



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 13, 2019

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

Sent via email to: yonlian.wu@sunnypharmtech.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner approve the request that the drug product Fluoxetine Hydrochloride 20 mg is suitable for submission as an ANDA was received by this office on 02/13/2019.

It was assigned docket number FDA-2019-P-0726. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)