FERRING
PHARMACEUTICALS

November 18, 2019

Dragos Roman, M.D., Director
Food and Drug Administration
Division of Gastroenterology and Inborn Errors Products
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

**Re:** **NDA No. 202535**
**Product:** **PREPOPIK® (sodium picosulfate, magnesium oxide, and anhydrous citric acid)**
**Submission:** **Response to Notification of Non-Compliance PREA 1902-2**
**Sequence:** **SN 0092**

Dear Dr. Roman:

Enclosed is Ferring's response to the Non-Compliance Letter regarding Post Marketing Requirement (PMR) - PREA 1902-2 dated October 4, 2019.

All files in submission were checked and verified to be free of viruses using McAfee® VirusScan Enterprises, Version 8.8.0.

Please call me at (973) 796-1687 or contact me via e-mail at erik.thygesen@ferring.com if you have any questions.

Sincerely,

Erik Thygesen, M.Sc. Pharm.
Sr. Director, Regulatory Affairs

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**Re:** **NDA No. 202535**
**Product:** **PREPOPIK® (sodium picosulfate, magnesium oxide, and anhydrous citric acid)**
**Submission:** **Post Marketing Requirement - PREA 1902-2 Request for Extension**
**Sequence:** **SN 0093**

Dear Dr. Roman:

Reference is made NDA No. 202535 PREPOPIK® (sodium picosulfate, magnesium oxide, and anhydrous citric acid) for Oral Solution.

**Post Marketing Requirement (PMR) - PREA 1902-2**

Please refer to the July 16, 2012 NDA approval letter for PREPOPIK wherein it was agreed that Ferring Pharmaceuticals Inc. (Ferring) will perform three post marketing studies under the Pediatric Research Study Act (PREA) including PREA 1902-2 (2 years to <9 years).

**1902-2 Conduct a randomized, single-blind, multicenter dose-ranging study comparing the safety and efficacy of Prepopik to community standard of care in children (ages 2 years to <9 years). This study will include PK assessments.**

Final Protocol Submission: February 2016
Study Completion: February 2019
Final Report Submission: August 2019

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**Request for Extension PMR PREA 1902-2**

Ferring requests an extension for PMR PREA 1902-2 with revised time lines to coincide with the agreed timelines for PMR PREA commitments in the CLENPIQ NDA described below.

**1902-2 Conduct a randomized, single-blind, multicenter dose-ranging study comparing the safety and efficacy of Prepopik to community standard of care in children (ages 2 years to <9 years). This study will include PK assessments.**

Study Completion: 12/2023
Study Submission: 06/2024

All files in submission were checked and verified to be free of viruses using McAfee® VirusScan Enterprises, Version 8.8.0.

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Sincerely,

Erik Thygesen, M.Sc. Pharm.
Sr. Director, Regulatory Affairs