

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-908

APPROVAL LETTER(S)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-908

Sucampo Pharmaceuticals, Inc.
4733 Bethesda Avenue, Suite 450
Bethesda, Maryland 20814

Dear Dr. Cormack:

Please refer to your new drug application (NDA) dated March 31, 2005, received March 31, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amitiza™ (Lubiprostone Capsules).

We acknowledge receipt of your submissions dated June 9, July 27, September 16, September 30, October 17, November 2, November 16, November 22, December 7, December 9, December 14, December 21, December 23, 2005 and January 3, 2006.

This new drug application provides for the use of Amitiza™ (Lubiprostone Capsules) for the treatment of chronic idiopathic constipation in the adult population.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling and submitted labeling (package insert submitted January 27, 2006 and immediate container and carton labels submitted January 28, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages 0 to 17 years until January 31, 2008.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

Deferred pediatric studies under PREA for the treatment of chronic idiopathic constipation in pediatric patients ages 0 to 17 years.

Protocol Submission:	by July 31, 2006
Study Start:	by January 31, 2007
Final Report Submission:	by January 31, 2008

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

We remind you of your postmarketing study commitments in your submission dated January 27, 2006. These commitments are listed below.

1. Perform a Phase IV study to assess the need for potential dose adjustment in patients with renal impairment.

Protocol Submission: by July 31, 2006
Study Start: by January 31, 2007
Final Report Submission: by January 31, 2008

2. Perform a Phase IV study to assess the need for potential dose adjustment in patients with hepatic impairment.

Protocol Submission: by July 31, 2006
Study Start: by January 31, 2007
Final Report Submission: by January 31, 2008

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Tanya Clayton, B.S., Regulatory Health Project Manager at (301) 796-0871.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Acting Director
Office of New Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure