DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

May 29, 2019

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

Sent via email to: shruti.patel@fresenius-kabi.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner designate Fulvestrant Injection, 50 mg/mL, manufactured by FK USA (NDA 210326), as a therapeutic equivalent, with an 'AB' rating, to the reference listed drug Fasolodex ®, NDA 021344, by Astrazeneca Pharmaceuticals LP was received by this office on 5/29/2019.

It was assigned docket number FDA-2019-P-2590. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.05.29 16:46:13 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of Operations (OO)