**Suitability Petition**
**Completeness Assessment Correspondence**

Lachman Consulting Services, Inc.
1600 Stewart Avenue, Suite 604
Westbury, NY 11590
Attn: Martin Shimer

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

Docket No. FDA-2024-P-3188

Dear Martin Shimer:

This is in reference to your petition received on July 3, 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: Levetiracetam in Sodium Chloride Injection, 1250 mg/100 mL (12.5 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 January 23, 2025.

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}*

Elizabeth Kim, MSN, APRN, FNP-BC
Regulatory Officer
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

**U.S. Food & Drug Administration**
**10903 New Hampshire Avenue**
**Silver Spring, MD 20993**
**www.fda.gov**

Elizabeth Kim

Digitally signed by Elizabeth Kim
Date: 7/23/2024 08:16:06AM
GUID: 5589699300c03b18e9f30807f0193d16