U.S. FOOD & DRUG ADMINISTRATION

Kevin McCabe
Associate General Counsel
TherapeuticsMD, Inc.
951 Yamato Road, Suite 220
Boca Raton, Florida 33487

Re: Docket No. FDA-2020-P-1334

October 23, 2020

Dear Mr. McCabe:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on May 1, 2020. Your petition requests, among other things, that the Agency refrain from receiving or approving any Abbreviated New Drug Application (ANDA) that references Imvexxy (estradiol vaginal inserts) unless it includes the same product labeling and is manufactured in qualitatively the same way as Imvexxy, including the "teardrop" shape. The petition also reiterates some requests from a related pending petition, FDA-2018-P-4714, including a request that the Agency issue a product-specific guidance for Imvexxy.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Nam E. Kim -S

Digitally signed by Nam E. Kim -S
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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