Sunny Pharmtech 祥翊製藥股份有限公司 Sunny Pharmtech Inc.

SUITABILITY PETITION

Identification of the Petitioner:
Sunny Pharmtech Inc.
No. 255, Longyuan 1st Rd., Longtan Dist.,
Taoyuan City 32542, Taiwan

Citation:

Sunny Pharmtech Inc. (Taiwan) submits this Suitability Petition under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act (FFDCA).

A. Action Requested

Petitioner requests that the Commissioner of the Food and Drug Administration approve the request that the drug product Fluoxetine Hydrochloride 20 mg is suitable for submission as an ANDA. The listed reference drug product (NDA 202133) is Fluoxetine Hydrochloride 60 mg, on which this petition is based is held by Alvogen Group Holdings LLC. The proposed drug Fluoxetine Hydrochloride 20 mg Tablets are of the same indication, pharmaceutical form and route of administration as that of the reference listed drug Fluoxetine Hydrochloride 60 mg Tablets. Therefore, the petitioner seeks a change of strength (quantitative change to the active substance of a drug product) as an additional strength to the RLD. A comparison is provided in the table (Table 1) below.

Table 1. Product Comparison

Parameter	FDA Approved Fluoxetine HCl tablets USP, 60 mg (Alvogen NDA 202133)	Proposed Generic Product Fluoxetine HCl tablets, USP, 60 mg and an additional 20 mg
Active Ingredient	Fluoxetine HCl	Fluoxetine HCl
Inactive Ingredients	mannitol, microcrystalline cellulose, maize starch, povidone, hypromellose, magnesium stearate, titanium dioxide, sucrose, glycerol, and polysorbate	mannitol, microcrystalline cellulose, pregelatinized starch, povidone, hypromellose, magnesium stearate, titanium dioxide, glycerin, and polysorbate
Indications	1. Major Depressive Disorder (MDD) 2. Obsessive Compulsive Disorder (OCD) 3. Bulimia Nervosa 4. Panic Disorder, with or without	1. Major Depressive Disorder (MDD) 2. Obsessive Compulsive Disorder (OCD) 3. Bulimia Nervosa 4. Panic Disorder, with or without

	agoraphobia	agoraphobia
Dosage Form	Tablet	Tablet
Route of Administration	Oral	Oral
Use Directions	See Table in Section B	See Table in Section B
Container Closure	White Plastic Bottle 48 mL, HDPE	White Plastic Bottle 75 mL, HDPE
How Supplied	Fluoxetine tablets, USP 60 mg, are available as 60-mg (fluoxetine base equivalent), film-coated, functional-scored, capsule-shaped, white tablets debossed with "FL 60" on one side ("FL" above the score and "60" below the score) in bottles of 30 tablets (NDC 47781-600-30).	Fluoxetine tablets, USP 60 mg, are available as 60-mg (fluoxetine base equivalent), capsule-shaped, film-coated white tablets which are functional-scored on both sides and debossed with "120" on one side in bottles of 30 tablets (NDC 69776-120-03). The 20 mg tablets are capsule-shaped, film-coated white tablets which are functional-scored on both sides and de bossed with "121" on one side in bottles of 30 tablets (NDC 69776-121-03).

B. Statement of Grounds

The RLD, Fluoxetine Hydrochloride Tablets, held by Alvogen Group Holdings LLC is a film coated solid oral dosage and is available only in 60 mg strength. A copy of the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluation is attached for Reference (Appendix 1).

The **Dosage and Administration Section** of the Alvogen approved labeling (60 mg) provided instructions as follows:

- Use another fluoxetine product for initial doses of 10 to 20 mg/day or for doses other than 30 mg or 60 mg

Indication	**Adult**	**Pediatric**
MDD (2.1)	20 mg/day in morning (initial dose) 20 mg/day (target dose) 80 mg/day (maximum dose studied)	10 to 20 mg/day (initial dose)* *This product has not been studies in doses greater than 20 mg/day in pediatric MDD.
OCD (2.2)	20 mg/day in morning (initial dose) 20 to 60 mg/day (target dose) 60 mg/day (target dose)	10 mg/day (initial dose) 10 to 60 mg/day (target dose)

Bulimia Nervosa (2.3)	60 mg/day in morning	--
Panic Disorder (2.4)	10 mg/day (initial dose) 20 mg/day (target dose) 60 mg/day (maximum dose studied)	--

- No additional benefits seen at higher doses above 20 mg/day in MDD (2.1. 14.1)
- Use a lower or less frequent dosage in patients with hepatic impairment, the elderly, and for patience with concurrent disease or on multiple concomitant medications (2.5, 8.6).

The addition of the 20 mg dosage strength to the proposed ANDA would make available the full range of dosage strengths for distribution and administration to both adult and pediatric patients, from the highest dosage 80 mg (i.e. 60 mg + 20 mg), 60 mg, 30 mg (if needed), 20 mg, to the lowest; 10 mg (i.e. half tablet of the 20 mg).
The proposed drug product also will be a film-coated scored solid oral dosage form; but containing 20 mg of Fluoxetine per tablet, with a formulation composition directly proportional to the in-house proposed 60 mg product.

Hence this petition is seeking a change of strength (addition of single 20 mg) from that of the approved RLD of 60 mg.

The proposed additional 20 mg strength of Fluoxetine does not pose questions of safety or effectiveness. In particular, the proposed strengths (Fluoxetine 60 mg and 20 mg) of the Petitioner's impending ANDA are aligned with the recommended product doses stated in the RLD's prescribing labeling. The uses, dosage form, and route of administration of the proposed drug products are the same as those of the RLD.

Whereas the 60 mg Fluoxetine tablet in the proposed ANDA is expected to be bioequivalent to the RLD (Alvogen's 60 mg) though bioequivalence study, the proposed additional 20 mg tablet drug product is expected to demonstrate bioequivalence to the RLD (Alvogen's 60 mg) through in-vitro dissolution testing. Hence the proposed drug products can be expected to have the same therapeutic effect as the RLD.

There are no proposed changes in labeling, with the exception of the obvious changes: company name, NDCs, supply configurations and the additional strength (20 mg) sought in this petition. The indications, uses, warning, directions of use will remain the same as that of the RLD. A draft labeling for the proposed product is included for reference in Appendix 2, and the RLD's approved labeling in Appendix 3. An annotated labeling detailing the differences between the RLD and proposed labeling is also presented for quick comparison (Appendix 4).

Requirements of the PREA (Pediatric Research Equity Act) which is codified at FDA Act Section 505B does not apply to a new strength, as is proposed in the present petition per FDA Act Section 505B(a)(1)(A). Hence PREA should not serve as an impediment to the Agency's granting of this petition.

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C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31. We confirm that no extraordinary circumstances exist that may significantly affect the quality of the environment as described in 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this applicable in this case; but will agree to provide an economic impact analysis if requested by the Commissioner in accordance with 21 CFR Section 10.30(b).

E. Certification

To the best of the knowledge and belief of the undersigned on behalf of Petitioner, this Suitability Petition includes all information and views on which the petition relies, and including representative data and information (if any) known to be unfavorable to the petition.

Sincerely,

Yonlian Wu

Feb. 13, 2019

Yon-Lian Wu, PhD
CEO, Sunny Pharmtech Inc.
Address: No. 255, Longyuan 1st Rd., Longtan Dist.,
Taoyuan City 32542, Taiwan
Phone: + 886-3-4809168
Email: yonlian.wu@sunnypharmtech.com

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Appendices:
1. Current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluation.
2. Draft labeling for the proposed ANDA (Fluoxetine HCl tablets, USP, 60 mg and 20 mg).
3. RLD's approved labeling.
4. Annotated labeling detailing differences between the RLD and proposed labeling.