CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-586

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-586

3M Health Care, Medical Division
Attention: Suzanne M. Danielson
Director of Regulatory Affairs and Quality
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000

Dear Ms. Danielson:

Please refer to your new drug application (NDA) dated October 24, 2003, received October 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DuraPrep™ Surgical (iodine povacrylex (0.7% available iodine) and 74% w/w isopropyl alcohol) Solution.

We acknowledge receipt of your submissions dated August 30, 2004, March 28, June 22, and September 19, 25, and 26, 2006. The March 28, 2006 submission constituted a complete response to our August 27, 2004 action letter.

This new drug application provides for the use of DuraPrep™ Surgical (iodine povacrylex (0.7% available iodine) and 74% w/w isopropyl alcohol) Solution for use as a patient preoperative skin preparation.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling submitted September 26, 2006 and must be in the "Drug Facts" format (21 CFR 201.66) for the following:

- 6-mL and 26-mL immediate container applicator barrel
- 6-mL and 26-mL Drug Facts
- 6-mL and 26-mL Principal Display Panel
- 6-mL and 26-mL shipping carton
- Package insert (Target Product Information)

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**FPL for approved NDA 21-586.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We have reviewed the submission and agree that a waiver is justified for DuraPrep™ Surgical (iodine povacrylex (0.7% available iodine) and 74% w/w isopropyl alcohol) Solution for children less than 2 months of age because your product labeling will include the following statement: Do not use in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism. We note that you have fulfilled the pediatric study requirement for this application in children greater than 2 months of age based on the determination that the permeability of skin in children > 2 months of age is essentially that of the adult skin.

We remind you of your postmarketing study commitment in your submission dated September 25, 2006. This commitment is listed below.

1. Description of Commitment:

   Demonstrate the drying time and vapor dissipation of the 6-mL and 26-mL solution in hair, at least shoulder length, under normal surgical suite conditions.

Protocol Submission:	by December 28, 2006
Study Start:	by March 28, 2007
Final Report Submission:	by June 28, 2008

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence.**"

In addition, we request that you submit one copy of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Please send one copy to this division.

Please submit one market package of each volume of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for

this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Laura E. Shay, Regulatory Project Manager, at (301) 796-0994.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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
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