**Date:** April 6, 2022

To,

Division of Dockets Management Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**CITIZEN PETITION (RELISTING PETITION)**

Novitium Pharma LLC
70 Lake Drive
East Windsor, NJ 08520

Dear Sir/Madam,

Novitium Pharma LLC, submits this relisting petition under 21 C.F.R. §10.25(a) and §10.30 and pursuant to Sections 505(j) and 505(w) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and 21 C.F.R. §§ 314.122 and 314.161 to request that the Food and Drug Administration ("FDA") to determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.

## I. Actions Requested

This petition requests the FDA to determine if the Reference Listed Drug (RLD), OXANDRIN (oxandrolone tablets, USP) 2.5 mg and 10 mg, NDA 013718 owned by Gemini Laboratories LLC was voluntarily withdrawn from sale for reasons of safety or effectiveness to facilitate the approval of generic version.

## II. Statement of Grounds

Under the FDC Act, an Abbreviated New Drug Application ("ANDA") must rely on FDA's approval findings for a Reference Listed Drug ("RLD"). See FDC Act § 505(j)(2). If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness. See 21 C.F.R. §§ 314.122 and 314.161. If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book. See id. § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as an RLD.

The Orange Book currently identifies OXANDRIN, approved on July 21, 1964 under NDA013718, in the "Discontinued Drug Product List" section of the Orange Book. To date, there is no Federal Register notice stating that this NDA was being withdrawn. This petitioner is not

aware of any information indicating that the withdrawal or discontinuation was made for safety or effectiveness reasons and believes the discontinuation of OXANDRIN under NDA 013718 was due only to commercial considerations.

Petitioner requests that FDA determine that OXANDRIN, approved under NDA 013718 was not withdrawn for reasons of safety or effectiveness.

## III. Environmental Impact

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

## IV. Economic Impact

Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. §10.30(b).

## V. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

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

Thanks,

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Shek Sarafdeen Seeni Mohamed
Director – Regulatory Affairs
Novitium Pharma LLC

For
Muthusamy Shanmugam
Founder and President,
Novitium Pharma LLC