

January 23, 2024

Frederik Defesche, President RegCon Solutions, LLC 10525 Vista Sorrento Parkway, Suite 100 San Diego, CA 92121

Sent via email to: fdefesche@regconsolutions.com

Dear Petitioner:

Your petition dated 01/22/2024 was received and processed under CFR 10.30 by this office on 01/22/2024 and it was assigned docket number FDA-2024-P-0425.

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,

Karen Malvin

Karen Malvin Acting Director

Dockets Management Staff

FDA/Office of Operations (OO)