zydus
pharmaceuticals

March 03, 2021

To,
Division of Docket management
Food and Drug Administration
Department of Health and Human Services,
5630, Fisher Lane, Room 1061 (HFA -305)
Rockville, MD 20852

Re: Docket No. FDA-2020-P-2299; Withdrawal

The undersigned ("petitioner") hereby withdraws Citizen Petition dated November 30, 2020 to designate ANDA 088306 (Dexamethasone tablets, 1 mg) and ANDA 087916 (Dexamethasone tablets, 2 mg) held by Hikma Pharmaceuticals USA Inc. ("Hikma") as both a RLD and a RS for purposes of FDA evaluation of ANDA for Dexamethasone tablets, 1 mg and 2 mg.

Sincerely,

03/03/2021

Srinivas Gurram (Srini)
Vice President & Head of RA and QA – North America
Zydus Pharmaceuticals (USA) Inc.

Office of Regulatory Affairs
Zydus Pharmaceuticals (USA) Inc.
73-B Route 31 North • Pennington, NJ 08534
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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 (Dexamethasaone 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 Gorham-bigby -S

Digitally signed by Dynna Gorham bigby -S
Date 2020.12.15 09:46:38 -05'00'

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