**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Silver Spring MD 20993

May 15, 2019

Virendra Srivastava
Alembic Pharmaceuticals Limited
Regd. Off.: Alembic Road
Vadodara – 390 003
INDIA

*Sent via email to: virendra.srivastava@alembic.co.in*

Dear Petitioner:

Your petition to the Food and Drug Administration requesting the FDA make a prompt determination that the discontinuation of the Reference Listed Drug (RLD), PROAMTINE (NDA # 019815) was not for safety and effectiveness reasons was received by this office on 05/15/2019.

It was assigned docket number FDA-2019-P-2370. Please refer 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 Digitally signed by Dynna Bigby
Date: 2019.05.15 12:06:44 -04'00'

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