

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-671

Microbiology Review(s)

Product Quality Microbiology Review

Review for HFD 170

17-May-2004

NDA: 21-671-BI

Drug Product Name: SKY0401
Non-proprietary Morphine Sulfate Sustained-Release Liposome Injection

Drug Product Classification:

Review Number: 2

Subject of this Review

Submission Date: July 18, 2003
Receipt Date: July 19, 2003
Consult Date: August 15, 2003
Date Assigned for Review: August 20, 2003

Submission History (for amendments only)

Date(s) of Previous Submission(s): July 18, 2003
Date(s) of Previous Micro Review(s): April 20, 2004

Applicant/Sponsor

Name: SkyePharma Inc.

Address: 10450 Science Center Drive
San Diego, CA 92121

Representative: Steve Jensen
Telephone: 858-625-2424

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

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A. 1. TYPE OF SUPPLEMENT: Original NDA
2. SUPPLEMENT PROVIDES FOR: Not applicable
3. MANUFACTURING SITE: SkyePharma Inc.
10450 Science Center Dr.
San Diego, CA 92121
4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
- 2 mL ready to use vial
 - 20 mg/2 mL, 15 mg/1.5 mL, 10 mg/mL
 - Epidural
5. METHOD(S) OF STERILIZATION: L J
6. PHARMACOLOGICAL CATEGORY: Analgesic
- B. SUPPORTING/RELATED DOCUMENTS: None
- C. REMARKS: This is the second review of this NDA.

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15 Page(s) Withheld



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_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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/s/

Stephen Langille
5/17/04 08:36:10 AM
MICROBIOLOGIST

Peter Cooney
5/17/04 08:44:33 AM
MICROBIOLOGIST

Product Quality Microbiology Review

Review for HFD 170

5-April-2004

NDA: 21-671

Drug Product Name: [Morphine Sulfate Sustained-Release Liposome Injection]
Non-proprietary

Drug Product Classification:

Review Number: 1

Subject of this Review

Submission Date: July 18, 2003
Receipt Date: July 19, 2003
Consult Date: August 15, 2003
Date Assigned for Review: August 20, 2003

Submission History (for amendments only)

Date(s) of Previous Submission(s):
Date(s) of Previous Micro Review(s):

Applicant/Sponsor

Name: SkyePharma Inc.

Address: 10450 Science Center Drive
San Diego, CA 92121

Representative: Steve Jensen
Telephone: 858-625-2424

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

Conclusion: Approvable pending revision

Product Quality Microbiology Data Sheet

- A. 1. TYPE OF SUPPLEMENT: Original NDA
2. SUPPLEMENT PROVIDES FOR: Not applicable
3. MANUFACTURING SITE: SkyePharma Inc.
10450 Science Center Dr.
San Diego, CA 92121
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 - Epidural
5. METHOD(S) OF STERILIZATION:
6. PHARMACOLOGICAL CATEGORY: Analgesic
- B. SUPPORTING/RELATED DOCUMENTS: None
- C. REMARKS:

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 21-671 is approvable pending the resolution of product quality microbiology issues.
- 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 -

[Individual ingredients]

B. Brief Description of Microbiology Deficiencies -
The Applicant failed to provide adequate information regarding:

- [
-
-
-
-
-
-]

C. Assessment of Risk Due to Microbiology Deficiencies -
Failure to address the microbiology deficiencies could result in endotoxin and/or microbial contamination of the drug product during the manufacturing process or during the shelf life of the product.

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.
- C. CC Block**
In DFS

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/s/

Stephen Langille
4/20/04 11:16:56 AM
MICROBIOLOGIST

Peter Cooney
4/20/04 11:31:01 AM
MICROBIOLOGIST