



NDA 209589/S-006

SUPPLEMENT APPROVAL

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

Dear Mr. Thygesen:

Please refer to your supplemental new drug application (sNDA) dated December 19, 2018, received December 19, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CLENPIQ (sodium picosulfate, magnesium oxide and anhydrous citric acid) oral solution.

We also refer to our approval letter dated October 18, 2019 which contained the following errors in the Prescribing Information: missing information in Highlights for Recent Major Changes dated 08/2019 and missing vertical lines in the left margin next to the corresponding text in the Full Prescribing Information. The following corrections were made:

Highlights

- Added date of 08/2019 to Recent Major Changes for Dosage and Administration (2.2)

Full Prescribing Information

- Added a vertical line in the left margin next to the following sections to correspond with the Recent Major Changes dated 08/2019 listed in Highlights:
 - Section 1 Indications and Usage.
 - Section 2.2 Dosage and Administration, Split-Dose Dosage Regimen
 - Section 5.1 Serious Fluid and Electrolyte Abnormalities

This replacement approval letter incorporates the correction of the errors. The effective approval date will remain October 18, 2019, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for changes to the prescribing information, including revised hydration instructions and removal of instructions regarding the option to use a “Day-Before” dosage regimen, to retain only the “Split-Dose” regimen.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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.

- Updated Recent Major Changes date for Dosage and Administration (2.1, 2.2) in the Highlights section of the Prescribing Information to 10/2019.
- Added Recent Major Changes item “Dosage and Administration, Day-Before Dosage Regimen (2.3) Removed 10/2019” to the Highlights section of the Prescribing Information.
- Added vertical lines in sections 2.1 and 2.2 to mark labeling changes.

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, 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*.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).

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

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>.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the Prescribing Information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵ For more information

³ When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.⁶

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}

Lisa Soule, M.D.
Associate Director
Division of Gastroenterology and Inborn Errors
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):

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

⁶ <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>

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/

LISA M SOULE
10/18/2019 12:00:00 AM