APPENDIX Z

SEPTEMBER 7, 1990

MEMORANDUM OF MEETING BETWEEN THE DEPARTMENT OF DEFENSE AND THE FOOD AND DRUG ADMINISTRATION

MEMORANDUM

DATE : September 7, 1990

FROM : Richard Klein and Ann Graham

SUBJ : September 7th meeting between FDA and DoD

TO : Stuart Nightingale

The following were in attendance at the meeting:

Department of Defense

Craig Lehmann	U.S. Army Medical R & D Command
Ronald Clawson	U.S. Army Medical R & D Command
Gregory Berezuk	U.S Army Human Use and Regulatory Affairs
George Sisson	Command Judge Advocator, Army Medical R & D
Walt Brandt	Army Biologics

FDA

Stuart Nightingale
Margaret Porter
Catherine Lorraine
William Lampkin
Carl Peck
Jim Bilstad
Ann Sutton
Karen Goldenthal
Robert Temple
Paula Botstein
Bill Damaska
Robert Sheridan
Ann Graham
Richard Klein
Linda Carter
Bonnie Lee
Ron Wilson
Ann Witt

- DoD will submit to FDA for review the training doctrine currently being developed for each product
- DoD will submit updated information on each product on an ad hoc basis, but at least once a week.
- FDA and DoD agreed to find a common interpretation of 10 USC 980 and 21 CFR 312 allowing DoD to comply with their statute and FDA regulations simultaneously.

- OHA will track the status of all DoD products being used for unique military purposes.

- DoD agreed to revise their protocols to expand post exposure observations in battlefield observations.

- Margaret Porter agreed to review and revise draft informed consent regulation, and bring it to the direct attention of the Commissioner.

- DoD still insists on a safety review under the terms of the MOU.

- Under the DoD directive the Secretary of Military Departments can dictate the use of unapproved FDA regulated products. DoD's current position is that this is not their primary choice at this time.

- DoD indicated that they want FDA review and agency assurance that the drugs are safe, as well as that their use is appropriate.

- OHA agreed to play a clearinghouse role for FDA, tracking drugs and medical devices.

- OHA and OGC will follow-up with George Sisson concerning the status of skin creme product.