ave
Building 275-5W-06
St. Paul, MN 55144-1000

Dear Ms. Battah:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 6, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Avagard (1% chlorhexidine gluconate, 61% ethyl alcohol) solution.

This "Changes Being Effected" supplemental new drug application provides for the addition of the "Allergy Alert" warning and related revisions to the Drug Facts labeling in accordance with the "Changes Being Effected" (CBE-0) Request Letter from the Agency dated February 2, 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 incorporation of the advice and minor editorial changes noted below:

1. On the principal display panel (PDP) of the 500 mL (9200) and 1.2 L (9216) immediate container labels, the expiration date location "placeholder" was omitted on your June 30, 2017 revised PDP labels. We remind you to include the expiration date on both immediate containers as required under 21 CFR 201.17.

2. On the Drug Facts label of the 500 mL and 1.2 L immediate containers, as specified in the FDA CBE Supplement Request letter and for consistency across chlorhexidine gluconate products, insert a serial comma between the words "sensitization" and "or", within the warning statement located under the "**Stop use and ask a doctor if**" warning subheading, so that the warning statement reads: "**Stop use and ask a doctor if** irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition."

3. Under the Drug Facts labeling "**Warnings"** heading, reformat the allergic reaction warning subheading by changing the first letter in "Alert" to lower case and inserting a colon after the "t" to appear as: "**Allergy alert:**" as required under 21 CFR 201.66 (c)(5)(ii)(B) and (d)(1).

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 Avagard (1% chlorhexidine gluconate, 61% ethyl alcohol) solution 500 mL and 1.2 L immediate containers labeling submitted on June 30, 2017, after incorporating the changes specified above, and to the Target Product Information package insert submitted on April 19, 2017, and 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 — 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 021074/S-012**." 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 CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosures:
Immediate Container and Carton Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

VALERIE S PRATT
09/06/2017