Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
Attn: John McNally

Sent via email to: john.mcnally@fresenius-kabi.com

Docket No. FDA-2024-P-4135

Dear John McNally:

This is in response to your petition received on August 29, 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: Vasopressin in 0.9% Sodium Chloride Injection, 50 units/50 mL (1 unit/mL). The listed drug product to which you refer in your petition is Vasopressin in 0.9% Sodium Chloride Injection, 20 units/100 mL (0.2 units/mL) and 40 units/100 mL (0.4 units/mL) approved under NDA 217569 and held by Baxter Healthcare Corporation.

Your petition requests a change in strength (total drug content and concentration) from that of the listed drug product (i.e., from 20 units/100 mL (0.2 units/mL) and 40 units/100 mL (0.4 units/mL) to 50 units/50 mL (1 unit/mL)). A change in strength 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, one of the requirements for approval of a petition under section 505(j)(2)(C) of the Act is that there is not "[a] drug product… approved in an NDA for the change described in the petition." 21 CFR 314.93(e)(1)(vi). Therefore, FDA denies your petition because drug products are approved in NDAs for the change described in the petition (Vasopressin in 0.9% Sodium Chloride Injection, 50 units/50 mL (1 unit/mL)), approved under NDA 217766, held by Long Grove Pharmaceuticals LLC, and Vasostrict, 50 units/50 mL (1 unit/mL), approved under NDA 204485, held by Endo Operations Ltd.).

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the decision not to approve your petition 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 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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