

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-897

CHEMISTRY REVIEW(S)

2nd Cycle

CHEMISTRY REVIEW

NDA 21-897

**VivitrolTM (naltrexone for extended-release
injectable suspension)**

Alkermes, Inc.

Jila H. Boal, Ph. D.

**Division of Pre-marketing Assessment III and
Manufacturing Science, ONDQA**

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Chemistry Review Data Sheet

1. NDA # 21-897
2. REVIEW #: 2
3. REVIEW DATE: April 7, 2006
4. REVIEWER: Jila H. Boal, Ph.D.

5. PREVIOUS DOCUMENTS:Previous Documents

Type C Industry Meeting Minutes
Pre-NDA CMC Meeting Minutes
Type C Industry Meeting Minutes
IND 61,138, Serial No. 069
Pre-NDA CMC Meeting Minutes
IND 61,138, Serial No. 078
IND 61,138, Serial No. 079
N-0000 (Original Application)
N-000BM (Amendment 0001)
N-0000 (Amendment 0002)
N-000-SU (Amendment 0013)
N-000-BC (Amendment 0017)
N-000-BC(Amendment 0029)
N-000-BC(Amendment 0032)
N-000-BC(Amendment 0033)
N-000-BC(Amendment 0034)
N-000-BC(Amendment 0035)
N-000-BC(Amendment 0036)

Document Date

July 11, 2002
February 2, 2005
July 11, 2002
December 10, 2004
February 2, 2005
February 22, 2005
February 25, 2005
31-March-2005
11-May-2005
31-March-2005
29-July-2005
16-August-2005
04-October-2005
14-October-2005
27-October-2005
November 3, 2005
November 4, 2005
November 14, 2005

6. SUBMISSION(S) BEING REVIEWED:Submission(s) Reviewed

N-000-BC(Amendment 0043)

Document Date

February 13, 2006

CHEMISTRY REVIEW

Chemistry Review Data Sheet

7. NAME & ADDRESS OF APPLICANT:

Name: *Alkermes, Inc.,*
Address: 88 Sidney Street
Cambridge, MA 02319
Representative: Priya Jambhekar, Global Vice President,
Regulatory and Government Affairs
Telephone: (617) 583-6547

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Vivitrol
- b) Non-Proprietary Name (USAN): Naltrexone
- c) Code Name/# (ONDC only): N/A
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 3 (new dosage form)
 - Submission Priority: P

9. **LEGAL BASIS FOR SUBMISSION:** 505 (b) (2). Reference listed drug (RLD) is Revia (Naltrexone HCl) Tablets, 50-mg (NDA 18-932).

10. **PHARMACOL. CATEGORY:** Treatment of alcohol dependence

11. **DOSAGE FORM:** Injectable Suspension

12. **STRENGTH/POTENCY:** 380 mg

13. **ROUTE OF ADMINISTRATION:** Intramuscular (IM)

14. **Rx/OTC DISPENSED:** X Rx OTC

15. **SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):**
Ruminant-derived materials from bovine spongiform encephalopathy (BSE)

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