Date: January 30, 2020

To,

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

CITIZEN PETITION (RELISTING PETITION)

Novitium Pharma LLC
70 Lake Drive
East Windsor, NJ 08520

Dear Sir/Madam,

Novitium Pharma LLC, a specialty pharmaceutical company focusing on developing and marketing of generic drugs, submits this relisting petition under 21 C.F.R. §10.25(a) and §10.30 to request the Commissioner of Food and Drug Administration (FDA) to determine whether the **Valsartan (PREXXARTAN) Oral Solution, 20 mg/5 mL, NDA #209139 of Carmel Biosciences Inc.** listed as Reference listed Drug (RLD) as per the orange book, was withdrawn from sale for reasons of safety or effectiveness.

I. Actions Requested

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

Request the FDA to determine if the Reference Listed Drug (RLD), Valsartan (PREXXARTAN) Oral Solution, 20 mg/5 mL, NDA #209139 made by Carmel Biosciences Inc. was withdrawn from sale for reasons of safety or effectiveness to facilitate the approval of generic version.

II. Statement of Grounds

A. Introduction

The orange book lists a reference listed drug (RLD), Valsartan (PREXXARTAN) Oral Solution, 20 mg/5 mL approved under NDA N209139 of Carmel Biosciences Inc.

Currently the RLD, Valsartan (PREXXARTAN) Oral Solution, 20 mg/5 mL approved under NDA N209139 of Carmel Biosciences Inc., is discontinued as per the current orange book as shown below;

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	VALSARTAN	PREXXARTAN	N209139	SOLUTION	ORAL	20MG/5ML		RLD		CARMEL BIOSCIENCES INC
DISCN	VALSARTAN	PREXXARTAN	N209139	SOLUTION	ORAL	80MG/20ML		RLD		CARMEL BIOSCIENCES INC

Therefore, Novitium Pharma LLC, requests that FDA promptly determine whether the listed drug was withdrawn from sale for reasons of safety or effectiveness to expedite the approval of our submitted ANDA #214102 for Valsartan oral solution, 20mg/5mL.

B. Factual Background

Novitium Pharma LLC has developed a generic version of **Valsartan (PREXXARTAN) Oral Solution** (NDA 209139).

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.

Carmel Biosciences Inc, the NDA holder, has discontinued the marketing of the RLD, Valsartan (PREXXARTAN) Oral Solution, 20 mg/5 mL and Valsartan (PREXXARTAN) Oral Solution, 80 mg/20 mL.

To cater to the market requirement as a generic player, we, Novitium pharma LLC have developed the generic drug product Valsartan oral solution, 20mg/5mL and subsequently submitted the ANDA #214102 to the agency for approval.

During the filing review of the ANDA #214102, the agency has instructed us to submit a relisting petition under 21 C.F.R. §10.25(a) and §10.30 to request the Commissioner of Food and Drug Administration (FDA) to determine whether the **Valsartan (PREXXARTAN) Oral Solution, 20 mg/5 mL, NDA #209139 of Carmel Biosciences Inc.** listed as Reference listed Drug (RLD) as per the orange book, was withdrawn from sale for reasons of safety or effectiveness. The agency has also commented that the approval of the ANDA #214102 will be dependent on FDA's response to the petition. Therefore, the advent of generic drug competitors would rely on the FDA's response to the petition.

In this regard, as per the Guidance for Industry "Referencing Approved Drug Products in ANDA Submissions", Novitium Pharma, submits a citizen's petition (relisting petition) requesting to determine whether the RLD (N209139) was withdrawn for safety or effectiveness reasons.

In addition, we would like to bring to the notice of the Agency that, as per the UNITED STATES SECURITIES AND EXCHANGE COMMISSION (Ref: https://www.sec.gov/Archives/edgar/data/1133519/000127956919001002/tv517778_20f.htm), the launch of PREXXARTAN® (valsartan) oral solution, is currently on hold pending resolution of the dispute between Carmel Biosciences, Inc. ("Carmel") and the third-party manufacturer and not due to reasons of safety or effectiveness.

Conclusion

For the foregoing reasons, We request FDA to immediately determine whether the RLD for Valsartan Oral Solution, 20 mg/5 mL was withdrawn for reasons of safety or effectiveness. The prompt action shall facilitate our generic product approval 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

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