February 8, 2024

Submitted Electronically

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUITABILITY PETITION
PRIORITY RTEVIEW REQUESTED

Dear Sir or Madam:

The undersigned submits this Suitability Petition electronically under Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §§ 10.20 and 10.30, to request the Commissioner of the Food and Drug Administration to declare that the drug product Ziprasidone Mesylate Injection, 20 mg/mL (1.0 mL label claim) is suitable for submission in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Ziprasidone Mesylate Injection, 20 mg/mL ziprasidone (1.0 mL label claim) in a prefilled syringe is suitable for submission as an ANDA. The reference listed drug product (RLD), upon which this petition is based, is GEODON® for injection (Ziprasidone Mesylate) equivalent to 20 mg/mL ziprasidone (a lyophilized powder), New Drug Application ("NDA") 020919 currently held by Viatris Specialty LLC (“VIATRIS”), as designated in the Orange Book (see copy of the page from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations [i.e., Orange Book, (Attachment 1)].

The petitioner seeks a change in dosage form from a lyophilized drug product to a liquid drug product that is equivalent to the reconstituted RLD product. The composition of the product would be Qualitatively and Quantitatively (Q1/Q2) identical to the RLD.

B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage form from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The RLD, GEODON® for injection (Ziprasidone Mesylate) by Viatris is a single-dose lyophilized drug product as ziprasidone mesylate (20 mg ziprasidone/mL when reconstituted according to label instructions). Each mL of ziprasidone mesylate for injection (when reconstituted) contains 20 mg of ziprasidone and 4.7 mg of methanesulfonic acid solubilized by 294 mg of sulfobutylether β-cyclodextrin sodium (SBECD). The proposed drug product is also a single dose drug product but provided as a solution where each mL of contains 20 mg of ziprasidone and 4.7 mg of methanesulfonic acid solubilized by 294 mg of sulfobutylether β-cyclodextrin sodium (SBECD). This petition is thus seeking a change in dosage form from a lyophilized drug product to a liquid drug product.

The proposed change in dosage form represents a dosage form that is consistent with the dosing recommendations of the RLD's approved labeling. The current dosing instructions in the approved labeling of the RLD states, "The recommended dose is 10 mg to 20 mg administered as required up to a maximum dose of 40 mg per day. Doses of 10 mg may be administered every two hours; doses of 20 mg may be administered every four hours up to a maximum of 40 mg/day.

There are no proposed changes in labeling except for the removal of the reconstitution instructions and references to dried/lyophilized product, and changes in the description of the dosage form. The uses, indications, warnings, and directions for use (excluding reconstitution which is not needed) will remain the same as that of the RLD. Draft labeling for the proposed product is included in Attachment 3, and the RLD's approved labeling is provided in Attachment 2.

Therefore, the petitioner's request for the Commissioner to find that a change in fill form from a lyophilized drug product to a liquid drug product should raise no questions of safety or effectiveness, and the Agency should approve the petition.

C. Pediatric Research Equity Act applicability

The proposed change in dosage form triggers the Pediatric Research Equity Act (PREA) which requires application sponsors to conduct studies in pediatric patients, if the Agency concludes that such studies would provide beneficial health data for the pediatric population. The Act specifically requires that a request for a new dosage form is subject to a pediatric evaluation. The Act also provides for a waiver from such requirement if the drug:

1. does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients;
and
2. is not likely to be used in a substantial number of pediatric patients.

Approved labeling for GEODON® does not contain any recommendations for use of this

product in pediatric populations and Section 8.4 of the labeling contains the statement "*The safety and effectiveness of Geodon have not been established in pediatric patients.*" This statement has appeared in labeling for GEODON ® from the original approval granted by FDA on June 21, 2002, through the most recently approved labeling on May 18, 2021, associated with Supplement 050. The current labeling states that "*Geodon was studied in one 4-week, placebo-controlled trial in patients 10 to 17 years of age with bipolar I disorder. However, the data were insufficient to fully assess the safety of Geodon in pediatric patients. Therefore, a safe and effective dose for use could not be established.'*

Petitioner requests a waiver of the pediatric study requirements under PREA "*for acute agitation in schizophrenic patients*." as the proposed Ziprasidone Mesylate Injection, 20 mg/mL product will not represent a meaningful therapeutic benefit over existing therapies where those therapies are Abilify®, Seroquel® and Zyprexa ® among others. Each of these products are adequately labeled for use of treatment of pediatric patients for Schizophrinia.

D. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25 .31.

E. Economic Impact Statement

Pursuant to 21 C.F.R. § 10.30(b), the Petitioner will, upon request by the Commissioner, submit economic impact information.

F. Certification

The undersigned certifies that to the best of its knowledge, this petition includes all information on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the petition.

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Attachment:

1. Excerpt from FDA's Orange Book
2. Approved Labeling for Reference Listed Drug
3. Draft insert labeling for Proposed Product