

August 27, 2018

Food and Drug Administration
Central Document Room
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705

Re.: NDA 22-372, SUPREP® Bowel Prep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution

IND 74,808; Oral Sulfate (Magnesium, Sodium, Potassium) Solution

RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Sir/Madam:

This communication is in response to FDA's Notification of Non-Compliance with PREA letter dated July 16, 2018 related to the following post-marketing required study:

1580-3: Conduct a randomized, single-blind, multicenter dose ranging study comparing the safety and efficacy of SUPREP to NuLYTELY in adolescents (12 years to 16 years).

As communicated via email on July 11, 2018 to Dr. Andrew Kelleher (FDA, Regulatory Project Manager), locked data sets were not received from the CRO (b) (4) until June 19, 2018. This has resulted in delay of submission of the final study report beyond the anticipated date of June 30, 2018.

Braintree has submitted the Final Study Report for the BLI800-502 study (responsive to PMR 1580-3), entitled "A Safety and Efficacy Study of a Bowel Cleansing Preparation (BLI800) in Pediatric Subjects Undergoing Colonoscopy" to our electronic submission vendor (b) (4) for publishing and submission to FDA.


Given the final status of the study report, (b) (4), we are not requesting a further extension of the timeline for PMR 1580-3.

Please be advised that the material and data contained in this submission are considered to be confidential. The legal protection of such confidential commercial material is claimed under the applicable provision of 18 U.S.C., Section 1905 or 21 U.S.C., Section 331(j) as well as the FDA regulations. Braintree Laboratories considers this information exempt from disclosure under exemption 4 of the Freedom of Information Act.

If you have any questions, or require additional information, please contact me at (781) 843-2202 or Vivian.Caballero@sebelapharma.com.

Sincerely,

**Vivian A
Caballero**

 Digitally signed by Vivian A Caballero
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