



NDA 202811/S-017

**SUPPLEMENT APPROVAL  
FULFILLMENT OF  
POSTMARKETING REQUIREMENT**

Allergan Sales, LLC  
Attention: Sanket Trivedi, MS  
Senior Manager, Regulatory Affairs  
5 Giralda Farms  
Madison, NJ 07940

Dear Mr. Trivedi:

Please refer to your supplemental new drug application (sNDA) dated January 30, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Linzess (linaclotide) capsules.

This Prior Approval supplemental new drug application provides for updates to section 8.2: Lactation of the Prescribing Information (PI) to reflect the findings of clinical study LIN-PK-01, titled "An Open-Label, Multiple-Dose, Milk-Only Lactation Study in Lactating Women Receiving Linaclotide Therapeutically," which was conducted in response to postmarketing requirement (PMR) 1915-7, as discussed below.

**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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- Update the date at the end of Highlights in the PI to the approval date and update the revision date at the end of the Medication Guide.
- Reformat the Table of Contents in the PI to move "10 OVERDOSAGE" to the second column.

**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.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, Instructions for Use, and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected"

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

(CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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*.<sup>2</sup>

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(I)(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).

### **FULFILLMENT OF POSTMARKETING REQUIREMENT**

We have received your submission dated January 30, 2020 containing the final report for the following postmarketing requirement listed in the April 30, 2013 postapproval postmarketing requirement letter.

1915-7	A milk-only lactation trial in lactating women receiving Linzess (linaclotide) therapeutically to assess concentrations of linaclotide and its active metabolite in breast milk using a validated assay in order to appropriately inform the Nursing Mothers' subsection of the labeling
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We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements listed in the April 30, 2015 postapproval postmarketing requirement letters that are still open.

### **REPORTING REQUIREMENTS**

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

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<sup>2</sup> 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>.

If you have any questions, call Andrew Dodson, PharmD, Regulatory Project Manager, at 301-796-8760.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, MD, MPH  
Deputy Director for Safety  
Division of Gastroenterology  
Office of Immunology and Inflammation  
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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**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.**  
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/s/  
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JOYCE A KORVICK  
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