



July 12, 2024

Gene Nakagawa
Newcastle Bioscience LLC
999 Vanderbilt Beach Road, Suite 200
Naples, FL 34108

Sent via email to: gene@newcastlebio.com

Dear Petitioner:

Your petition dated 07/09/2024 was received and processed by this office on 07/09/2024 and it was assigned docket number FDA-2024-P-3293.

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

Please note, the acceptance of the 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)