

January 26, 2024

Jay R. Deshmukh Kasowitz Benson Torres LLP 1633 Broadway New York, NY 10019

Sent via email to: JDeshmukh@kasowitz.com

Dear Petitioner:

Your petition dated 01/24/2024 was received and processed under CFR 10.30 by this office on 01/25/2024 and it was assigned docket number FDA-2024-P-0521.

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

Please note, the acceptance of this 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

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