DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021074/S-011 **SUPPLEMENT APPROVAL**

3M Health Care
Attention: Kristin Totushek, RAC (US)
Regulatory Affairs Specialist
3M Center, 2510 Conway Ave
Building 275-5W-06
St. Paul, MN 55144-1000

Dear Ms. Totushek:

Please refer to your Supplemental New Drug Application (sNDA) dated July 15, 2016, received July 19, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Avagard (1% chlorhexidine gluconate, 61% ethyl alcohol) solution.

This "Prior Approval" supplemental new drug application proposes labeling changes to the 500 mL and 1.2 L bottle package configurations. The following labeling changes were made:

- Background graphics
- Font style
- Minor changes to text location in Principal Display Panel
- Location of the lot/expiration date (500 mL only)

We have completed our review of this application. 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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the labeling submitted on July 15, 2016, for the following:

- Avagard™ 500 mL immediate container Principal Display Panel and Drug Facts Labeling
- Avagard™ 1.2 L immediate container Principal Display Panel and Drug Facts Labeling

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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021074/S-011."** 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 me 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 container Principal Display Panel and Drug Facts Labeling

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/s/

THERESA M MICHELE
11/04/2016