



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 14, 2020

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA designate ANDA 088306 (Dexamethasone tablets, 1 mg) and ANDA 087916 (Dexamethasone tablets, 2 mg) held by Hikma Pharmaceuticals USA Inc. as both a RLD and a RS for purposes of FDA evaluation of ANDA for Dexamethasone tablets, 1 mg and 2 mg was received by this office on 12/11/2020.

It was assigned docket number FDA-2020-P-2299. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

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