



**Suitability Petition
Completeness Assessment Correspondence**

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

Sent via email to: SKoblitz@hpm.com

Docket No. FDA-2024-P-2753

Dear Sara 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: Fentanyl Citrate Injection USP, 5 mg/100 mL (50 mcg/mL), 25 mg/500 mL (50 mcg/mL), 50 mg/1,000 mL (50 mcg/mL), and 100 mg/2,000 mL (50 mcg/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 25, 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}

Ankit Ghodasara, Pharm.D.
Supervisory Pharmacist
Division of Filing Review



Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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Ankit
Ghudasara

Digitally signed by Ankit Ghudasara

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