

APPENDIX DD

JANUARY 8, 1991

LETTER FROM DAVID KESSLER, M.D., COMMISSIONER, FOOD AND
DRUG ADMINISTRATION, TO ENRIQUE MENDEZ, JR., M.D.,
ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 8, 1991

Enrique Mendez, Jr., M.D.
Assistant Secretary for Defense, Health Affairs
Department of Defense
Washington, DC 20301-1220

Dear Dr. Mendez:

I have received your request dated December 28, 1990, and submitted pursuant to 21 CFR 50.23(d) for a determination that obtaining informed consent is not feasible for the investigational agent pyridostigmine bromide 30 mg tablets.

In reviewing the justification for your request, I have considered the pertinent factors set forth in the regulation. Based upon your assessment of the military operation, I find that there is no available satisfactory alternative therapy for the prevention of the effects of exposure to organophosphorus nerve agents. Based on your agreement to ~~provide and disseminate information to all military personnel concerning the use of pyridostigmine,~~ as stated in LTC Berezuk's January 8, 1991 letter to Dr. Stuart Nightingale, I concur with your assessment that informed consent is not feasible and that withholding treatment would be contrary to the best interests of military personnel. rs. 8

Unless circumstances change, my determination expires one year from the date of this letter, or when the Department of Defense informs the Commissioner of Food and Drugs that the specific military operation creating the need for the investigational agent has ended, whichever is earlier.

Sincerely,

David A. Kessler, M.D.
Commissioner of Food and Drugs