

**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:** _____ 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:**

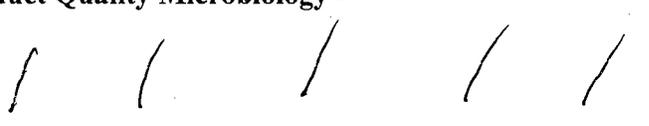
filename: N021897R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 21-897 is 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

✓ 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

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 Draft Labeling

 Deliberative Process

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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