

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-908

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-180

30 SEPTEMBER 2005

NDA: 21-908

Drug Product Name

Proprietary: —

Non-proprietary: lubiprostone

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
3/31/2005	3/31/2005	5/13/2005	5/20/2005

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Sucampo Pharmaceuticals

Address: 4733 Bethesda Avenue, Suite 450, Bethesda, MD 20814

Representative: Gayle Dolecek, Regulatory Agent

Telephone: 301-838-3120

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
 2. **SUBMISSION PROVIDES FOR:** A new drug product
 3. **MANUFACTURING SITE:** []
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Non-sterile, soft-gel capsule for oral administration, 24 mcg/capsule
 5. **METHOD(S) OF STERILIZATION:** N/A
 6. **PHARMACOLOGICAL CATEGORY:** Laxative
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** The drug product is a soft-gel capsule for oral administration. There is some concern on the part of the medical division that the drug product could be used as an abortifacient if inserted vaginally. Therefore, a product quality microbiology consult was requested to assess the specifications in the context of intravaginal administration.

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Executive Summary

- I. Recommendations**
- A. Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
 - B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A
- II. Summary of Microbiology Assessments**
- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is a non-sterile, liquid-filled, soft gel capsule with — specifications.
 - B. Brief Description of Microbiology Deficiencies** – N/A
 - C. Assessment of Risk Due to Microbiology Deficiencies** – N/A
- III. Administrative**
- A. Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
 - B. Endorsement Block** _____
James L. McVey (Microbiology Team Leader)
 - C. CC Block**
N/A

1 Page(s) Withheld

 1 ✓ § 552(b)(4) Trade Secret / Confidential

 § 552(b)(5) Deliberative Process

 § 552(b)(4) Draft Labeling

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/s/

Bryan Riley
10/3/2005 02:37:57 PM
MICROBIOLOGIST

James McVey
10/5/2005 07:27:38 AM
MICROBIOLOGIST