DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 24, 2019

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

Sent via email: nicole.chutipisalkul@fresenius-kabi.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA designate Glucagon for Injection, 1 mg per vial, manufactured by FK USA (NDA 201849), as a therapeutic equivalent, with an 'AP' rating, to the reference listed drug (RLD) GlucaGen®, NDA 020918, by Novo Nordisk was received by this office on 10/24/2019.

It was assigned docket number FDA-2019-P-4962. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Digitally signed by Karen Malvin
Date: 2019.10.24 16:05:13 -04'00'

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)