U.S. FOOD & DRUG ADMINISTRATION

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-4155

MAR 0 2 2020

Dear Mr. Mahanna:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on September 5, 2019. Your petition requests that the Agency assign a therapeutic equivalence code of "AP" to fosaprepitant dimeglumine for injection, equivalent 150 milligrams base/vial, approved under new drug application 210064.

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
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov