Nicole Chutipisalkul
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Re: Docket No. FDA-2019-P-4962 4/21/2020

Dear Ms. Chutipisalkul:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on October 24, 2019. Your petition requests that the Agency designate Glucagon for Injection, 1 mg per vial, manufactured by Fresenius Kabi USA, LLC (NDA 201849), as a therapeutic equivalent, with an 'AP' rating, to the listed drug GlucaGen® (NDA 020918) by Novo Nordisk.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.04.21 16:47:05 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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