Fresenius Kabi USA, LLC

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Citizen Petition
Docket Number FDA-2019-P-2590

18 December 2024

Division of Dockets Management
Food and Drug Administration
(HFA-305) Room 1061
5630 Fishers Lane
Rockville, MD 20852

Dear Sir/Madam:

Reference is made to our Citizen Petition (Docket Number FDA-2019-P-2590) requesting the Commissioner of the Food and Drug Administration designate Fresenius Kabi USA, LLC's (FK USA) Fulvestrant Injection approved under 505(b)(2) NDA 210326 as therapeutically equivalent to the reference listed drug (RLD) Faslodex®, NDA 021344, by AstraZeneca Pharmaceuticals LP.

The FDA has since updated the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") to indicate Fulvestrant Injection, 250 mg per 5 mL (50 mg/mL) (NDA 210326), as therapeutically equivalent with an 'AO' rating to Faslodex (fulvestrant) Injection, 250 mg per 5 mL (50 mg/mL) (NDA 021344). Therefore, we request that our Citizen Petition (Docket Number FDA-2019-P-2590) be withdrawn.

Regards,

Peter Baer

Digitally signed by Peter Baer
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