U.S. FOOD & DRUG ADMINISTRATION

Shruti Patel
Regulatory Specialist
Fresenius Kabi, USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Re: Docket No. FDA-2019-P-2590

NOV 14 2019

Dear Sir/Madam:

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 May 24, 2019. Your petition requests that the Commissioner of FDA designate Fulvestrant Injection, 50 milligrams/milliliter, manufactured by FK USA (new drug application (NDA) 210326), as a therapeutic equivalent, with an 'AB' rating, to the reference listed drug Faslodex, NDA 021344, by AstraZeneca Pharmaceuticals LP.

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