



NDA 202535-S06

**SUPPLEMENT APPROVAL**

Ferring Pharmaceuticals Inc.  
Attention: Erik Thygesen, Director  
US Regulatory Affairs  
100 Interpace Parkway  
Parsippany, NJ 07054

Dear Erik Thygesen:

Please refer to your supplemental new drug application (sNDA) dated and received, May 17, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prepopik (sodium picosulfate, magnesium oxide, and anhydrous citric acid) for oral solution.

We also refer to our letter dated April 17, 2023, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we have determined should be included in the labeling for Prepopik. This information pertains to the risk of syncope.

This supplemental new drug application provides for revisions to the labeling for Prepopik. The agreed upon changes to the language included in our April 17, 2023, letter are as follows (additions are noted by underline and deletion are noted by ~~strikethrough~~). Please refer to the attached agreed label.

(b) (4)

## **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](http://www.fda.gov).<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effectuated” (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>

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

<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>.

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).

### **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, call Jacqueline LeeHoffman, Safety Regulatory Project Manager, at (240) 402-8689.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D., M.P.H.  
Deputy Director for Safety  
Division of Gastroenterology (DG)  
Office of Immunology and Inflammation (OII)  
Center for Drug Evaluation and Research

#### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

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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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