Date: August 23, 2022
Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

# Citizen Petition Withdrawal Letter

Fujian Shengdi Pharmaceutical Co., Ltd. submitted a petition to request that the Commissioner of Food and Drugs designate Dextrose 2.5% and Sodium Chloride 0.45% Injection in Plastic Container (2.5GM/100ML; 450MG/100ML) from FRESENIUS KABI USA LLC with the application No. A211190 as an additional RS for Dextrose 2.5% and Sodium Chloride 0.45% Injection (2.5GM/100ML; 450MG/100ML). The petition was assigned docket number FDA-2022-P-1739 and was received by Food and Drug Administration on July 28, 2022.

On August 10, 2022, Fujian Shengdi Pharmaceutical Co., Ltd. received a response to this petition via Email from Food and Drug Administration, which recommend withdrawing the petition and instead submitting a controlled correspondence to make the request according to the final guidance "Referencing Approved Drug Products in ANDA Submissions," In the guidance, FDA states that applicants may submit controlled correspondence to ask FDA to designate a new reference listed drug or select a reference standard. Fujian Shengdi Pharmaceutical Co., Ltd. hereby requests withdrawal of the citizen petition (Docket No. FDA-2022-P-1739).

Respectfully submitted,

Sincerely,

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