

**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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.