



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 26, 2019

Ms. Guoying Tan
Sr. Director of Regulatory Affairs
Sunshine Lake Pharma Co., Ltd.
Northern Industry Road 1#, Song Shan Lake,
Dongguan, 523808
Guangdong, China

Sent via email to: tanguoying@hecpharm.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner declare that the drug product Lacosamide Granules for Oral Solution, 10 mg/mL is suitable for submission as an abbreviated new drug application was received by this office on 02/26/2019.

It was assigned docket number FDA-2019-P-0915. 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)