U.S. FOOD & DRUG ADMINISTRATION

Suitability Petition
Completeness Assessment Correspondence

Lachman Consultant Services, Inc.
1600 Stewart Ave., Suite 604
Westbury, NY 11590
Attn: Martin H. Shimer

Sent via email to: m.shimer@lachmanconsultants.com

Docket No. FDA-2024-P-0667

Dear Martin H. Shimer:

This is in reference to your petition received on February 5, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission, in accordance with 21 C.F.R. §314.93(b), to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Magnesium Sulfate in Water for Injection, 3 g/100 mL (30 mg/mL). The petition was examined for initial completeness (i.e. Completeness Assessment) under CFR 10.30 and the Agency has made a threshold determination that the petition is complete.

This petition is subject to the provisions of the Generic Drugs User Fee Amendments of 2022 (GDUFA III) whereby any suitability petitions submitted in FY 2024-2027 will receive a goal date of 6 months after the completeness assessment. The GDUFA goal date for review of this petition is August 26, 2024.

If you have any questions, contact ANDAFiling@fda.hhs.gov.

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

{See appended electronic signature page}

Diana Guon, Pharm.D., BCPS
Pharmacist
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Diana Guon

Digitally signed by Diana Guon
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