U.S. FOOD and DRUG ADMINISTRATION
OFFICE OF NEW DRUG CHEMISTRY

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS
—Review of Chemistry, Manufacturing, and Controls—

NDA #: 21-084  CHEM.REVIEW #: 1  REVIEW DATE: January 10, 2000

SUBMISSION/TYPE DOCUMENT DATE CDER DATE ASSIGNED DATE
ORIGINAL 18-AUG-99 19-AUG-99 20-AUG-99
BC 02-SEP-99 03-SEP-99 04-SEP-99
BC 09-DEC-99 09-DEC-99 09-DEC-99

NAME & ADDRESS OF APPLICANT:
Commander
U.S. Army Medical Research and Material Command
ATTN: MCMR-RCQ-RA
504 Scott Street
Ft. Detrick, MD 21702-5012

Contact:
Daikee Liu, Ph.D.
(301) 619-2051

DRUG PRODUCT NAME
Proprietary:

Nonproprietary/USAN:
Topical Skin Protectant
Fomblin Y25 TSP and Polymist F5A TSP
50% Perfluorooalkylypolyether (PFPE) plus 50%
Polytetrafluoroethylene (PTFE)

Code Names/#’s:
Chemical Type:
Therapeutic Class:

1
P

PATENT STATUS:
U.S. Patent No. 5,607,979

Issue date: 04 March 1997
Expiration date: 30 May 2015
Patent Owner: The United States of America as represented by the Secretary
of the Army.

Type of Patent: Drug product composition
Claims: The formulation and composition of a cream made of certain
PTFE resins as protectants against CW agents.

PHARMACOLOGICAL INDICATION:
Barrier paste for protection against chemical
warfare agents.
NDA 21-084 Topical Skin Protectant
U.S. Army-Office of the Surgeon General

**DOSAGE FORM:**
- paste
- neat

**STRENGTHS:**
- topical

**ROUTE OF ADMINISTRATION:**
- topical

**DISPENSED:**
- X R, ___ OTC

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLC. FORMULA & WT:**

A. Polytetrafluoroethylene (PTFE), known commercially as Teflon
   CAS number: 9002-84-0
   Structure:
   \[
   \begin{array}{c}
   F \\
   C \\
   F \\
   \end{array} 
   \begin{array}{c}
   F \\
   C \\
   F \\
   \end{array}
   
   B. Chemical nomenclature: Perfluoroalkyloxyether (PFPE) (oil)
   CAS number: 69991-67-9
   Structure:
   \[
   \begin{array}{c}
   CF_3 \\
   CF_3 \left( O - CF - CF_2 \right)_n \left( O - CF_2 \right)_m \end{array}
   \]
   \[ \text{OCF}_3 \]

**SUPPORTING DOCUMENTS:**

IND — Topical Skin Protectant; U.S. Army


DMF — Type II. ____________ Polymist F5A TSP. Letter of authorization for FDA access dated 165-JUN-98. Date of last review: 15-OCT-99.

DMF — Type III. ____________ Letter of authorization for FDA access: 16-JUN-98. Date of last review: DEC-99.

DMF — Type I. ____________ Letter of authorization for FDA access: 13-OCT-87. Date of last review: Not reviewed.
NDA 21-084 Topical Skin Protectant
U.S. Army-Office of the Surgeon General

RELATED DOCUMENTS: None

CONSULTS: Labeling and Nomenclature Committee; Microbiology

REMARKS/COMMENTS: 1. The recommendation is made to call Topical Skin Protectant a paste and not a — see discussion in Section F, Labeling.

2. An information request letter was issued 24-SEP-99 regarding the drug substance Fomblin Y25 TSP, referenced in DMF

3. An information request letter was issued 05-NOV-99 regarding the drug substance Polymist F5A TSP, referenced in DMF

4. A CMC information request letter for NDA 21-084 was issued 10-NOV-99. A copy of this letter is presented in Appendix IV.

CONCLUSIONS & RECOMMENDATIONS:

The application is recommended as APPROVABLE under section 505 of the FFD&C Act, pending an overall EER recommendation.

/ S /

William C. Timmer, Ph.D.
Review Chemist, HFD-540/830

/ S /

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader, HFD-540/830

cc:
Original DMF (2 copies)
HFD-540/DMF/Division File
HFD-540/DD/JWilkin
HFD-540/Chem/WCTimmer
HFD-540/ChemTL/WHDeCamp
HFD-540/PM/FHCross
HFD-540/MO-TL/SWalker
HFD-540/MO/MOOkun
HFD-540/Pharm-TL/AJJacobs
HFD-540/Pharm/LReid
HFD-540/Biopharm/EDBashaw
HFD-830/DD/CWChen
HFD-830/DD/DDD/BBDunn

File Name: ___________________________
U.S. FOOD & DRUG ADMINISTRATION

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS
—Review of Chemistry, Manufacturing, and Controls—

NDA #: 21-084
CHEM REVIEW #: 2
REVIEW DATE: February 7, 2000

SUBMISSION/TYPE DOCUMENT DATE CDER DATE ASSIGNED DATE
ORIGINAL 18-AUG-99 19-AUG-99 Chem Review #1
BC 02-SEP-99 03-SEP-99 Chem Review #1
BZ 32-NOV-99 24-NOV-99 24-NOV-99
BC 09-DEC-99 09-DEC-99 Chem Review #1
BC 26-JAN-00 27-JAN-00 28-JAN-00

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B. Chemical nomenclature: Perfluoroalkyloxyether (PFPE) (oil)
   CAS number: 69991-67-9
   Structure:
   \[
   \text{CF}_3 \left( \text{O} - \text{CF} - \text{CF}_2 \right)_n \left( \text{O} - \text{CF}_2 \right)_m \text{OCF}_3
   \]

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NDA 21-084 Topical Skin Protectant
U.S. Army-Office of the Surgeon General

RELATED DOCUMENTS: None

CONSULTS: Microbiology

REMARKS/COMMENTS:

CONCLUSIONS & RECOMMENDATIONS:

The application is recommended for APPROVAL under section 505 of the FFD&C Act.

/S/
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APPEARS THIS WAY ON ORIGINAL