DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-908/S-005

Sucampo Pharmaceuticals, Inc.
Attention: Robert S. Cormack, Ph.D.
4520 East-West Highway, 3rd Floor
Bethesda, MD 20814

Dear Dr. Cormack:

Please refer to your supplemental new drug application dated June 29, 2007, received June 29, 2007 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amitiza (lubiprostone) Capsules, 8 mcg.

We acknowledge receipt of your submissions dated: August 16, August 31, September 17, September 19, October 10, October 24, and November 21, 2007; and February 7, March 12, March 24, and April 10, 2008.

This supplemental new drug application provides for the use of Amitiza (lubiprostone) Capsules, 8 mcg twice daily for treatment of Irritable Bowel Syndrome with constipation in women $\geq$ 18 years old.

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

LABELING

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels).

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-908/S-005."

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission"FPL for approved supplement NDA 21-908/S-005." Approval of this/these submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration

are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 5 years because necessary studies are impossible or highly impracticable. This is because Irritable Bowel Syndrome with constipation does not occur in this age group or the population is too small.

We are deferring submission of your pediatric study for ages 6 to 17 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

1. Deferred pediatric study under PREA for the treatment of Irritable Bowel Syndrome with constipation in pediatric patients ages 6 to 17. The design consists of a 12-month multi-center, double-blinded, placebo-controlled safety and efficacy study including a safety evaluation of the effects of lubiprostone treatment on bone growth.

   Protocol Submission: by October 31, 2008
   Study Start: by January 15, 2009
   Final Report Submission: by December 31, 2011

Submit final study reports to this NDA. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designate**d "Required Pediatric Assessment".**

POSTMARKETING COMMITMENT

We remind you of your postmarketing study commitment in your submission dated April 23, 2008. This commitment is listed below.

2. Conduct a double-blinded clinical trial testing a single treatment arm of Amitiza versus placebo in male and female patients with Irritable Bowel Syndrome with constipation, utilizing a higher dose than recommended for this indication (e.g., 16 mcg twice daily).

Protocol Submission:	by December 15, 2008
Study Start:	by April 29, 2009
Final Report Submission:	by April 29, 2011

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 summary 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."

PROMOTIONAL MATERIALS

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
5901-B Ammendale Road
Beltsville, MD 20705-1266

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

REPORTING REQUIREMENTS

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

We ask that you submit all adverse events related to dyspnea or chest discomfort as 15-day reports, per reporting regulation 21 CFR 314.80.

If you have any questions, call Thomas Moreno, Regulatory Project Manager, at (301) 796-2247.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Donna Griebel

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