DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-524/S-010 **SUPPLEMENT APPROVAL**

3M – Infection Prevention Division
Attention: Sue Danielson
Regulatory Affairs and Quality
3M Center
Building 275-5W-06
St. Paul, MN 55144-1000

Dear Ms. Danielson:

Please refer to your Supplemental New Drug Application (sNDA) dated August 31, 2011, received September 7, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:
Chlorascrub™ Swab (3.15% w/v chlorhexidine gluconate with 70% v/v isopropyl alcohol) swab
Chlorascrub™ Swabstick (3.15% w/v chlorhexidine gluconate with 70% v/v isopropyl alcohol) swab
Chlorascrub™ Maxi Swabstick (3.15% w/v chlorhexidine gluconate with 70% v/v isopropyl alcohol) swab

This "Prior Approval" supplemental new drug application provides for a change in the proprietary names from 1) Chlorascrub™ Swab to Prevantics ™ Swab, 2) Chlorascrub™ Swabstick to Prevantics ™ Swabstick, and 3) Chlorascrub™ Maxi Swabstick to Prevantics ™ Maxi Swabstick.

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, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling listed below:

1. Swab Immediate Container (Foil Pouch)
2. Swab 100-Count Outer Carton
3. Swab Secondary Packaging that Hold Ten 100-Count Cartons
4. Swab Immediate Container (Foil Pouch) for 3,000-Count Carton
5. Swab 100-Count Outer Carton
6. Swab Secondary Packaging that Hold Ten 100-Count Cartons
7. Swab Immediate Container (Foil Pouch) for 3,000-Count Carton

8. Swab Package Insert (Back Panel) for 3,000-Count Carton
9. Swab Package Insert (Front Panel) for 3,000-Count Carton
10. Swab Outer Carton for 3,000 Count
11. Swabstick Immediate Container (Foil Pouch)
12. Swabstick 50-Count Outer Carton
13. Swabstick Secondary Packaging that Holds Ten 50-Count Carton
14. Swabstick Immediate Container (Foil Pouch) for 500-Count Carton
15. Swabstick Package Insert (Back Panel) for 500-Count Carton
16. Swabstick Package Insert (Front Panel) for 500-Count Carton
17. Swabstick Outer Carton for the 500-CountMaxi-Swabstick Immediate Container (Foil Pouch
18. Maxi-Swabstick 30-Count Outer Carton
19. Maxi-Swabstick Secondary Packaging that Hold Ten 30-Count Cartons
20. Maxi-Swabstick Immediate Container (Foil Pouch) for 300-Count Carton
21. Maxi-Swabstick Package Insert (Back Panel) for 300-Count Carton
22. Maxi-Swabstick Package Insert (Front Panel) for 300-Count Carton
23. Maxi-Swabstick Outer Carton for the 300-Count
24. Reduced Length Swabstick Immediate Container (Foil Pouch for 500-Count Carton
25. Reduced Length Swabstick Package Insert (Back Panel) for 500-Count Carton
26. Reduced Length Swabstick Package Insert (front Panel) for 500-Count Carton
27. Reduced Length Swabstick Outer Carton for the 500-Count

This FPL 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 – 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 21-524/S-010**." Approval of this submission by FDA is not required before the labeling is used.

Please submit one market package of the drug product when it is available, and send to:

Celia R. Peacock, MPH, RD
Senior Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5357
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

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 Celia Peacock, Regulatory Project Manager at (301) 796-4154.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES
Carton and Container Labeling

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

/s/

JOEL SCHIFFENBAUER
03/01/2012