



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 19, 2019

Muthusamy Shanmugam, President
Novitium Pharma LLC
70 Lake Drive
East Windsor, NJ 08520

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate a Reference Standard for Oxandrin (Oxandrolone) Tablets 2.5mg & 10mg (NDA 013718) was received by this office on 08/16/2019.

It was assigned docket number FDA-2019-P-3907. 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
Dockets Management Staff
FDA/Office of Operations (OO)