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

September 13, 2023

Re: Docket No. FDA-2022-P-0558

Dear Director Mohamed:

This letter responds to your citizen petition received on April 6, 2022, requesting that the Food and Drug Administration (FDA) determine whether Oxandrin (oxandrolone) tablets 2.5 milligrams (mg) and 10 mg, were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, were withdrawn from sale for reasons of safety or effectiveness. Accordingly, FDA will remove Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, from the list of drug products published in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book). FDA will not accept or approve abbreviated new drug applications that refer to this drug product.

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-4078.

Sincerely,

Alexandria S. Fujisaki -S
Digitally signed by Alexandria S. Fujisaki -S
Date: 2023.09.13 09:40:54 -04'00'

Alexandria Fujisaki, J.D.
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure