



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

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

February 24, 2023

Re: Docket No. FDA-2022-P-2075

Dear Dr. Hodgson:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 30, 2022. Your petition requests that the FDA assign a Therapeutic Equivalence Code of “AP” for Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), 100 mg/vial under New Drug Application 211875.

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
Date: 2023.02.24 16:15:51
-05'00'

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