

July 31, 2020

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

Re: Docket No. FDA-2020-P-0511

Dear Mr. Shanmugam:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on January 30, 2020, and submitted on behalf of Novitium Pharma, LLC. Your petition requests that the Agency determine whether PREXXARTAN (valsartan), oral solution, 20 mg/5mL, new drug application 209139, and held by Carmel Biosciences, Inc., was withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Carol Bennett -S,
0.9.2342.1.9200300.100.1.1-2000004958
Date: 2020.07.31 09:39:52 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research