DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 204135

ANDA TENTATIVE APPROVAL

Breckenridge Pharmaceutical, Inc.
15 Massirio Drive, Suite 201
Berlin, CT 06037
Attention: Joanna L. Walsh
Senior Manager, Regulatory Affairs

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution, 17.5 grams/3.13 grams/1.6 grams per 6 ounces.

Reference is also made to your amendments dated June 1, 2012; and August 11, and October 31, 2014; and January 15, May 21, June 5, and October 21, 2015.

We have completed the review of this ANDA, and based upon the information you presented to date we concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the exclusivity issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention.

The reference listed drug (RLD) upon which you have based your ANDA, Suprep Bowel Prep Kit, Oral Solution, 17.5 grams/3.13 grams/1.6 grams per 6 ounces, of Braintree Laboratories Inc. (Braintree), is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,946,149 (the '149 patent) is scheduled to on expire March 7, 2023.

Your ANDA contains a paragraph IV certification to the '149 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution, 17.5 grams/3.13 grams/1.6 grams per 6 ounces, under this ANDA. You have notified the agency that Breckenridge Pharmaceutical, Inc. (Breckenridge)

complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that litigation was initiated within the statutory 45-day period against Breckenridge for infringement of the '149 patent in the United States District Court for the Southern District of New York [Braintree Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc., Civil Action No. 1:12-cv-06851]. You have also notified the agency that the court entered summary judgment of non-infringement for the '149 patent. Braintree has appealed this decision, and that appeal is pending.

However, we are unable to grant final approval to your ANDA at this time. Prior to the submission of your ANDA, another applicant or applicants submitted a substantially complete ANDA providing for Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution, 17.5 grams/3.13 grams/1.6 grams per 6 ounces, and containing a paragraph IV certification.[1] Your ANDA will be eligible for final approval on the date that is 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the FD&C Act.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval (see the guidance for industry, Amendments and Easily Correctable Deficiencies Under GDUFA). Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with cGMPs are subject to Agency review before final approval of the ANDA will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a "FINAL APPROVAL REQUESTED."

In addition to the amendment requested above, the Agency may request, at any time prior to the date of final approval, that you submit an additional amendment containing information as specified by the Agency. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

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[1] The agency has determined that there was a change in the requirements for approval imposed after the date of submission of the first applicant or applicants. Therefore, eligibility for the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the FD&C Act for Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution, 17.5 g/3.13 g/1.6 g per 6 ounces has not been forfeited under section 505(j)(5)(D)(i)(IV) of the FD&C Act.

This drug product may not be marketed without final Agency approval under section 505 of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505 of the FD&C Act, and will not be listed in the Orange Book.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

In addition, we note that GDUFA requires that certain non-manufacturing sites and organizations listed in generic drug submissions comply with the self-identification requirement. The failure of any facility, site, or organization to comply with its obligation to self-identify and/or to pay fees when due may raise significant concerns about that site or organization and is a factor that may increase the likelihood of a site inspection prior to approval. FDA does not expect to give priority to completion of inspections that are required simply because facilities, sites, or organizations fail to comply with the law requiring self-identification or fee payment.

Additionally, we note that the failure of any facility referenced in the application to self-identify and pay applicable fees means that FDA will not consider the GDUFA application review goal dates to apply to that application.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs and Drug Master Files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Jeannettee Joyner, Regulatory Project Manager, at (240) 402-1015.

Sincerely yours,

{See appended electronic signature page}

Carol A. Holquist, RPh
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

Digitally signed by Carol Holquist
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