Generic drug manufacturer	:	Novitium Pharma LLC
Generic drug manufacturer's address	:	70 lake drive, East windsor, NJ 08520
Name of the Regulatory Contact	:	Muthusamy Shanmugam
Title		Founder and President
Corporate Email address	:	RAoffice@novitiumpharma.com
Contact phone number	:	845-652-0377

CITIZEN PETITION

Date: June 22, 2020

To,

Division of Dockets Management Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madam,

Novitium Pharma LLC, a specialty pharmaceutical company focusing on developing and marketing of generic drugs, submits this citizen petition under 21 C.F.R. § 10.30 to request the Commissioner of Food and Drug Administration (FDA) to designate a Reference standard (RS) for METHYLTESTOSTERONE 10MG oral Capsule.

I. Actions Requested

This petition requests the Commissioner of FDA to take the following actions:

FDA designate the generic product METHYLTESTOSTERONE 10MG oral Capsule made by Impax Laboratories Inc (A204851) as the RS since METHYLTESTOSTERONE 10MG oral Capsule of Impax Laboratories Inc is the only one available in the market at present.

II. Statement of Grounds

A. Introduction

The orange book lists a reference standard TESTRED (METHYLTESTOSTERONE) 10MG oral Capsule approved under ANDA A083976 of VALEANT PHARMACEUTICALS INTERNATIONAL. There is no mention of any RLD in the current orange book.

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	METHYLTESTOSTERONE	METHYLTESTOSTERONE	A204851	CAPSULE	ORAL	10MG	AB			IMPAX LABORATORIES INC
RX	METHYLTESTOSTERONE	TESTRED	A083976	CAPSULE	ORAL	10MG	AB		RS	VALEANT PHARMACEUTICALS INTERNATIONAL
DISCN	METHYLTESTOSTERONE	METHYLTESTOSTERONE	A084967	CAPSULE	ORAL	10MG				HEATHER DRUG CO INC
DISCN	METHYLTESTOSTERONE	VIRILON	A087750	CAPSULE	ORAL	10MG				CHARTWELL STAR RX LLC

Currently the RS TESTRED (METHYLTESTOSTERONE) 10MG oral Capsule approved under ANDA A083976 of VALEANT PHARMACEUTICALS INTERNATIONAL is not available on the market and therefore, Novitium Pharma LLC, requests that FDA promptly designate a RS to facilitate generic drug development.

B. Factual Background

RS is needed for METHYLTESTOSTERONE 10MG oral Capsule to facilitate product development

The Drug Price Competition and Patent Term Restoration Act (Public Law 98- 417), informally known as the Hatch-Waxman Act, was passed in 1984 by United States Congress to encourage the development of generic products. Compared to brand name products, generic products have the same therapeutic effects on patients, but are generally sold at much lower price. The flourish of generic products greatly reduced the drug price and saved the public healthcare costs. A reference listed drug (RLD) (21 CFR 314.94 (a) (3) means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA. The availability of RLD is critical for generic manufacturer to develop its generic product.

However, there is no mention of any RLD in the current orange book.

Nevertheless, the current orange book lists a reference standard TESTRED (METHYLTESTOSTERONE) 10MG oral Capsule approved under ANDA A083976 of VALEANT PHARMACEUTICALS INTERNATIONAL. This reference standard is not available on the market for generic manufacturers to develop generic version for METHYLTESTOSTERONE 10MG oral Capsule.

In this regard, Novitium Pharma, submits a citizen's petition requesting FDA designate the generic product made by Impax Laboratories Inc (A204851) as the RS since METHYLTESTOSTERONE 10MG oral Capsule of Impax Laboratories Inc is the only one available in the market at present.

Conclusion

For the foregoing reasons, FDA should immediately designate a RS for METHYLTESTOSTERONE 10MG oral Capsule. The prompt action shall facilitate the generic product development which is beneficial to the reduction of drug price and subsequently, to the reduction of overall public healthcare costs.

C. Environmental Impact

The actions requested in this petition will have no significant effect on the human environment.

D. Economic Impact

Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

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 petitioners which are unfavorable to the petition.

For correspondence, please contact Novitium Pharma LLC, Regulatory Affairs Office by email at RAOffice@novitiumpharma.com, by phone (845) 652-0377 or fax (609) 469-5920.

Thanks,

Muthusamy Shanmugam

Digitally signed by Muthusamy Shanmugam
Date: 2020.06.22 16:57:50 -04'00'

Muthusamy Shanmugam
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