DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 30, 2020

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

Sent via email to: KKarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA determine that Paclitaxel for Injectable Suspension, in a 50 mg/vial and 300 mg/vial lyophilized powder, is suitable for submission in an ANDA. was received by this office on 01/29/2020.

It was assigned docket number FDA-2020-P-0512. 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: 2020.01.31 15:29:43 -05'00'

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