



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 20, 2019

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

Sent via email to: jim.mahanna@actavis.com

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA assign in the Agency's Orange Book a TE code of "AO" to Teva's Fulvestrant Injection, 250 mg/5 ml (50 mg/ml) was received by this office on 08/20/2019.

It was assigned docket number FDA-2019-P-3937. 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
Supervisory Administrative Proceedings Specialist
Dockets Management Staff
FDA/Office of Operations (OO)