DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

May 28, 2019

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

Sent via email to: ramesh.jhawar@ajantapharma.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to confirm whether an OB Listed discontinued Drug (FORTAMET®) (metforminhydrochloride extended-release tablets 500 mg and 1 g), approved under New Drug Application (NDA) N021574, held by Andrx Labs LLC, is not discontinued for safety and efficacy reason was received by this office on 05/27/2019.

It was assigned docket number FDA-2019-P-2559. 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 Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2019.05.28 11:23:00 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of Operations (OO)