

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-983

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

10 AUG 2006

NDA: 21-983
21-983 BC

Drug Product Name
Proprietary: Pending
Non-proprietary: Atropine Injection and
Pralidoxime Chloride Injection
Drug Product Priority Classification: 5P

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
24-MAR-2006	28-MAR-2006	08-MAY-2006	17-MAY-2006
04-MAY-2006	05-MAY-2006	08-MAY-2006	17-MAY-2006

Submission History (for amendments only) – N/A

Applicant/Sponsor

Name: Meridian Medical Technologies, Inc.
Address: 1945 Craig Road
St. Louis, MO 63146

Representative: Thomas Freund
Director, Regulatory Affairs
Telephone: 314-682-3156

Name of Reviewer: Anastasia G. Lolas

Conclusion: Recommended for approval based on product quality microbiology with one comment to be provided to the applicant (see Section H of review)

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** New drug application
2. **SUBMISSION PROVIDES FOR:** Commercialization of the army product, nerve gas antidote
3. **MANUFACTURING SITE:** Meridian Medical Technologies, Inc.
2555 Hermelin Drive
St. Louis, MO 63144

Assembly, labeling and release testing of the product take place at Meridian Medical's 1945 Craig Road facility located in St. Louis, MO.

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Sterile solution in a pre-assembled dual chamber auto-injector
 - Intramuscular injection
 - 2.1 mg/0.7 mL atropine and 600 mg/2 mL pralidoxime chloride

5. **METHOD(S) OF STERILIZATION:** _____

b(4)

6. **PHARMACOLOGICAL CATEGORY:** Nerve gas antidotes/adjuncts

B. **SUPPORTING/RELATED DOCUMENTS:**

- Microbiology Reviews #1 and #2 of NDA 21-175 (dated 03-MAY-2000 and 17-SEP-2001); original NDA review with approval recommendation. The labeling and stability protocol were not provided for review.
- Microbiology Review #1 of NDA 21-175/SCS-001 (dated 23-AUG-2002); several manufacturing changes were reviewed and recommended for approval such as new equipment for washing and _____ of components, new _____ for container components and filling equipment, new filling room for the new automated filling machine.
- Microbiology Review #1 of NDA 21-175/SCS-003 (dated 22-JUL-2004); a new _____ for sterilization of cartridge bodies in the _____ was reviewed and recommended for approval.
- Microbiology Review #1 of NDAs 20-124/SCS-019 and 21-175/SCS-009 (dated 08-SEP-2005); _____ for sterilization of components and filling equipment were reviewed and recommended for approval.
- Microbiology Review #1 of NDAs 20-124/SCS-024 and 21-175/SCS-011 (dated 02-AUG-2006); the new _____ used to sterilize bulk product receiving vessels was reviewed and recommended for approval.

b(4)

b(4)

b(4)

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- C. **REMARKS:** The original application was submitted to obtain approval to use the product in combat operations. NDA 21-983 is being submitted in order to obtain market approval for the auto-injector product so that it can be used by EMS —
———— The BC amendment describes all the CMC changes that have occurred since the approval of NDA 21-175.

b(4)

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Executive Summary**I. Recommendations**

- A. Recommendation on Approvability** – Recommended for approval based on product quality microbiology with one comment to be provided to the applicant (see Section H of review)
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The two product solutions are formulated separately and are _____ filled into the dual chamber auto-injector. A plunger separates the two chambers of the auto-injector. b(4)
- B. Brief Description of Microbiology Deficiencies** – None
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
Anastasia G. Lolas
- B. Endorsement Block**
James L. McVey
- C. CC Block**
N/A

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 ✓ Trade Secret / Confidential (b4)

 Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

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/s/

Anastasia Lolas
8/10/2006 09:39:26 AM
MICROBIOLOGIST

James McVey
8/11/2006 11:00:51 AM
MICROBIOLOGIST