



August 5, 2024

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

Sent via email to: ddesai@zydususa.com

Dear Petitioner:

Your petition was received and processed by this office on 08/02/2024 and it was assigned docket number FDA-2024-P-3699.

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

Please note, the acceptance of the 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
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)