



April 16, 2024

Gene Nakagawa, President
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999 Vanderbilt Beach Road, Suite 200
Naples, FL 34108

Sent via email to: gene@newcastlebio.com

Dear Petitioner:

Your petition dated 04/15/2024 was received and processed under CFR 10.30 by this office on 04/15/2024 and it was assigned docket number FDA-2024-P-1870.

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)