U.S. FOOD & DRUG ADMINISTRATION

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

November 20, 2024

Re: Docket No. FDA-2024-P-2515

Dear Dr. Narvekar:

This letter responds to your citizen petition received on May 22, 2024, requesting that the Food and Drug Administration (FDA) determine whether FORTESTA (testosterone) gel, 10 milligrams (mg)/0.5 gram (gm) actuation, approved under the new drug application 021463, held by Endo Operations Ltd., has been withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain FORTESTA (testosterone) gel, 10 mg/0.5 gm actuation, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-9917.

Sincerely,

Swati V. Rawani -S

Digitally signed by Swati V. Rawani -S
Date: 2024.11.20 09:51:55 -05'00'

Swati Rawani
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure