



January 23, 2024

Srinivas Gurram
Zydus Pharmaceuticals (USA) Inc.
73- B Route 31 North
Pennington, NJ 08534

Sent via email to: d-desai@zydususa.com

Dear Petitioner:

Your petition dated 01/22/2024 was received and processed under CFR 10.30 by this office on 01/22/2024 and it was assigned docket number FDA-2024-P-0435.

Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of this 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,

Karen Malvin

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)