U.S. FOOD & DRUG ADMINISTRATION

Suitability Petition
Completeness Assessment Correspondence

Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005
Attn: Sara W. Koblitz

Sent via email to: SKoblitz@hpm.com

Docket No. FDA-2024-P-2752

Dear Sara W. Koblitz:

This is in reference to your petition received on June 6, 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: Bupivacaine Hydrochloride Injection, 250 mg/100 mL (2.5 mg/mL), 1,250 mg/500 mL (2.5 mg/mL), 2,500 mg/1 L (2.5 mg/mL), 5,000 mg/2 L (2.5 mg/mL), 500 mg/100 mL (5 mg/mL), 2,500 mg/500 mL (5 mg/mL), 5,000 mg/1 L (5 mg/mL), and 10,000 mg/2 L (5 mg/mL) pharmacy bulk package. 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 December 11, 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}

Elizabeth Kim, MSN, APRN, FNP-BC
Regulatory Officer
Division of Filing Review

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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Elizabeth Kim

Digitally signed by Elizabeth Kim
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