

Date – May 22, 2024

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane,
Room 1061 (HFA-305)
Rockville, MD 20852

Citizen Petition

Dear Sir/ Madam,

The undersigned, for Encube Ethicals Private Limited (Encube), respectfully submits this petition pursuant to the Federal Food, Drug and Cosmetic Act (“FDC Act”) and in accordance with regulations at 21 C.F.R. § 10.25(a), § 10.30, and 21 C.F.R. § 314.161 and 314.122, requesting the Commissioner of Food and Drug Administration to provide a determination on whether a listed drug has been withdrawn for reasons of safety or effectiveness as outlined below.

A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drug Administration determine whether the Reference Listed Drug (RLD), Fortesta (testosterone) (10 mg/0.5 gm Actuation) Gel (NDA# 021463) held by ENDO OPERATIONS LTD, has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or effectiveness reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products in the Orange Book. The list, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the “Orange Book”, lists all FDA approved drug products. These drug products are eligible for submission under Section 505(j) of the FD&C Act as ANDAs. Fortesta (testosterone) (10 mg/0.5 gm Actuation) Gel (NDA# 021463) held by ENDO OPERATIONS LTD, was Approved on December 29, 2010. The product was then considered to be a “Reference Listed Drug Product” in the Orange Book.

Fortesta (testosterone) (10 mg/0.5 gm Actuation) Gel (NDA# 021463) now appears in the “Discontinued Section” of the Orange Book (refer [Attachment-I](#)), indicating that it is currently not available for sale. Currently, the orange book displays Testosterone Gel (10 mg/0.5 gm Actuation) (A204571) of ACTAVIS LABORATORIES UT INC INDIRECT WHOLLY OWNED SUB OF TEVA PHARMACEUTICALS USA INC as RS as mentioned in the below [Attachment-I](#).

If an RLD appears in the discontinued section of the Orange Book and the FDA has not determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, a person wishing to submit an ANDA for the drug must submit a citizen petition under 21 C.F.R. § 10.25(a) and § 10.30 before or at the same time of the ANDA submission, seeking a determination on whether the listed drug

has been withdrawn from sale for safety or effectiveness reasons. Such a petition must contain all evidence available to the petitioner concerning the reason that the drug product was withdrawn from sale under 21 C.F.R. § 314.122(a).

The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 C.F.R. § 314.161 (a)(1)).

If the FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book. See *id.* See 21 C.F.R. § 314.122, § 314.161, and § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

Petitioner is further unaware of any reason why Fortesta (testosterone) (10 mg/0.5 gm Actuation) Gel (NDA# 021463) may have been removed from sale and believes the discontinuation of Fortesta (testosterone) (10 mg/0.5 gm Actuation) Gel (NDA# 021463) was due to only commercial considerations. Petitioner requests that FDA determine whether the NDA holder for Fortesta (testosterone) (10 mg/0.5 gm Actuation) Gel (NDA# 021463) has withdrawn the product for reason of safety or effectiveness.

C. Environmental Impact

In Accordance with the requirements set forth in 21 C.F.R. § 25.31 (a), the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment

D. Economic Impact

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. The Petitioner hereby commits to promptly provide this information, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Sincerely,

Dr Milind
S Narvekar

Digitally signed by
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Date: 2024.05.22
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Dr. Milind Narvekar

Vice President Regulatory Affairs

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