

March 28, 2024

Kurt R. Karst Hyman, Phelps & McNamara, P.C 700 Thirteenth Street, N.W., Suite1200 Washington, DC 20005-5929

Sent via email to: KKarst@hpm.com

Dear Petitioner:

Your petition dated 3/26/2024 was received and processed under CFR 10.30 by this office on 3/26/2024 and it was assigned docket number FDA-2024-P-1483.

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,

Maria Myrill Lead Administrative Proceedings Specialist Dockets Management Staff FDA/Office of Operations (OO)