April 7, 2022

Shek Sarafdeen Seeni Mohamed
Novitium Pharma LLC
70 Lake Drive
East Windsor, NJ 08520

Sent via email to: raoffice@anipharmaceuticals.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug 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OXANDRIN (oxandrolone tablets, USP) 2.5 mg and 10 mg, NDA 013718 owned by Gemini Laboratories LLC was voluntarily withdrawn from sale for reasons of safety or effectiveness to facilitate the approval of generic version was received and processed under CFR 10.30 by this office on 04/06/2022.

It was assigned docket number FDA-2022-P-0558. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.04.07 16:04:48 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)