Fresenius Kabi USA, LLC

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Citizen Petition
Docket Number FDA-2019-P-4962

12 March 2025

Division of Dockets Management
Food and Drug Administration
(HFA-305) Room 1061
5630 Fishers Lane
Rockville, MD 20852

Dear Sir/Madam:

Reference is made to our Citizen Petition (Docket Number FDA-2019-P-4962) requesting the Commissioner of the Food and Drug Administration designate Fresenius Kabi USA, LLC's (FK USA) Glucagon for Injection approved under NDA 201849 as therapeutically equivalent to the reference listed drug (RLD) GlucaGen®, NDA 020918, by Novo Nordisk.

The FDA issued a General Advice letter dated 16 August 2023 regarding the TE (therapeutic equivalence) evaluation for Glucagon for Injection. Following this, FK USA has decided to forgo the request. In light of this decision, we respectfully request the withdrawal of our Citizen Petition (Docket Number FDA-2019-P-4962).

Regards,

Robert Muren
Sr. Manager Regulatory Affairs
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Robert Muren

Digitally signed by Robert Muren
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