

May 23, 2024

Dr. Milind Narvekar, Vice President Regulatory Affairs Encube Ethicals Private Limited Unit No. 24, Steelmade Industrial Estate, Andheri (East) Mumbai, Maharashtra, 400059, India

Sent via email to: milind.n@encubeethicals.com

Dear Petitioner:

Your petition dated 05/22/2024 was received and processed under CFR 10.30 by this office on 05/22/2024 and it was assigned docket number FDA-2024-P-2515.

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,

Maria Myrill Lead Administrative Proceedings Specialist Dockets Management Staff FDA/Office of Operations (OO)