U.S. FOOD & DRUG ADMINISTRATION

Prabha Kannan
Manager, Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

September 25, 2020

Re: Docket No. FDA-2020-P-1246

Dear Ms. Kannan:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated April 2, 2020. Your petition requests that the Agency designate Fresenius Kabi USA, LLC's Acetaminophen Injection, 10 milligrams/milliliter, approved under new drug application (NDA) 204767 as therapeutically equivalent with an 'AP' rating to the reference listed drug Ofirmev, NDA 022450, held by Mallinckrodt Hosp Products IP Ltd.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

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: 2020.09.25 11:38:18 -04'00'

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

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