APPENDIX CC

DECEMBER 31, 1990

LETTER FROM ENRIQUE MENDEZ, JR., M.D., DEPARTMENT OF DEFENSE, TO THE FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

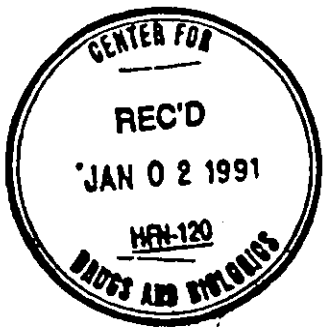
REPLY TO ATTENTION OF

December 31, 1990

Human Use Review and
Regulatory Affairs Office

9.1

SUBJECT: IND 23,509 - Pyridostigmine Bromide 30mg Tablets (Serial No. 022)



Division of Neuropharmacological
Drug Products (HFN-120)
Office of Drug Review I
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir:

Enclosed in triplicate is a request from the Assistant Secretary of Defense (Health Affairs) to the Commissioner of Food and Drugs for a determination that obtaining informed consent is not feasible for the subject investigational drug. This request is made under the provisions of 21 CFR 50.23(d)(1) as published in the Federal Register of December 21, 1990. This regulation requires such a request be submitted as an amendment to the IND.

If you have questions concerning this submission, please contact the undersigned at (301) 663-2165.

Sincerely,

Gregory P. Berezuk
Lieutenant Colonel, Medical
Service Corps
Chief, Human Use Review and
Regulatory Affairs Office

Enclosure

Copy Furnished:

U.S. Army Medical Materiel Development Activity,
ATTN: SGRD-UMP

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

David A. Kessler, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Doctor Kessler:

Under the provisions of 21 CFR 50.23(d)(1) (as published in the Federal Register of December 21, 1990), I request a determination that obtaining informed consent is not feasible for pyridostigmine bromide 30mg tablets, IND 23,509, because of military combat exigencies in Operation Desert Shield. This determination would apply to the use of this drug by American military personnel at risk of attack with chemical weapons involving organophosphorous nerve agents.

As summarized in enclosure 1 and supported by documentation in the IND file, available evidence supports the safety and effectiveness of pyridostigmine pretreatment, in conjunction with other drugs as treatments, for this purpose. If threatened with these chemical weapons, the interests of individual service personnel and the overall needs of the military service will require that pyridostigmine be used by all threatened personnel. No satisfactory alternative regimen involving investigational or approved drug products is available to deal with these life-threatening weapons. Under these circumstances, withholding pyridostigmine from any threatened individual would be contrary to that individual's best interests. The recommendation for use of pyridostigmine without informed consent has been concurred in by a duly constituted institutional review board, enclosure 2.

Your prompt attention to this request is appreciated. A copy of this request is being filed as an amendment to IND 23,509. Should you need further information concerning this request, please contact

Lieutenant Colonel Gregory P. Berezuk, U.S. Army Medical Research and Development Command, ATTN: SGRD-HR, Fort Detrick, Frederick, Maryland, 21702-5012, telephone (301) 663-2165.

Sincerely,

Enrique Mendez, Jr., M.D.

Enclosures

Copies Furnished:

Division of Neuropharmacological
Drug Products (HFN-120)
Office of Drug Review I
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Office of Health Affairs (HFY-1)
ATTN: Dr. Nightingale
Room 14-95
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857