

April 18, 2024

Janet Ransom, PhD., Sponsor's Representative on behalf of Amivas Fast Track Drugs and Biologics, LLC 20010 Fisher Avenue, Suite G Poolesville, MD 20837

Sent via email to: btock@fasttrackresearch.com

Dear Petitioner:

Your petition dated 04/17/2024 was received and processed under CFR 10.30 by this office on 04/17/2024 and it was assigned docket number FDA-2024-P-1913.

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