7-5/2013/EU/WC/0123 Government of India Directorate General of Health Services Central Drugs Standard Control Organisation

(International Cell)

FDA Bhawan, Kotla Road, New Delhi- 110002. Dated:-

To

0 9 DEC 2020

M/s. Piramal Pharma Limited, Sy. Nos. 7-70, 70/1 & 70/2, Digwal (V), Kohir (M), Sangareddy (D) Telagana State, India

Subject: Submitting the letter for change of firm name in Written Confirmation Certificate for active substances exported to EU for medicinal products for human use - Regarding

Sir,

This is with reference to your application no. PEL/068/ADMN/2020-2021 dated 22.10.2020 wherein it is requested for Change of firm name in WC certificate No. 0123 issued by this office on 22.07.2019.

In this regard, your application has been examined and it is approved. Amended Certificate is enclosed for your reference.

All the other conditions of Written Confirmation Certificate will remain same.

Yours Sincerely,

Encl: as stated above.

(Dr. V.G.Somani)

Drugs Controller General(India)

W. 3/1/20

a.

Copy to: The Deputy Drugs Controller (I), Zonal Office, CDSCO Bhawan, S.R Nagar, Hyderabad -500038



Amended WC-0123

CERTIFICATE NO. :

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name of site:

M/s. Piramal Pharma Limited.

2. Manufacturer's Licence Number: 220/ AP/MD/96/B&F/R

The name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0123) granted on date 22.07.2019 is hereby amended as follows:

In place of:

"M/s. Piramal Enterprises Limited, Sy. Nos. 7-70, 70/1 & 70/2, Digwal (V), Kohir (M), Sangareddy (D), Telagana State, India."

Read as:

"M/s. Piramal Pharma Limited, Sy. Nos. 7-70, 70/1 & 70/2, Digwal (V), Kohir (M), Sangareddy (D), Telagana State, India."

All the other conditions of Written Confirmation Certificate will remain same.

Signature

Stamp of the authority and date

0 9 DEC 2020