**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration
Rockville, MD 20857

May 4, 2020

Kevin W. McCabe
Associate General Counsel
Therapeutics MD, Inc.
951 Yamato Road, Suite 220
Boca Raton, FL 33487

*Sent via email to*: KMcCabe@TherapeuticsMD.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA from receiving or approving any marketing application that references Imvexxy® (estradiol vaginal inserts), NDA #208564, unless (a) the application is submitted as an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Food Drug and Cosmetic Act ("FDCA") and the ANDA product is manufactured qualitatively the same as Imvexxy, including the teardrop shape, for the reasons discussed herein (*i.e.*, has the same Q3 macro and microstructure as Imvexxy) or (b) the application is submitted under section 505(b)(2) of the FDCA. To that end, TherapeuticsMD requests that FDA issue product-specific guidance setting forth such requirements.

Your petition was received by our office on 05/01/2020 and it was assigned docket number FDA-2020-P-1334. 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: 2020.05.04 20:46:29 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)