U.S. FOOD & DRUG ADMINISTRATION

Muthusamy Shanmugam
President
Novitium Pharma LLC
70 Lake Drive
East Windsor, NJ 08520

Re: Docket No. FDA-2019-P-1980

OCT 18 2019

Dear Mr. Shanmugam:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on April 23, 2019. Your petition requests that the Agency designate the generic product made by PAR Pharmaceutical Inc. (A077827) as the reference standard of Oxandrin Tablets (NDA 013718).

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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