FDA U.S. FOOD & DRUG ADMINISTRATION

FEB 0 6 2020

James Mahanna
Senior Director
Associate General Counsel
NA Generics IP
Teva Pharmaceuticals USA, Inc.
200 Elmora Avenue
Elizabeth, NJ 07202

Re: Docket No. FDA-2019-P-3937

Dear Mr. Mahanna:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on August 20, 2019. Your petition requests that the FDA assign a therapeutic equivalence code of "AO" to Teva's Fulvestrant Injection, 250 milligram (mg)/5 milliliter (50 mg/ml) (New Drug Application 210063).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

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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