



August 31, 2022

Donald Hodgson, PhD, President
HBT Labs, Inc.
536 Vanguard Way
Brea, CA 92821

Sent via email to: dhodgson@hbt-labs.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug assign a Therapeutic Equivalence Code for Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), 100 mg/vial under New Drug Application 211875 was received and processed under CFR 10.30 by this office on 08/30/2022.

It was assigned docket number FDA-2022-P-2075. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)

cc: cchang@hbt-labs.com