DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 10, 2022

Hindy Schiff
Ascend Laboratories, LLC
339 Jefferson Road
Parsippany, NJ 07054

Sent via email to: hschiff@ascendlaboratories.com

Dear Petitioner:

Your submission requesting that the Commissioner of the Food and Drug Administration to determine that the proposed Solriamfetol Tablets, 37.5mg is suitable for ANDA submission was received and processed under CFR 10.30 by this office on 02/09/2022.

It was assigned docket number FDA-2022-P-0151. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.02.10 13:35:53 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)