



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

September 6, 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](mailto:jim.mahanna@actavis.com)*

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting to assign in the Agency's Orange Book a TE code of "AP" to Teva's Fosaprepitant Dimeglumine for Injection, Eq. 150 mg base/vial was received by this office on 09/05/2019.

It was assigned docket number FDA-2019-P-4155. 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)