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

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Submission History (for amendments only)

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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

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☐ 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

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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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/s/

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

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