



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 response to your petition received on January 22, 2024, by the U.S. Food and Drug Administration (FDA or Agency) and your amendment dated February 15, 2024, requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Ziprasidone Mesylate Injection, 20 mg/mL. The listed drug product to which you refer in your petition is Geodon (Ziprasidone Mesylate) for Injection 20 mg/mL, approved under NDA 020919 and held by Viatris Specialty LLC.

Your request involves a change in dosage form from that of the listed drug product (i.e., from lyophilized powder to ready to use solution). The change that you request is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act. However, for the reasons explained below, the Agency denies your request.

We have reviewed your petition under section 505(j)(2)(C) of the Act and FDA's implementing regulations at 21 CFR 314.93. FDA will approve a petition properly submitted under § 314.93 unless FDA finds, among other grounds for denying such a petition, Investigations must be conducted to show the safety and effectiveness of the proposed drug product (i.e., the proposed change – the difference in active ingredient, route of administration, dosage form or strength – from the RLD). 21 CFR 314.93(e)(1)(i). See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(i).

In addition, the Pediatric Research Equity Act (PREA) provides that a person who submits an application or supplement under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall submit assessments adequate to evaluate the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation for which the drug is safe and effective, unless this requirement is waived. Section 505B of the Act. If a change proposed in a suitability petition triggers the need for pediatric studies under PREA to assess safety and efficacy in a relevant pediatric subpopulation and FDA does not waive the requirement,

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



the proposed product will not be eligible to be approved in an ANDA and the suitability petition must be denied. See section 505(j)(2)(A) of the Act ("The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii) [of Section 505(j)(2)(A)]."). Because you are seeking a change in dosage form, this proposed product triggers PREA.

The Agency has determined that clinical trials are required under PREA. Your petition states that a waiver should be granted for acute agitation in schizophrenic pediatric patients because the product fails to represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is unlikely to be used in a substantial number of all pediatric age groups. The Agency grants a partial waiver in pediatric patients of birth to less than 12 years of age with acute agitation associated with schizophrenia on the basis that necessary studies would be impossible or highly impracticable because of the low prevalence of schizophrenia in this age group. However, the Agency disagrees with your contention that the petitioned drug fails to represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is unlikely to be used in a substantial number of pediatric patients aged 12 to less than 17 years of age. The Agency, therefore, denies your request to waive the pediatric assessment required under PREA for patients aged 12 to less than 17 years of age.

Therefore, this petition is being denied because clinical trials are required under PREA for the approval of the requested change to the drug product. The request for a waiver of the pediatric study requirements under PREA has been denied. Please contact the Division of Psychiatry (DP) in the Office of New Drugs (OND) at (301) 796 - 2260 if you wish to pursue approval of your product under section 505(b) of the Act.

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.



Sincerely,

William Chong, M.D.
Director
Office of Safety and Clinical Evaluation
for Lilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research



William
Chong

Digitally signed by William Chong

Date: 8/27/2024 08:09:14AM

GUID: 508da7450002bdd54805b3a331b19b0d