



## DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

June 23, 2020

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

*Sent via email to:* [RAoffice@novitiumpharma.com](mailto:RAoffice@novitiumpharma.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA to designate the generic product METHYLTESTOSTERONE 10MG oral Capsule made by Impax Laboratories Inc (A204851) as the RS since METHYLTESTOSTERONE 10MG oral Capsule of Impax Laboratories Inc is the only one available in the market at present was received by this office on 06/22/2020.

It was assigned docket number FDA-2020-P-1605. 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 Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)