

October 8, 2020

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

RE: FDA-2020-P-1605
Withdrawal of ANDA Suitability Petition
METHYLTESTOSTERONE 10 mg oral Capsule

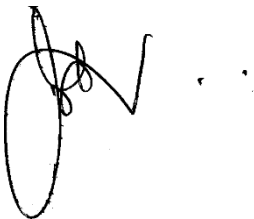
Dear Sir/Madam:

On June 22, 2020, the undersigned submitted a Suitability Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and 21 C.F.R. §§ 10.20, 10.30, and 314.93. The Suitability Petition requested that the Food and Drug Administration ("FDA") 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

I herewith withdraw the above-described Suitability Petition. Please terminate the proceeding under Docket FDA-2020-P-1605.

For correspondence, please contact Novitium Pharma LLC, Regulatory Affairs Office by email at RAOffice@novitiumpharma.com, by phone (845) 652-0377 or fax (609) 469-5920.

Thanks,

A handwritten signature in black ink, appearing to be 'M. Shanmugam', with a large loop at the start and a trailing flourish.

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