Braintree LABORATORIES · INC

RESPONSE TO PREA NON-COMPLIANCE LETTER

DEFERRAL EXTENSION REQUESTED

ORIGINAL
S0174

December 12, 2014

RECEIVED
DEC 15 2014
CDR

Donna Griebel, MD
Division of Gastroenterology Drug Products
Office of Drug Evaluation III
Food and Drug Administration
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

Notification of Non-Compliance with PREA

Dear Dr. Griebel:

This communication is in response to FDA's Notification of Non-Compliance with PREA letter dated December 2, 2014.

Braintree is currently conducting the BLI800-501 study, entitled "Efficacy, Safety and Tolerability of a Bowel Cleansing Preparation (BLI800) in Pediatric Subjects Undergoing Colonoscopy". This PMR study is being conducted to fulfill the PREA requirement outlined below.

> "1580-2: Conduct an open-label pilot study assessing the efficacy and tolerability of SUPREP in adolescents (12 years to 16 years). The adult formulation (and any age appropriate reformulations) will be evaluated for tolerability and efficacy in this pilot study"

The completion date of this study was originally estimated for August 31, 2014. The recruitment period had to be extended by approximately 3 months to reach the target enrollment (32 subjects). The slower than expected recruitment in this study was primarily due to the fact that pediatric colonoscopy is an orphan population in the United States (recognized by FDA), as well as difficulty obtaining caregiver consent to the

aggressive follow up schedule required by the protocol, which was developed in response to feedback from FDA and EMA.

The last subject was enrolled on November 19, 2014, with the last colonoscopy currently scheduled for December 15, 2014. Based on these dates, Braintree requests a deferral with the following revised milestones:

Study Completion Date: January 15, 2015 *(to allow for the 30 day follow-up visit)*

Final Study Report: April 15, 2015

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 or Mark Cleveland at (781) 843-2202.

Sincerely,

Vivian A. Caballero
Vice President, Regulatory Affairs

cc: Food and Drug Administration
Center for Drug Evaluation and Research
Pediatric and Maternal Health Staff
5901-B Ammendale Road
Beltsville, MD 20705