NDA 021908/S-018

SUPPLEMENT APPROVAL
RELEASE FROM POSTMARKETING REQUIREMENT

Sucampo Pharma Americas, LLC
Attention: Brett Begovich
Senior Regulatory Affairs Associate - Strategy
1425 U.S. Route 206
Bedminster, NJ 07921

Dear Mr. Begovich:

Please refer to your supplemental new drug application (sNDA) dated May 20, 2020, received May 20, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Amitiza (lubiprostone) capsules.

This Prior Approval supplemental new drug application provides for updates to subsection 8.4 Pediatric Use in the Prescribing Information following release from postmarketing requirements 675-3 and 675-4 (described below) and clarifies that safety and effectiveness have not been established in pediatric patients with irritable bowel syndrome with constipation, pediatric functional constipation, or opioid-induced constipation.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

RELEASE FROM POSTMARKETING REQUIREMENT

We have received your submission requesting release from the following postmarketing requirements listed in our September 1, 2016 postapproval postmarketing requirement letter:

675-3 Conduct a safety and efficacy study of lubiprostone in pediatric patients with irritable bowel syndrome with constipation (IBS-C) ages 6 years to < 18 years. The design will consist of a 12-week multi-center, double-blinded, placebo-controlled safety and efficacy study.

Final Protocol Submission: 05/2017
Study Completion: 06/2020
Final Report Submission: 09/2020

675-4 Conduct an open-label extension safety study of lubiprostone, including a safety evaluation of the effects of lubiprostone treatment on bone growth, in pediatric patients ages 6 years to < 18 years with irritable bowel syndrome with constipation (IBS-C) who participated in the 12-week efficacy study conducted to address PMR 675-3.

Final Protocol Submission: 05/2017
Study Completion: 06/2021
Final Report Submission: 09/2021

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

We have reviewed your submission and have determined that you are released from the above postmarketing requirement because FDA has determined that studies in pediatric patients for IBS-C are impossible or highly impracticable for this specific drug development program (section 505B(a)(4)(A)(i) of the Act).

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our April 29, 2008 supplemental approval letter and September 1, 2016 postapproval postmarketing requirement letter.

REPORTING REQUIREMENTS

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, contact Andrew Kelleher, Ph.D., Regulatory Project Manager, at (301) 796-9330 or email andrew.kelleher@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Jessica J. Lee, M.D., M.M.Sc.
Director
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling
  - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JESSICA J LEE
11/30/2020 01:23:31 PM