Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, NW , Suite 1200
Washington, DC 20005-5929
Attn: Sara W. Koblitz

Sent via email to: Skoblitz@hpm.com

Docket No. FDA-2024-P-2757

Dear Sara W. Koblitz:

This is in response to your petition received on June 6, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Oxytocin Injection, 1,000 units/100 mL (10 units/mL), 5,000 units/500 mL (10 units/mL), 10,000 units/1 L (10 units/mL), and 20,000 units/2 L (10 units/mL) pharmacy bulk package. The listed drug product to which you refer in your petition is Oxytocin Injection, 10 units/mL SDV, 100 units/10 mL (10 units/mL) and 300 units/30 mL (10 units/mL) MDV approved under NDA 018248 and held by Fresenius Kabi USA, LLC.

Your request involves a change in strength from that of the listed drug product (i.e., from 10 units/mL SDV, 100 units/10 mL (10 units/mL) and 300 units/30 mL (10 units/mL) MDV to 1,000 units/100 mL (10 units/mL), 5,000 units/500 mL (10 units/mL), 10,000 units/1 L (10 units/ml), and 20,000 units/2 L (10 units/mL) pharmacy bulk package). 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, that any of the proposed changes from the RLD would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(iv).

The Agency has determined that your proposed change in strength raises questions of safety and effectiveness. The proposed change in strength will introduce new risks of medication errors to the marketplace, with potential for serious outcomes, if approved as generic equivalents to the RLD under an ANDA. Specifically, the Agency has identified risks for product preparation errors, including inappropriate use of the proposed pharmacy bulk package and use of

expired drug product, as well as risks for wrong dose errors, including the potential for significant overdose. To prevent these identified errors and risks, significant labeling changes would be required, including to the Dosage and Administration, Overdosage, and Warnings and Precautions sections to distinguish the proposed drug product from the oxytocin infusion bags prepared using the RLD drug product.

Therefore, this petition is being denied because significant labeling changes would be needed to address the newly introduced safety or effectiveness problem posed by the proposed strength, which differs from the listed drug product. Please contact OND (Division of Urology, Obstetrics and Gynecology (DUOG)) at (301) 796 - 2130 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 Iilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

William Chong

Digitally signed by William Chong
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