DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

April 3, 2020

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

Sent via email to: Prabha.Kannan@fresenius-kabi.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requests that the FDA designate Acetaminophen Injection 10 mg/mL, manufactured by FK USA (NDA 204767), as a therapeutic equivalent, with an 'AP' rating, to the reference listed drug (RLD) Ofirmev®, NDA 022450, by Mallinckrodt Hosp Products IP Ltd., was received by our office on 04/02/2020.

It was assigned docket number FDA-2020-P-1246. 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,

Dynna Bigby Digitally signed by Dynna Bigby Date: 2020.04.03 12:06:39 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)