CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-897

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD-170

24-October-2005

NDA: NDA 21-897-BI

Drug Product Name
Proprietary: VIVITREX®
Non-proprietary: naltrexone injection
Drug Product Priority Classification: Priority

Review Number: 2

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
10/3/05	10/3/05	10/19/05	10/19/05

Submission History (for amendments only)

Submission Date(s)	Microbiology Review #	Review Date(s)
3/31/05	1	9/23/05

Applicant/Sponsor
Name: Alkermes, Inc.
Address: 88 Sidney St.
Cambridge, MA 02319

Representative: Priya Jambhekar
Telephone: (617) 583-6547

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

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Amendment to the original submission

2. **SUBMISSION PROVIDES FOR:** [redacted] of Vivitrex®

3. **MANUFACTURING SITE:** Alkermes Controlled Therapeutics, II (Alkermes, Inc.)
265 Olinger Circle
Wilmington, OH 45177
Tel: (937) 382-5642
CFN #: 1528810

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**

- Injectable suspension
- Intra-muscular
- 380 mg

5. **METHOD(S) OF STERILIZATION:** [redacted]

6. **PHARMACOLOGICAL CATEGORY:** Treatment of alcohol dependence

B. **SUPPORTING/RELATED DOCUMENTS:** DMF [redacted]

C. **REMARKS:**

filename: N021897R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability -
NDA 21-897 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 -

B. Brief Description of Microbiology Deficiencies -
No deficiencies were identified based upon the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies -
Failure to address the microbiology deficiencies could lead to microbial and/or endotoxin contamination of the drug product.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
Microbiology Supervisor/Team Leader Name

C. CC Block
N/A

6 Page(s) Withheld

1 Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

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/s/

Stephen Langille
10/24/2005 12:44:09 PM
MICROBIOLOGIST

Bryan Riley
10/24/2005 12:48:49 PM
MICROBIOLOGIST

Product Quality Microbiology Review
Review for HFD-170

19-September-2005

NDA: NDA 21-897

Drug Product Name
Proprietary: VIVITREX®
Non-proprietary: naltrexone injection
Drug Product Priority Classification: Priority

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
3/31/05	3/31/05	5/13/05	8/22/05

Submission History (for amendments only)

Submission Date(s)	Microbiology Review #	Review Date(s)
Not applicable	Not applicable	Not applicable

Applicant/Sponsor
Name: Alkermes, Inc.
Address: 88 Sidney St.
Cambridge, MA 02319

Representative: Priya Jambhekar
Telephone: (617) 583-6547

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

Conclusion: Approvable pending revision

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Original submission

2. **SUBMISSION PROVIDES FOR:** ~~_____~~ of Vivitrex®

3. **MANUFACTURING SITE:** Alkermes Controlled Therapeutics, II (Alkermes, Inc.)
265 Olinger Circle
Wilmington, OH 45177
Tel: (937) 382-5642
CFN #: 1528810

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
   - Injectable suspension
   - Intra-muscular
   - 380 mg

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

6. **PHARMACOLOGICAL CATEGORY:** Treatment of alcohol dependence

B. **SUPPORTING/RELATED DOCUMENTS:** DMF ~~_____~~

C. **REMARKS:**

filename: N021897R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability -

NDA 21-897 is approvable pending the resolution of microbiology deficiencies.

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 lead to microbial and/or endotoxin contamination of the drug product.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

Microbiology Supervisor/Team Leader Name

C. CC Block

N/A

16 Page(s) Withheld

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/s/

Stephen Langille
9/23/2005 08:54:27 AM
MICROBIOLOGIST

Bryan Riley
9/23/2005 09:03:13 AM
MICROBIOLOGIST