



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 30, 2019

Jayant Muley
General Manager, Regulatory Affairs
Encube Ethicals Private Limited
Unit No. 24, Steelmade Industrial Estate
Marol Village, Andheri (E)
Mumbai, Maharashtra
India, 400059

Sent via email to: Jayant.m@encubeethicals.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner to designate Fluorouracil Topical Solution, 5% manufactured by Taro Pharmaceutical Industries Ltd. approved by FDA (ANDA #A076526) to be listed as a Reference Standard was received by this office on 04/30/2019.

It was assigned docket number FDA-2019-P-2074. 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 Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office Operations (OO)