Lachman Consulting Services, Inc.
1600 Stewart Avenue, #604
Westbury, NY 11590
Attn: Martin Shimer

*Sent via email to:* m.shimer@lachmanconsultants.com

Docket No. FDA-2024-P-3567

Dear Martin Shimer:

This is in response to your petition received on July 25, 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: Sertraline Hydrochloride Capsules, 25 mg (base), 50 mg (base), and 100 mg (base). The listed drug product to which you refer in your petition is Sertraline Hydrochloride Capsules, 150 mg (base) and 200 mg (base), approved under NDA 215133 and held by Almatica Pharma, LLC.

Your request involves a change in strength from that of the listed drug product (i.e., from 150 mg (base) and 200 mg (base)/capsule/oral to 25 mg (base), 50 mg (base), and 100 mg (base)/capsule/oral). 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, investigations must be conducted to show the safety and effectiveness of the proposed drug product or 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 strength raises questions of safety and effectiveness. The proposed change in strength is not supported by the RLD labeling and would jeopardize the safe or effective use of the product in the absence of significant labeling changes and investigations to ensure the safe and effective use of the product.

Therefore, this petition is being denied because the requested change would, at least, necessitate significant labeling changes to address the newly introduced

safety or effectiveness problem posed by the proposed strengths, which differ from the listed drug product. Additionally, investigations must be conducted to show the safety and effectiveness of the proposed drug products. Please contact Division of Psychiatry, Office of Neuroscience in the Office of New Drugs at (240) 402 - 4857 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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