March 26, 2021

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

RE: FDA-2019-P-1980
Withdrawal of ANDA Citizen Petition
OXANDROLONE TABLETS, USP

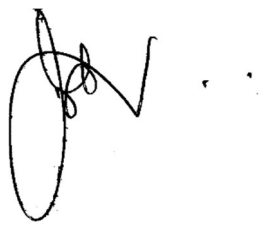
Dear Sir/Madam:

On April 23, 2019, the undersigned submitted a Citizen 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 Citizen Petition requested that the Food and Drug Administration ("'FDA'‘) designate the generic product Oxandrolone Tablets, 10 mg made by PAR Pharmaceutical Inc (A077827) as the Reference Standard (RS) for the Reference listed drug (RLD), Oxandrin (Oxandrolone) Tablets of Gemini Laboratories to facilitate the generic product development, since the RLD is discontinued and not available in the market.

I herewith withdraw the above-described Citizen Petition. Please terminate the proceeding under Docket FDA-2019-P-1980.

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,



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