ajanta pharma USA inc

One Grande Commons
440 US Hwy 22 East, Ste 150
Bridgewater, NJ 08807

T 908.252.1165
F 908.393.5505
E info@ajantapharma.com
W www.ajantausa.com

May 27, 2019

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061,
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam,

Ajanta Pharma Limited files this petition pursuant to 21 CFR 10.25 and 10.30, and in accordance with 21 CFR 314.122 and 314.161, requesting the FDA (Food and Drugs Administration) commissioner to confirm whether an OB Listed discontinued Drug (FORTAMET®) has been voluntarily withdrawn for the reasons other than safety or effectiveness as outlined below.

A. Action Requested

The petitioner request the FDA commissioner to confirm that FORTAMET® (metformin hydrochloride 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.

B. Statement of Grounds

Under the FDC Act 505(j)(2), an ANDA must rely for safety and effectiveness on a Reference Listed Drug (RLD). As per 21 CFR 314.122 and 314.161, if a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness.

Also, as per 21 CFR 314.162, if FDA determines and withdraws a listed drug from sale for reasons of safety and efficacy, then the drug listing is removed from the Orange Book. However, if FDA determines that the listed drug was withdrawn from sale not for the reasons of safety and efficacy, then it remains listed in the Orange Book and may be cited in an ANDA as an RLD.

The Orange Book lists the FORTAMET® (Metformin hydrochloride extended-release tablets 500 mg and 1 g), NDA N021574 as an RLD with the market-status as discontinued in the "Discontinued Drug Product List" section of the Orange Book. Currently, the Orange book

lists ANDA - A090692 of Lupin Ltd. as Reference standard (RS) for Metformin Hydrochloride Extended-Release Tablets 1 g.

Based on above cited facts, it appears that FORTAMET® (metformin hydrochloride extended-release tablets 500 mg and 1 g) has been withdrawn from the market for reasons other than the safety and efficacy. Please confirm.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

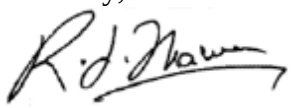
D. Economic Impact Statement

The petitioner will, upon request by the commissioner, submit economic impact information in accordance with 21 CFR 10.30(b).

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavourable to the petition.

Sincerely,



Ramesh Jhawar, PhD.
President & Designated U. S. Agent
Ajanta Pharma USA Inc
440 US Hwy 22 East
Bridgewater, NJ 08807
Tel: 908 252 1165
Fax: 908 393 5505
Cell: 203 434 7616
e-mail: ramesh.jhawar@ajantapharma.com
Web site: ajantapharma.com