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: 

6. PHARMACOLOGICAL CATEGORY: Analgesic

B. SUPPORTING/RELATED DOCUMENTS: None

C. REMARKS: This is the second review of this NDA.

filename: c:\reviews\21-671r2.doc
Executive Summary

I. Recommendations

A. Recommendation on Approvability -
   NDA 21-671 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 is
   Individual ingredients

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

B. Endorsement Block
   Stephen E. Langille, Ph.D.
   Peter Cooney, Ph.D.

C. CC Block
   In DFS
15 Page(s) Withheld

☑ § 552(b)(4) Trade Secret / Confidential

☐ § 552(b)(5) Deliberative Process

☐ § 552(b)(5) Draft Labeling
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/ 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:
Non-proprietary Morphine Sulfate Sustained-Release Liposome Injection

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

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: 

6. PHARMACOLOGICAL CATEGORY: Analgesic

B. SUPPORTING/RELATED DOCUMENTS: None

C. REMARKS:

filename: c:\reviews\21-671.doc
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 -

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
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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

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