



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 23, 2021

Shashank Upadhye, Attorney
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Sent via email to: shashank@ipfdalaw.com

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug Administration determine whether Vigabatrin for oral solution, 25 g/bottle is suitable for submission in an ANDA was received and processed under CFR 10.30 by this office on 02/22/2022.

It was assigned docket number FDA-2022-P-0214. 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 Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)