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RESEARCH**

APPLICATION NUMBER: 21-084

CHEMISTRY REVIEW(S)

JAN 21 2000

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

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
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:
Daikie Liu, Ph.D.
(301) 619-2051

DRUG PRODUCT NAME

Proprietary:
Nonproprietary/USAN:

Topical Skin Protectant
Fomblin Y25 TSP and Polymist F5A TSP
50% Perfluoroalkylpolyether (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:

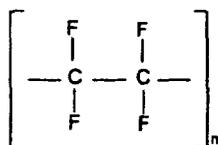
Barrier paste for protection against chemical
warfare agents.

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

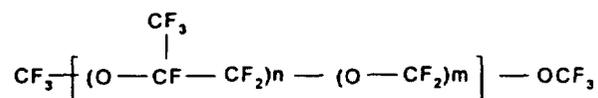
DOSAGE FORM: paste
STRENGTHS: neat
ROUTE OF ADMINISTRATION: topical
DISPENSED: X R, ___ OTC

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

- A. Polytetrafluoroethylene (PTFE), known commercially as Teflon
CAS number: 9002-84-0
Structure:



- B. Chemical nomenclature: Perfluoroalkylpolyether (PFPE) (oil)
CAS number: 69991-67-9
Structure:



SUPPORTING DOCUMENTS:

IND ——— Topical Skin Protectant; U.S. Army

DMF ——— Type II. ————— Fomblin Y25 TSP. Letter
of authorization for FDA access dated 09-AUG-99. Date of last review:
23-SEP-99.

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.

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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 *1/24/00*

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/MOkun
HFD-540/Pharm-TL/AJacobs
HFD-540/Pharm/LReid
HFD-540/Biopharm/EDBashaw
HFD-830/DD/CWChen
HFD-830/DDD/BBDunn
File Name: _____

/S/ 1/28/00
/S/ .2/4/00

FEB 7 2000

U.S. FOOD & 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 #:** 2 **REVIEW DATE:** February 7, 2000

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
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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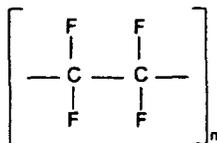
Barrier paste for protection against chemical warfare agents.

FEB - 7 2000

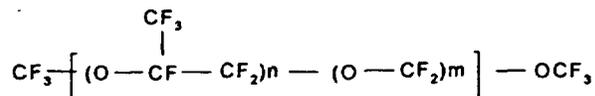
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**NDA 21-084 Topical Skin Protectant
U.S. Army-Office of the Surgeon General**

RELATED DOCUMENTS: None

CONSULTS: Microbiology

REMARKS/COMMENTS:

CONCLUSIONS & RECOMMENDATIONS:

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1000 /S/

William C. Timmer, Ph.D.
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Office of New Drug Chemistry

**APPEARS THIS WAY
ON ORIGINAL**