DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-586/S-002 **SUPPLEMENT APPROVAL**

3M Health Care, Infection Prevention Division
Attention: Diane L. Gibbs, RAC
Regulatory Affairs Manager
3M Center Building 275-5W-06
St. Paul, MN 55144-1000

Dear Ms. Gibbs:

Please refer to your supplemental new drug application dated September 4, 2009, received September 11, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DuraPrep™ Surgical (iodine povacrylex (0.7% available iodine) and isopropyl alcohol (74% w/w)) Solution.

We acknowledge receipt of your amendment dated March 1, 2010 and your email correspondence dated March 11, 2010.

This "Changes Being Effected" supplemental new drug application provides for revised flammability warning statements to the labeling for the DuraPrep™ 6-, and 26- mL applicator (marked sterile) package sizes in response to the August 4, 2009 supplemental labeling request letter.

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 minor editorial revisions listed below.

LABELING

Submit final printed labeling (FPL), with the revisions listed below, 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 labeling submitted on September 4, 2009 and March 1, 2010 with the inclusion of the minor editorial revisions listed below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Labeling submitted September 4, 2009

- DuraPrep 26 ml-sterile consumer information insert
- DuraPrep 26 ml-sterile immediate container (handle)
- DuraPrep 6 ml-sterile consumer information insert
- DuraPrep 6 ml-sterile immediate container (handle)

Labeling submitted March 1, 2010

- DuraPrep 26 ml-sterile outer container (pouch with Drug Facts)
- DuraPrep 6 ml-sterile outer container (pouch with Drug Facts)
- DuraPrep package insert (Target Product Information)

Minor Editorial Revisions to be Included in the FPL:

The final printed labeling for the package insert (Target Product Information) must reflect the following minor editorial revisions (as required in FDA's August 4, 2009 letter) listed below:

- Under the heading **Warnings,** revise the statement "**To reduce risk of fire,** prep carefully" to appear as follows: "**To reduce risk of fire, PREP CAREFULLY:".**

The entire statement needs to be in bold print with the phrase "prep carefully" in all upper case letters.

- Revise the statement **"Wet hair is flammable"** to be printed in red bold print throughout the labeling.

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 (October 2005). 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 21-586/S-002**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Larry Bauer, Regulatory Project Manager, at (301) 796-4842.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21586	SUPPL-2	3M HEALTH CARE INC	DURAPREP SURGICAL SOLUTION(IODOPHOR 0.7%

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

/s/

ANDREA LEONARD SEGAL
03/11/2010