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

March 25,2021

Re: Docket No. FDA-2019-P-4962

Dear Ms. Chutipisalkul:

Thank you for your letter of January 15, 2021 to Docket No. FDA-2019-P-4962 concerning the above-referenced citizen petition. 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. In your recent letter you ask for a status update on your request.

Please be assured that we are actively working to address the request raised in your citizen petition. As you may be aware, the regulatory standard for determining whether two products are therapeutically equivalent (TE) is a different standard than the approval standards applicable to an application submitted under section 505(b)(2) of the Federal Food, Drug & Cosmetic Act.

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: 2021.03.25 14:53:04 -04'00'

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