



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

April 24, 2019

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

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner to designate a reference standard (RS) for Oxandrin (Oxandrolone) tablets 2.5mg and 10mg (NDA 013718) was received by this office on 04/23/2019.

It was assigned docket number FDA-2019-P-1980. 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 of the Executive Secretariat (OES)