Suitability Petition
Completeness Assessment Correspondence

Premier Consulting
8000 Jarvis Avenue, Suite 100
Newark, CA 94560
Attn: Seth DePuy

Sent via email to: seth.depuy@premierconsulting.com

Docket No. FDA-2024-P-3571

Dear Seth DePuy:

This is in reference to your petition received on July 29, 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: Amlodipine and Benazepril Hydrochloride Oral Liquid, 5 mg/40 mg per 5 mL, 10 mg/20 mg per 5 mL, and 10 mg/40 mg per 5 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 February 16, 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}

Kaitlin Harves, Pharm.D.
Pharmacist
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs

Center for Drug Evaluation and Research

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Kaitlin Harves

Digitally signed by Kaitlin Harves
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