

**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
- SPONSOR 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. REMARKS: 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. CONCLUSIONS: The submission is approvable. The "List of Microbiology Deficiencies and Comments" is attached.

1  
5-3-2000  
JSL  
David Hussong, Ph.D.  
JSL 5/3/00

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

6 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. NDA 21-175
- SPONSOR 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: 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 REVIEW: September 17, 2001

- C. REMARKS: 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. CONCLUSIONS: The submission is recommended for approval.

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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

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