DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 202511

ANDA APPROVAL

Lupin Inc.
400 Campus Drive
Somerset, NJ 08873
Attention: Scott Talbot
Vice President, Quality Assurance and Regulatory Affairs

Dear Sir:

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 g/3.13 g/1.6 g per 6 ounces.

Reference is made to our tentative approval letter issued on May 29, 2015, and to your amendments dated November 9, 2016; and January 13, 2017.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is **approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution, 17.5 g/3.13 g/1.6 g per 6 ounces to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Suprep Bowel Prep Kit of Braintree Laboratories (Braintree).

The RLD upon which you have based your ANDA, Braintree's Suprep Bowel Prep Kit, 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 expire on 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 g/3.13 g/1.6 g per 6 ounces, under this ANDA. You have notified the agency that Lupin Inc. (Lupin) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that litigation was initiated against Lupin for infringement of the '149 within the statutory 45-day period in the United States District Court for the District of New Jersey [Braintree Laboratories Inc., v. Lupin Atlantis Holdings SA, Civil Action No. 3:11-cv-01341PGS-LHG]. You have also notified the Agency that on September 19, 2016, a Final Consent Judgment and Order was entered by the Court.

With respect to 180-day generic drug exclusivity, we note that Lupin was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Lupin is eligible for 180 days of generic drug exclusivity for Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution, 17.5 g/3.13 g/1.6 g per 6 ounces. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The agency notes that Lupin failed to obtain tentative approval of this ANDA within 40[1] months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). Nevertheless, the agency has determined that the failure to obtain tentative approval within the 40-month period was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed. Please submit correspondence to this ANDA informing the agency of the date of commercial marketing.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & 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.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research

[1] For applications submitted between January 9, 2010, and July 9, 2012, containing a paragraph IV certification (or amended to first contain a paragraph IV certification during that period of time), and approved or tentatively approved during the period of time beginning on July 9, 2012, and ending on September 30, 2015, section 1133(a) of FDASIA extended this period to 40 months. For applications submitted between January 9, 2010, and July 9, 2012 (or amended to first contain a paragraph IV certification during that period of time), and approved or tentatively approved during the period of time beginning on October 1, 2015, and ending on September 30, 2016, section 1133(a) of FDASIA extended this period to 36 months. In addition, if an application was submitted between January 9, 2010, and July 9, 2012 containing a paragraph IV certification (or amended to first contain a paragraph IV certification during that period of time), and FDA had not approved or tentatively approved the application but must consider whether the applicant had forfeited exclusivity because a potentially blocked application is ready for approval, FDA applied the 36-month period if it made the forfeiture determination between the period of time beginning on October 1, 2015, and ending on September 30, 2016. For all other applications, the 30-month period set forth in section 505(j)(5)(D)(i)(IV) of the FD&C Act applies. This ANDA was submitted November 8, 2011, and tentatively approved on May 29, 2015.

Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

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 1 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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

Carol A. Holquist, RPh
Acting 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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