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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Rockville, MD 20857

May 8, 2020

Yang Liu Qilu Pharmaceutical Co., LTD. 8888 Lvyou Road Jinan, Shandong 250104, CHINA

Sent via email to: qilupharma@qilu-pharma.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA designtes a second RLD for Piperacillin and Tazobactam for Injection (EQ 36 GM BASE/VIAL; EQ 4.5 GM BASE/VIAL) as the currently designated RLD/RS - Zosyn (EQ 36GM BASE/VIAL; EQ 4.5GM BASE/VIAL) is in drug shortage and not available was received by this office on 05/06/2020.

It was assigned docket number FDA-2020-P-1356. 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 in that it 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)