



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

September 23, 2020

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

Dear Mr. Shanmugam:

This letter responds to your citizen petition received on January 30, 2020, requesting that the Food and Drug Administration (FDA) determine whether Prexxartan (valsartan) oral solution, 20 milligrams (mg)/5 milliliters (mL), new drug application (NDA) 209139, held by Carmel Biosciences, Inc., was withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Prexxartan (valsartan) oral solution, 20 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Prexxartan (valsartan) oral solution, 20 mg/5 mL, in the “Discontinued Drug Product List” section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 893-4962.

Sincerely,

Robin A.  
Fastenau -S

Digitally signed by Robin A. Fastenau -S  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People,  
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Date: 2020.09.23 08:17:15 -04'00'

Robin A. Fastenau  
Office of Regulatory Policy  
Center for Drug Evaluation and Research

Enclosure