## DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Silver Spring MD 20993

March 10, 2020

Kurt R. Karst Hyman, Phelps & McNamara, P.C. 700 Thirteenth Street, N.W., Suite 1200 Washington, DC 20005-5929

Sent via email to: <a href="mailto:kkarst@hpm.com">kkarst@hpm.com</a>

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA declare that Acetaminophen Injection, 500 mg/50 mL (10 mg/mL) and 650 mg/65 mL (10 mg/mL), are suitable for submission in an Abbreviated New Drug Application was received by this office on 03/09/2020.

It was assigned docket number FDA-2020-P-1071. 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 Supervisory Administrative Proceedings Officer Division of Dockets Management FDA/Office of Operations (OO)