FRESENIUS KABI

Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

15 January 2021

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

CITIZEN PETITION
Docket No. FDA-2019-P-4962

Dear Sir/Madam:

Fresenius Kabi USA, LLC (FK USA) submits this correspondence to citizen petition Docket No. FDA-2019-4962 submitted on 24 October 2019. Pursuant to the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.30 requesting the Commissioner of the Food and Drug Administration to designate FK USA's Glucagon for Injection approved under 505(b)(2) NDA 201849 as therapeutically equivalent with an 'AP' rating to the reference listed drug (RLD) GlucaGen®, NDA 020918, by Novo Nordisk.

An interim response was received on 21 April 2020 stating that the FDA has been unable to reach a decision on the citizen petition. FK USA hereby requests a status update on the citizen petition to designate FK USA's Glucagon for Injection NDA 201849 as therapeutically equivalent with an 'AP' rating to the listed drug GlucaGen® NDA 020918. Furthermore, FK USA received a supplement request letter dated 01 January 2021 and is in the process of updating the labeling to include the statement of pH adjusters. These labeling revisions will align with the RLD's recent package insert approved on 03 September 2020.

FK USA certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,

Nicole Chutipisalkul

Digitally signed by Nicole Chutipisalkul
DN: c=US, st=Illinois, l=Lake Zurich, o=Fresenius Netcare, ou=IT, cn=Nicole Chutipisalkul, email=Nicole.Chutipisalkul@fresenius-kabi.com
Reason: I am the author of this document
Date: 2021.01.15 10:44:17 -06'00'

Nicole Chutipisalkul
Sr. Regulatory Affairs Specialist
Fresenius Kabi USA, LLC
Phone: (847) 550-7093
Fax: (847) 550-7121
Email: nicole.chutipisalkul@fresenius-kabi.com