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RESEARCH**

APPLICATION NUMBER:

201743Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

3 January 2010

NDA: 201-743

Drug Product Name

Proprietary: Not applicable

Non-proprietary: Argatroban Injection (in Dextrose)

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
13 April 2010	13 April 2010	29 April 2010	29 April 2010

Submission History (for amendments only): Not applicable

Applicant/Sponsor

Name: Sandoz Inc.

Address: 2555 W. Midway Blvd.,
P.O. Box 446
Broomfield, CO 80038

Representative: Alison Sherwood

Telephone: (303) 438-4513

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** 505(b)(2) application
 2. **SUBMISSION PROVIDES FOR:** New drug product application
 3. **MANUFACTURING SITE:** Sandoz Canada Inc.
145 Jules-Leger Street
Boucherville Canada
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Sterile aqueous injection
 - Intravenous injection
 - 1 mg/mL (125 mL)
 5. **METHOD(S) OF STERILIZATION:** (b) (4)
 6. **PHARMACOLOGICAL CATEGORY:** Thrombosis patients
- B. **SUPPORTING/RELATED DOCUMENTS:** NDA 22-485, DMF (b) (4).
- C. **REMARKS:** NDA 201-743 was submitted in eCTD format.

filename: N201743R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 201-473 is recommended for approval from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**
Not applicable

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
The drug product (b) (4)
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
Stephen E. Langille, Ph.D.
- B. Endorsement Block**
James McVey – Team Leader
- C. CC Block**
N/A

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/s/

STEPHEN E LANGILLE
01/18/2011

JAMES L MCVEY
01/20/2011
I concur.