Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, DC 20005
Attn: Kurt Karst

Sent via email to: KKarst@hpm.com

Docket No. FDA-2024-P-0545

Dear Kurt Karst:

This is in response to your petition received on January 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: Buspirone Hydrochloride Oral Solution, 2 mg/mL. 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 Company.

Your request involves a change in dosage form and strength from that of the listed drug product (i.e., from Buspar (Buspirone Hydrochloride) Tablets, 5 mg, 10 mg, 15 mg, and 30 mg to Buspirone Hydrochloride Oral Solution, 2 mg/mL). The changes that you request are the type of changes that are 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 investigations must be conducted to show the safety and effectiveness of the proposed drug product or 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)(i) and 21 CFR 314.93(e)(1)(iv).

The Agency has determined that your proposed change in dosage form and strength raises questions of safety and effectiveness. The recommended initial dose for the reference listed drug is 15 mg daily (7.5 mg bid) with the maximum daily dosage of 60 mg per day, while the recommended initial dose for the proposed drug product is 12 mg daily (6 mg bid) with the maximum daily dosage of 48 mg per day. The proposed change in dosage form and strength is not supported by the reference listed drug labeling, and investigations would be needed to show the safety and effectiveness of the proposed drug product, which

could also introduce risks related to medication errors and jeopardize the safe or effective use of the product in the absence of significant labeling changes to address the newly introduced safety or effectiveness problem.

In addition, the Pediatric Research Equity Act (PREA) provides that a person who submits an application or supplement under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall submit assessments adequate to evaluate the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation for which the drug is safe and effective, unless this requirement is waived. Section 505B of the Act. If a change proposed in a suitability petition triggers the need for pediatric studies under PREA to assess safety and efficacy in a relevant pediatric subpopulation and FDA does not waive the requirement, the proposed product will not be eligible to be approved in an ANDA and the suitability petition must be denied. See section 505(j)(2)(A) of the Act ("The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii) [of Section 505(j)(2)(A)].").

Because you are seeking a change in dosage form, this proposed product triggers PREA. This petition is being denied because investigations must be conducted to show the safety and effectiveness of the proposed drug product, and significant labeling changes would be needed to address the newly introduced safety or effectiveness problem posed by the proposed dosage form and strength, which differs from the listed drug product. Therefore, because your petition does not meet the applicable requirements under section 505(j)(2)(C) of the Act and 21 CFR 314.93, it is not necessary to address the question of whether pediatric studies are necessary under PREA. Please contact the Division of Psychiatry in the Office of Neuroscience 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 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 Ilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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William Chong

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