

January 29, 2024

Kurt Karst Hyman, Phelps & McNamara, P.C. 700 13th Street, N.W. Suite 1200 Washington, D.C. 20005

Sent via email to: KKarst@hpm.com

Dear Petitioner:

Your petition dated 01/29/2024 was received and processed under CFR 10.30 by this office on 01/29/2024 and it was assigned docket number FDA-2024-P-0545.

Please refer to this docket number in future correspondence on this subject with the Agency.

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

Sincerely,

Dynna Bigby Lead Administrative Proceedings Specialist Dockets Management Staff FDA/Office of Operations (OO)