



## DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

January 30, 2020

Muthusamy Shanmugam  
Founder and President  
Novitium Pharma LLC  
70 Lake Drive  
East Windsor, NJ 08520

*Sent via email to:* [RAOffice@novitiumpharma.com](mailto:RAOffice@novitiumpharma.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting 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Listed Drug (RLD), Valsartan (PREXXARTAN) Oral Solution, 20 mg/5 mL, NDA #209139 made by Carmel Biosciences Inc. was withdrawn from sale for reasons of safety or effectiveness to facilitate the approval of generic version was received by this office on 01/30/2020.

It was assigned docket number FDA-2020-P-0511. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby  
Supervisory Administrative Proceedings Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)