

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 21-084

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

December 9, 1999

REPLY TO
ATTENTION OF:

Office of the Deputy Chief of Staff
for Regulatory Compliance and Quality

SUBJECT: New Drug Application (NDA No. 21-084) for Topical Skin Protectant (TSP)

Jonathan K. Wilkin, M.D.
Director, Division of Dermatologic
and Dental Drug Products
Office of Drug Evaluation
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-540
Rockville, Maryland 20857



Dear Doctor Wilkin:

Enclosed are four official and four desk copies of our response to the November 19, 1999 telephonic request from CDR Frank Cross, Project Manager at the Division of Dermatologic and Dental Drug Products, regarding Environmental Assessment (EA) issues in the pending NDA 21-084, Topical Skin Protectant. CDR Cross requested that we provide the planned quantity of the TSP to be manufactured in response to your requests for: 1) a Categorical Exclusion from submitting an EA and 2) an update of Section 2.4.2.2 Fielding of TSP in the NDA (Volume 1.38, Page 057). Our specific responses are as follows:

1. FDA Comment: Sponsor has not made a "Request for Categorical Exclusion."

Response:

The U.S. Army Office of The Surgeon General hereby requests that the FDA grant a Categorical Exclusion for submitting an EA for this NDA. This request is being made because the TSP NDA meets applicable requirements for such exclusion under 21CFR§25.31(a) and (b) and because, to the best of the applicant's knowledge, no extraordinary circumstances exist as set forth in 21CFR§25.21(a) and (b).

The TSP NDA approval meets the criteria under 21CFR§25.31(a) for a Categorical Exclusion from the requirement to provide an EA because such approval will not result in an increase of the use of the active ingredients of this product within the meaning of the regulation and the statute it is based upon.

TSP is a mixture (50/50 w/w) of two perfluorinated components that are known to be inert, immiscible, non-wetting, and stable. The two components, Polymist[®] F5A and Fomblin[®] Y 25,

in wide use in the United States. Polymist® F5A is used in medical/surgical products. Amblin® Y 25 is used in cosmetics and lubricants.

The TSP is intended to be held in the Department of the Army's inventory for release to service members in the event of war. Therefore, approval of TSP, unlike other drugs, will not likely result in the actual use of active ingredients in the United States.

The TSP NDA approval also meets the criteria under 21CFR§25.31(b) for a Categorical exclusion from the requirement to provide an EA based on the rationale that (1) the TSP components are insoluble in water and (2) the estimated concentration of TSP at the point of entry into the aquatic environment, or the Expected Introduction Concentration (EIC), will be less than 1 ppb. The FDA's method of calculating the EIC was used to support this statement. The analysis of the EIC-aquatic is provided as enclosure 1 of this submission.

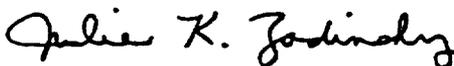
2. FDA Request: Provide an update to NDA Volume 1.38, Page 057, Section 2.4.2.2 regarding the fielding of TSP.

Response:

The update Section 2.4.2.2, Fielding of TSP, is provided as enclosure 2 of this submission.

Please contact Ms. Kathie Mantine at 301-619-2809 (alternate 7550), facsimile 301-619-7803, or electronic mail kathie.mantine@det.amedd.army.mil for regulatory questions. The point of contact at the U.S. Army Medical Materiel Development Activity for technical questions is Dr. DaiKee Liu at 301-619-2051.

Sincerely,



Julie K. Zadinsky
Colonel, Army Nurse Corps
Deputy Chief of Staff for
Regulatory Compliance and Quality

Copies Furnished:

- U.S. Army Medical Research and Materiel Command, ATTN: MCMR-SGS
- U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ (Dr. Carton)
- U.S. Army Medical Materiel Development Activity, ATTN: MCMR-UMP
- EER Systems Inc., ATTN: Dr. Joseph Sinkule

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