



Ramesh Jhavar, PhD.  
President & Designated U.S. Agent  
Ajanta Pharma USA Inc  
440 US Hwy 22 East  
Bridgewater, NJ 08807

Re: Docket No. FDA-2019-P-2559

JUL 29 2019

Dear Dr. Jhavar:

This letter responds to your citizen petition received on May 27, 2019, requesting that the Food and Drug Administration (FDA) determine whether FORTAMET (metformin hydrochloride) extended-release tablets, 500 milligrams (mg) and 1 gram (g) (NDA 021574, approved on April 27, 2004), were withdrawn from sale for safety or effectiveness reasons.

FDA has reviewed its records and determined that FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain FORTAMET (metformin hydrochloride) extended-release tablets, 500 mg and 1 g, 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 (301) 796-3702.

Sincerely,

Carlarease Hunter  
Office of Regulatory Policy  
Center for Drug Evaluation and Research

Enclosure