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

Sent via email to: Skoblitz@hpm.com

Docket No. FDA-2024-P-2758

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 products: Ropivacaine Hydrochloride Injection, 200 mg/100 mL (2 mg/mL), 1,000 mg/500 mL (2 mg/mL), 2,000 mg/1 L (2 mg/mL), 4,000 mg/2 L (2 mg/mL), 500 mg/100 mL (5 mg/mL), 2,500 mg/500 mL (5 mg/mL), 5,000 mg/1 L (5 mg/mL), 10,000 mg/2 L (5 mg/mL), 1,000 mg/100 mL (10 mg/mL), 5,000 mg/500 mL (10 mg/mL), 10,000 mg/1 L (10 mg/mL), and 20,000 mg/2 L (10 mg/mL) pharmacy bulk package (PBP). The listed drug product to which you refer in your petition is Naropin (Ropivacaine Hydrochloride) Injection USP, 20 mg/10 mL (2 mg/mL), 40 mg/20 mL (2 mg/mL), 100 mg/20 mL (5 mg/mL), 100 mg/10 mL (10 mg/mL), 150 mg/20 mL (7.5 mg/mL), and 200 mg/20 mL (10 mg/mL) single-dose vials and single-dose ampules; 50 mg/10 mL (5 mg/mL) and 75 mg/10 mL (7.5 mg/mL) single-dose ampules; 150 mg/30 mL (5 mg/mL) single-dose vials; 200 mg/100 mL (2 mg/mL) single-dose infusion bottles and single-dose flexible bags; 400 mg/200 mL (2 mg/mL) single-dose infusion bottles and single-dose flexible bags; and, 500 mg/100 mL (5 mg/mL), and 1 g/200 mL (5 mg/mL) single-dose infusion bottles approved under NDA 020533 and held by Fresenius Kabi USA LLC.

Your request involves a change in strength from that of the listed drug product (i.e., from Ropivacaine Hydrochloride Injection USP, 20 mg/10 mL (2 mg/mL), 40 mg/20 mL (2 mg/mL), 100 mg/20 mL (5 mg/mL), 100 mg/10 mL (10 mg/mL), 150 mg/20 mL (7.5 mg/mL), and 200 mg/20 mL (10 mg/mL) single-dose vials and single-dose ampules; 50 mg/10 mL (5 mg/mL) and 75 mg/10 mL (7.5 mg/mL) single-dose ampules; 150 mg/30 mL (5 mg/mL) single-dose vials; 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL) single-dose infusion bottles and single-dose flexible bags; and 500 mg/100 mL (5 mg/mL), and 1 g/200 mL (5 mg/mL) single-dose infusion bottles to Ropivacaine Hydrochloride Injection, 200 mg/100 mL (2 mg/mL), 1,000 mg/500 mL (2 mg/mL), 2,000 mg/1 L (2 mg/mL), 4,000 mg/2 L (2 mg/mL), 500 mg/100 mL (5 mg/mL), 2,500 mg/500 mL (5 mg/mL), 5,000 mg/1 L (5 mg/mL), 10,000 mg/2 L (5 mg/mL), 1,000 mg/100 mL (10 mg/mL), 5,000 mg/500 mL (10 mg/mL), 10,000 mg/1 L (10 mg/mL), and 20,000 mg/2 L (10 mg/mL) PBP. 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.

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, a drug product is approved in an NDA for the change described in the petition. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(vi).

For the reasons explained below, the Agency approves your request to submit an ANDA for Ropivacaine Hydrochloride Injection 1,000 mg/500 mL (2 mg/mL), 2,000 mg/1 L (2 mg/mL), 4,000 mg/2 L (2 mg/mL), 2,500 mg/500 mL (5 mg/mL), 5,000 mg/1 L (5 mg/mL), 10,000 mg/2 L (5 mg/mL), 1,000 mg/100 mL (10 mg/mL), 5,000 mg/500 mL (10 mg/mL), 10,000 mg/1 L (10 mg/mL), and 20,000 mg/2 L (10 mg/mL) PBP, and denies your request to submit an ANDA for Ropivacaine Hydrochloride Injection, 200 mg/100 mL (2 mg/mL) and 500 mg/100 mL (5 mg/mL) PBP.

Proposed Ropivacaine Hydrochloride Injection 1,000 mg/500 mL (2 mg/mL), 2,000 mg/1 L (2 mg/mL), 4,000 mg/2 L (2 mg/mL), 2,500 mg/500 mL (5 mg/mL), 5,000 mg/1 L (5 mg/mL), 10,000 mg/2 L (5 mg/mL), 1,000 mg/100 mL (10 mg/mL), 5,000 mg/500 mL (10 mg/mL), 10,000 mg/1 L (10 mg/mL), and 20,000 mg/2 L (10 mg/mL) PBP

The Agency finds that the proposed changes in strength for the proposed drug products do not pose questions of safety or effectiveness. The uses, dosage form, and route of administration of the proposed drug products are the same as that of the listed drug products. The proposed change is consistent with dosing recommendations in the labeling of the listed drug. In addition, if shown to meet bioequivalence requirements, the proposed drug products can be expected to have the same therapeutic effect as the reference listed drug products. Therefore, FDA concludes that the proposed changes would not jeopardize the safe or effective use of the product so as to necessitate significant labeling changes, and investigations are not necessary to show the safety and effectiveness of these proposed strengths.

The approval of this petition, in part, to allow an ANDA to be submitted for the aforementioned strengths of the proposed drug product does not mean that FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by FDA.

To permit review of your ANDA submission for these strengths, you must submit all information required under section 505(j)(2)(A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioequivalence requirements under section 505(j)(2)(A)(iv) of the Act. During the

review of your application, FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you must refer in your ANDA to the appropriate petition docket number cited above and include a copy of this letter in the ANDA submission. 21 CFR 314.94(a)(3)(iii). Please note that once an application is approved for a product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a petition may not be utilized as the basis for submission of an ANDA.

Proposed Ropivacaine Hydrochloride Injection, 200 mg/100 mL (2 mg/mL) and 500 mg/100 mL (5 mg/mL) PBP

With respect to your proposed strength change from Ropivacaine Hydrochloride Injection USP, 20 mg/10 mL (2 mg/mL), 40 mg/20 mL (2 mg/mL), 100 mg/20 mL (5 mg/mL), 100 mg/10 mL (10 mg/mL), 150 mg/20 mL (7.5 mg/mL), and 200 mg/20 mL (10 mg/mL) single-dose vials and single-dose ampules; 50 mg/10 mL (5 mg/mL) and 75 mg/10 mL (7.5 mg/mL) single-dose ampules; 150 mg/30 mL (5 mg/mL) single-dose vials; 200 mg/100 mL (2 mg/mL), 400 mg/200 mL (2 mg/mL), 500 mg/100 mL (5 mg/mL), and 1 g/200 mL (5 mg/mL) single-dose infusion bottles; 200 mg/100 mL (2 mg/mL), 400 mg/200 mL (2 mg/mL) single-dose flexible bags to Ropivacaine Hydrochloride Injection, 200 mg/100 mL (2 mg/mL), and 500 mg/100 mL (5 mg/mL) PBP, the Agency has determined that a drug product is approved in an NDA for the change described in the petition.

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). FDA, therefore, denies your petition to submit an ANDA for the Ropivacaine Hydrochloride Injection, 200 mg/100 mL (2 mg/mL) and 500 mg/100 mL (5 mg/mL) PBP because a drug product is approved in an NDA for the change described in the petition (Naropin (Ropivacaine Hydrochloride) Injection, 200 mg/100 mL (2 mg/mL) and 500 mg/100 mL (5 mg/mL), approved under NDA 020533, and held by Fresenius Kabi USA LLC).

If you disagree with our determination concerning the approvability of your petition with regard to the Ropivacaine Hydrochloride Injection, 200 mg/100 mL (2 mg/mL) and 500 mg/100 mL (5 mg/mL) PBP, 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 approving your petition in part and denying your petition in part 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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