



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-908/S-004

Sucampo Pharmaceuticals, Inc.  
Attention: Robert Cormack, Ph.D, RAC  
Associate Director, Regulatory Affairs  
4733 Bethesda Ave., Suite 450  
Bethesda, MD 20814

Dear Dr. Cormack:

Please refer to your supplemental new drug application dated November 15, 2006, received November 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Amitiza (lubiprostone) Capsules.

We acknowledge receipt of your submission dated March 28, 2007.

This supplemental new drug application provides for reformatting of the package insert to comply with the physician's labeling rule.

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.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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

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

If you have any questions, call Brian Strongin, R.Ph., M.B.A., Chief, Regulatory Project Management Staff, at (301) 796-1008.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D.  
Acting Director  
Division of Gastroenterology Products  
Office of Drug Evaluation III

Enclosure

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

/s/

-----  
Joyce Korvick  
5/16/2007 05:21:27 PM