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April 23, 2019

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

CITIZEN PETITION

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Novitium Pharma LLC a specialty pharmaceutical company focusing on developingand 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 Oxandrin (Oxandrolone) Tablets 2.5mg & 10mg (NDA 013718). The 2.5mg & 10mg are currently designated as RLD in the Orange book. The 10mg is currently designated as RS in the Orange book.

Currently the brand name manufacturer, Gemini Laboratories has discontinued the distribution of Oxandrin Tablets. RLD/RS for this product is not available on the market and therefore, Novitium Pharma LLC, requests that FDA promptly designate a RS to facilitate generic drug development.

I. Actions Requested

This petition requests the Commissioner of FDA to take the following actions:
FDA designate the generic product made by PAR Pharmaceutical Inc (A077827) as the RS of Oxandrin Tablets (NDA 013718) since PAR has the maximum share of sales in the market.

II. Statement of Grounds

A. Introduction

As per the orange book, Oxandrin (Oxandrolone) Tablets 2.5mg & 10mg (NDA 013718) was originally made by Gemini Laboratories LLC and was approved by FDA prior to Jan 1 1982. There are four generic manufacturers that have gained FDA approval to market this product: PAR Pharmaceutical Inc (A077827; current market leader), Upsher-Smith Laboratories LLC (A076761 & A078033), Roxane Laboratories Inc (A077249) and Sandoz Inc (A076897). Roxane Laboratories Inc (A077249) and Sandoz Inc (A076897) were discontinued later.

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B. Factual Background

Novitium Pharma has licensed the Approved NDA 013718 from the NDA Holder, Gemini Laboratories LLC to manufacture and market the drug product recently. Being the regulatory agent for Oxandrin Tablets, we are aware that Oxandrin Tablets is neither manufactured nor marketed by its brand name manufacturer, Gemini Laboratories LLC and hence RLD/RS is not available in the market.

Subsequently, Novitium Pharma has contacted FDA to designate the generic product made by PAR Pharmaceutical Inc (A077827) as the RS of Oxandrin Tablets. FDA has assigned the docket no.: FDA-2018-P-3422 for this citizen petition.

However, on March 04, 2019, we received a communication from FDA stating that we will be notified once FDA reaches a decision on this. In continuation of this, we would like to provide additional information that we received a request from FDA on July 27, 2018 to submit a PLR/PLLR conversion labeling supplement to FDA.

Considering the fact this NDA was approved long before on 07/21/1964, we were left with only minimum information to update the label. Based on the FDA's request, we have updated the label with the available minimum information we have and submitted the revised label to FDA. Subsequently, FDA refused to file our response owing to the reason that we did not provide a complete response to all the FDA's comments. Now that there is no possibility for the availability of the RLD from the NDA holder to be in the market, Novitium Pharma is contacting FDA to designate the generic product made by PAR Pharmaceutical Inc (A077827) as the RS of Oxandrin Tablets.

We were advised by FDA that:

"You may petition the Agency through citizen petition procedure under 21 CFR 10.25(a) and 21 CFR 10.30. If the citizen petition is granted, a new listed drug will be designated as reference standard. We note that FDA has the authority to designate a reference standard."

We believe we shall apply FDA's guidance for Oxandrin Tablets 2.5mg & 10mg.

RS is needed for Oxandrin Tablets 2.5mg & 10mg 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.

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Gemini Laboratories LLC, the brand name manufacturer, has discontinued Oxandrin Tablets 2.5mg & 10mg (NDA 013718) and therefore, currently there is no RLD/RS available on the market for generic manufacturers to develop generic version for Oxandrin Tablets 2.5mg & 10mg. As suggested by FDA, Novitium Pharma, submits a citizen's petition requesting a RS for Oxandrin Tablets 2.5mg & 10mg (NDA 013718).

Conclusion

For the foregoing reasons, FDA should immediately designate a RS for Oxandrin Tablets 2.5mg & 10mg (NDA 013718). 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.

Respectfully submitted,

Muthusamy Shanmugam

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