Suitability Petition
Completeness Assessment Correspondence

RegCon Solutions, LLC
10525 Vista Sorrento Parkway, Suite 100
San Diego, CA 92121
Attn: Frederik Defesche

Sent via email to: fdefesche@regconsolutions.com

Docket No. FDA-2024-P-0425

Dear Frederik Defesche:

This is in reference to your petition received on January 22, 2024, by the U.S. Food and Drug Administration (FDA or Agency) and your amendment dated February 8, 2024, 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: Ziprasidone Mesylate Injection, 20 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 27, 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

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Ankit Ghodasara

Digitally signed by Ankit Ghodasara
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