Yon-Lian Wu
Sunny Pharmtech Inc.
No. 255, Longyuan 1st Rd., Longtan Dist.
Taoyuan City 32542, Taiwan

Docket No. FDA-2019-P-0726

Dear Yon-Lian Wu:

This is in response to your petition received on February 13, 2019, 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: Fluoxetine Hydrochloride Tablets USP, 20 mg. The listed drug product to which you refer in your petition is Fluoxetine Hydrochloride Tablets USP, 60 mg approved under NDA 202133 and held by Almatica Pharma LLC.

Your petition requests a change in strength from that of the listed drug product (i.e., from 60 mg to 20 mg). 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 a drug product is approved in multiple NDAs for the change described in the petition (Prozac® [Fluoxetine Hydrochloride] Tablets USP, 20 mg, approved under NDA 020974, held by Eli Lilly and Co, and Sarafem® [Fluoxetine Hydrochloride] Tablets USP, 20 mg, approved under NDA 021860, held by Allergan Pharmaceuticals International Ltd.)[1]

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.

[1]The Agency notes that NDAs 020974 and 021860 are listed on the Discontinued Drug Product List in FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book). See Orange Book Preface at section 1.11 for more information on the discontinued section of the Orange Book. An ANDA may be submitted that relies on a listed drug approved for safety and effectiveness under section 505(c) of the Act but has been voluntarily withdrawn from sale in the United States. See 21 CFR 314.122(a). Please note that a determination whether an RLD has been withdrawn for safety or effectiveness reasons must be made before FDA may approve an ANDA that refers to an RLD that has been voluntarily withdrawn from sale. 21 CFR 314.161(a).

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 H. Chong -S

Digitally signed by William H. Chong -S
Date: 2023.07.17 20:29:49 -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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov