CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-175

MICROBIOLOGY REVIEW

RW

REVIEW FOR HFD-120 OFFICE OF NEW DRUG CHEMISTRY MICROBIOLOGY STAFF MICROBIOLOGIST'S REVIEW #1 OF NDA

May 3, 2000

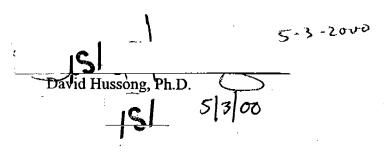
A.	1.	NDA	21-175	
	-	<u>SPONSOR</u>	U.S. Army Office of the Surgeon General Office of the Deputy Chief of Staff for Regulatory Compliance and Quality 504 Scott Street Fort Detrick, Maryland 21702-5012	
	2.	PRODUCT NAME: Nerve Agent Antidote Delivery System (atropine/2-PAM)		
	3.	DOSAGE FORM AND ROUTE OF ADMINISTRATION: Dual Chamber Autoinjector Syringe		
	4.	METHOD(S) OF STERILIZATION:		
	5.	PHARMACOLOGICAL CATEGORY: Antidote to organophosphorus nerve poison		
	6.	DRUG PRIORITY CLASSIFICATION: 3P		
B.	1.	DATE OF INITIAL SUBMISSION: December 01, 1999		
	2.	DATE OF AMENDMENT: (none)		
	3.	RELATED DOCUMENTS: NDAs 17-106 (Atropen) and 18-986 (Pralidoxime Chloride Injection, Combopen) from Meridian Medical Technologies, Inc. These NDAs have already been supplemented to provide for processing of the drug into autoinjectors in (see NDA 17-106/S-018 and NDA 18-986/S-013).		
	4.	ASSIGNED FOR REVIEW: January 12, 2000		

C. <u>REMARKS</u>: The current application describes a product that administers atropine and pralidoxime chloride in a single injection. This product is for emergency use under field conditions where prompt treatment following exposure is critical.

The applications for the individual antidote products Atropen (NDA 17-106) and Pralidoxime Chloride Injection Combopen (NDA 18-986) are owned by Meridian Medical Technologies, Inc., the manufacturer of the dual chamber autoinjector. Since these individual products are approved, the combination of the two reduces the focus of this review to those aspects unique to the dual syringe dosage form.

The request for consultative review includes volumes 1.6, 1.7 and 1.8 of the submission. These volumes contained microbiological quality information from the CMC technical section. The application forms, references, letters of authorization, NDA summary, batch records, labeling and the stability protocol were not provided for consultative review.

D. <u>CONCLUSIONS</u>: The submission is approvable. The "List of Microbiology Deficiencies and Comments" is attached.



cc:

Original NDA 21-175 HFD 160/Consult File HFD 120/Division File HFD 120/CSO/R. Nighswander HFD 120/Chemist/W. Rzeszotarski HFD 805/D. Hussong

Drafted by: D. Hussong, 05/03/2000

R/D initialed by: P. Cooney

_____ page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

REVIEW FOR HFD-120 OFFICE OF NEW DRUG CHEMISTRY MICROBIOLOGY STAFF MICROBIOLOGIST'S REVIEW #2 OF NDA

September 17, 2001

A.	1.	<u>NDA</u>	21-175	
		<u>SPONSOR</u>	U.S. Army Office of the Surgeon General Office of the Deputy Chief of Staff for Regulatory Compliance and Quality 504 Scott Street Fort Detrick, Maryland 21702-5012	
,	2.	PRODUCT NAME: Nerve Agent Antidote Delivery System (atropine/2-PAM)		
	3.	DOSAGE FORM AND ROUTE OF ADMINISTRATION: Dual Chamber Autoinjector Syringe		
	4.	METHOD(S) OF STERILIZATION:		
	5.	PHARMACOLOGICAL CATEGORY: Antidote to organophosphorus nerve poison		
6. <u>DRUG PRIORITY CLASSIFICATION</u> :		DRUG PRIORITY	CLASSIFICATION: 3P	
B.	1.	DATE OF INITIAL SUBMISSION: December 01, 1999		
	2.	DATE OF AMENDMENT: August 15, 2001 (subject of this review)		
	3.	RELATED DOCUMENTS: NDAs 17-106 (Atropen) and 18-986 (Pralidoxime Chloride Injection, Combopen) from Meridian Medical Technologies, Inc. These NDAs have already been supplemented to provide for processing of the drug into autoinjectors in (see NDA 17-106/S-018 and NDA 18-986/S-013).		
	4.	ASSIGNED FOR R	EVIEW: September 17, 2001	

- C. <u>REMARKS</u>: The current submission responds to questions about labeling, needle design chemistry and sterilization. The product is intended to administer atropine and pralidoxime chloride in a single injection. This product is for emergency use under field conditions where prompt treatment following exposure is critical.
- D. <u>CONCLUSIONS</u>: The submission is recommended for approval.

David Hussong, Ph.D.

cc:

Original NDA 21-175 HFD 160/Consult File HFD 120/Division File HFD 120/CSO/R. Nighswander HFD 120/Chemist/W. Rzeszotarski HFD 805/D. Hussong

Drafted by: D. Hussong, 09/17/2001 R/D initialed by: P. Cooney