DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021586/S-005 **SUPPLEMENT APPROVAL**

3M Health Care (Infection Prevention Division)
Attention: Ann M. Hupperts, MS, RAC
Regulatory Affairs Specialist
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Dear Ms. Hupperts:

Please refer to your Supplemental New Drug Application (sNDA) dated January 12, 2015, received January 15, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DuraPrep™ (iodine povacrylex and isopropyl alcohol solution) Surgical Solution.

We acknowledge receipt of your amendment dated March 11, 2015.

This "Changes Being Effected" sNDA proposes to revise labeling to indicate whether the product is sterile or non-sterile (for this sNDA, the following statements have been added: "Non-sterile Solution" and "Applicator is sterile if package is intact"). This submission is in response to the Agency's November 17, 2013 Supplement Request letter in which we requested labeling changes to inform consumers whether topical antiseptic drug products indicated for patient preoperative or preinjection skin preparation are sterile or non-sterile.

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

1. DuraPrep 6-mL and 26-mL immediate container applicator labels, submitted January 12, 2015
2. DuraPrep 6-mL and 26-mL Consumer Information Leaflet, submitted January 12, 2015
3. Target Product Information, resubmitted May 19, 2015 (originally submitted in the November 25, 2014 Annual Report)

Although no revisions were made to the 6-mL and 26-mL outer containers (pouch with Drug Facts), submit the outer container (pouch with Drug Facts) labels as part of the FPL for this

supplement to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

Submit in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL 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 021586/S-005".** 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 Celia Peacock, Senior Regulatory Project Manager at (301) 796-4154.

Sincerely,

Theresa Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:
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/

THERESA M MICHELE
06/08/2015