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RESEARCH**

*APPLICATION NUMBER:*  
**22-180**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

12 September 2008

**NDA:** 22-180

**Drug Product Name**

**Proprietary:** Ferumoxytol Injection

**Non-proprietary:** N/A

**Drug Product Priority Classification:** S1

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

Letter	Stamp	Review Request	Assigned to Reviewer
December 18, 2007	December 19, 2007	January 22, 2008	January 31, 2008

**Submission History (for amendments only) – N/A**

**Applicant/Sponsor**

**Name:** AMAG Pharmaceuticals, Inc.

**Address:** 125 Cambridge Park Drive, Cambridge, MA  
02140

**Representative:** Dr. Mohammed A. Salem, VP, Regulatory Affairs

**Telephone:** 617-498-3332, Fax: 617-499-3360

**Name of Reviewer:** Vinayak B. Pawar, Ph.D.

**Conclusion:** The application is recommended for approval from microbiology product quality standpoint.

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## Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original NDA
2. **SUBMISSION PROVIDES FOR:** A drug product for the treatment of iron deficiency anemia.
3. **MANUFACTURING SITE:** AMAG Pharmaceuticals, Inc., 1 Mooney Street, Cambridge, MA 02138
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Intravenous injection in 510mg, 255mg and 127.5 mg/vial. **b(4)**
5. **METHOD(S) OF STERILIZATION:** \_\_\_\_\_
6. **PHARMACOLOGICAL CATEGORY:** Treatment of iron deficiency anemia.
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** The consult requests review of NDA 22-180 for Ferumoxytol injection. The entire submission 3.7 GB has been submitted through FDA Electronic Submission Gateway in an eCTD format. IQA has been filed on January 8, 2008 by Eldon Leutzinger.

**filename:** C:\my documents\review\NDA\N022180R1

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**Executive Summary**

**I. Recommendations**

- A. **Recommendation on Approvability** – Based on the sterility assurance of the product, the application is recommended for approval from product quality microbiology standpoint.
- 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** - Ferumoxytol is formulated with the excipient Mannitol USP, \_\_\_\_\_  
\_\_\_\_\_

b(4)

- B. **Brief Description of Microbiology Deficiencies** - None
- C. **Assessment of Risk Due to Microbiology Deficiencies** - None

**III. Administrative**

- A. **Reviewer's Signature** \_\_\_\_\_  
Vinayak B. Pawar, Ph.D.
- B. **Endorsement Block** \_\_\_\_\_  
Bryan Riley, Ph.D.
- C. **CC Block**  
N/A

8 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/  
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Vinayak Pawar  
9/15/2008 05:19:09 PM  
MICROBIOLOGIST

Recommended for approval from microbiology product quality standpoint.

Bryan Riley  
9/16/2008 09:27:53 AM  
MICROBIOLOGIST  
I concur.