

Date: May 7, 2020
Division of Dockets Management,
Department of Health and Human Services,
Food and Drug Administration,
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852

CITIZEN PETITION

Qilu Pharma, INC. as the US Agent of Qilu Pharmaceutical Co., Ltd., submits this petition under 21 CFR §10.20 & §10.30 to request the commissioner of Food and Drugs to designate a second RLD for Piperacillin and Tazobactam for Injection (EQ 36 GM BASE/VIAL; EQ 4.5 GM BASE/VIAL).

A. Action Requested

Qilu Pharma, INC. respectfully requests that FDA designate 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. This is in connection with the development of our generic drug for a potential ANDA submission of Piperacillin and Tazobactam for Injection, USP (EQ 36 GM BASE/VIAL; EQ 4.5 GM BASE/VIAL).

B. Statement of Grounds

As listed in the orange book, the currently designated RLD/RS of Piperacillin and Tazobactam for Injection (EQ 36 GM BASE/VIAL; EQ 4.5 GM BASE/VIAL) is Zosyn held by WYETH PHARMACEUTICALS LLC with the application No. N050684. The detailed information from FDA website is as below:

Active Ingredient	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM
Proprietary Name	ZOSYN
Dosage Form; Route of Administration	INJECTABLE; INJECTION
STRENGTH	EQ 36GM BASE/VIAL; EQ 4.5GM BASE/VIAL

Reference Listed Drug	Yes
Reference Standard	Yes
TE Code	AP
Application Number	N050684
Product Number	004
Approval Date	Oct 22, 1993
Applicant Holder Full Name	WYETH PHARMACEUTICALS LLC
Marketing Status	Prescription

However, the WYETH's Zosyn (EQ 36 GM BASE/VIAL; EQ 4.5GM BASE/VIAL) is in drug shortage and not available for a long time, we are unable to obtain the necessary samples of RLD through normal drug distribution channel. The undersigned kindly requests Agency to designate a second RLD for Piperacillin and Tazobactam for Injection (EQ 36 GM BASE/VIAL; EQ 4.5GM BASE/VIAL). The detailed information for approved generic drugs of Piperacillin and Tazobactam for Injection (EQ 36 GM BASE/VIAL; EQ 4.5GM BASE/VIAL) from FDA website is listed as below:

Marketing Status	Active Ingredient	Proprietary Name	Application Number	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	PIPERACILLIN AND TAZOBACTAM	A207848	INJECTABLE	INJECTION	EQ 36GM BASE/VIAL ; EQ 4.5GM BASE/VIAL	AP			APOLLO PHARMACEUTICALS INC
RX	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	PIPERACILLIN AND TAZOBACTAM	A203720	INJECTABLE	INJECTION	EQ 36GM BASE/VIAL ; EQ 4.5GM BASE/VIAL	AP			FRESENIUS KABI ANTI INFECTIVES SRL
RX	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	PIPERACILLIN AND TAZOBACTAM	A090498	INJECTABLE	INJECTION	EQ 36GM BASE/VIAL ; EQ 4.5GM BASE/VIAL	AP			ISTITUTO BIOCHIMICO ITALIANO SPA
RX	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	PIPERACILLIN AND TAZOBACTAM	A207146	INJECTABLE	INJECTION	EQ 36GM BASE/VIAL ; EQ 4.5GM BASE/VIAL	AP			WOCKHARDT BIO AG

Remark

At time of filing this CITIZEN PETITION, Piperacillin and Tazobactam for Injection (EQ 36 GM BASE/VIAL; EQ 4.5GM BASE/VIAL) from FRESENIUS KABI ANTI INFECTIVES SRL is not available based on the drug shortage database.

C. Environmental Impact

Any environmental analysis report for the action requested is not required as cited under 21CFR 25.31 (a).

D. Economic Impact

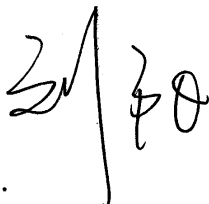
Information regarding economic impact will be made upon request.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Respectfully submitted,

Sincerely,



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