Epic Pharma, LLC
227-15 North Conduit Avenue
Laurelton, NY 11413
Attn: Xiaofeng Meng

Sent via email to: RADept@epic-phamra.com

Docket No. FDA-2022-P-1039

Dear Xiaofeng Meng:

This is in response to your petition received on June 7, 2022, by the U.S. Food and Drug Administration (FDA or Agency) and your amendment dated August 16, 2023, requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug products: Buspirone Hydrochloride Tablets USP, 2.5 mg, 3.75 mg, and 12.5 mg. The listed drug product to which you refer in your petition is Buspar (Buspirone Hydrochloride) Tablets, 5 mg, 10 mg, 15 mg and 30 mg, approved under NDA 018731 and held by Bristol Myers Squibb Co. Pharmaceutical Research Institute.

Your request involves a change in strength from that of the listed drug product (i.e., from 5 mg, 10 mg, 15 mg, and 30 mg to 2.5 mg, 3.75 mg, and 12.5 mg). 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, that investigations must be conducted to show the safety and effectiveness of the proposed drug product or of any of its active ingredients, its route of administration, dosage form, or strength which differs from the reference listed drug. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(i).

For the reasons explained below, the Agency approves your request to submit an ANDA for Buspirone Hydrochloride Tablets, 2.5 mg and 12.5 mg, and denies your request to submit an ANDA for Buspirone Hydrochloride Tablets, 3.75 mg.

Proposed Buspirone Hydrochloride Tablets, 2.5 mg and 12.5 mg

The Agency finds that the proposed change in strength from 5 mg, 10 mg, 15 mg, and 30 mg to 2.5 mg and 12.5 mg for the proposed drug products does 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 product. 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 product. Therefore, FDA concludes that the

proposed change to 2.5 mg and 12.5 mg tablets would not jeopardize the safe or effective use of the products so as to necessitate significant labeling changes, and investigations are not necessary to show the safety and effectiveness of the proposed strengths.

The approval of this petition, in part, to allow an ANDA to be submitted for the aforementioned strengths of the proposed drug products does not mean that FDA has determined that an ANDA will be approved for the drug products. 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 Buspirone Hydrochloride Tablets, 3.75 mg

With respect to your proposed strength change from Buspirone Hydrochloride Tablets, 5 mg, 10 mg, 15 mg, and 30 mg to Buspirone Hydrochloride Tablets, 3.75 mg, the Agency has determined that the proposed drug product raises questions of safety and effectiveness. We have determined that because the RLD labeling does not provide for the safe and effective use of a 3.75 mg dose as part of the dosage titration regimen, investigations must be conducted to show the safety and effectiveness of the proposed drug product (see 21 CFR 314.93(e)(1)(i)).

FDA, therefore, denies your petition to submit an ANDA for Buspirone Hydrochloride Tablets, 3.75 mg because investigations must be conducted to show the safety and effectiveness of the proposed drug product. Please contact the Office of New Drugs' Division of Psychiatry in the Office of Neuroscience (OND/ON/DP) 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 with regard to Buspirone Hydrochloride Tablets, 3.75 mg, 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 H. Chong -S

Digitally signed by William H. Chong -S
Date: 2024.10.22 07:51:32 -04'00'

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