



Deeannah Seymour
pH-D Feminine Health, LLC
305 Williams Avenue
Madison, TN 37115

Mark C. Faulkner
Vireo Systems, Inc.
305 Williams Avenue
Madison, TN 37115

April 13, 2023

Re: Docket No. FDA-2022-P-2571

Dear Ms. Seymour and Mr. Faulkner:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on October 17, 2022. Your petition requests that the Agency “issue a guidance for industry and FDA staff reiterating the Agency’s position, since 1994, that OTC vaginal products marketed solely as deodorants, or to reduce vaginal odor, are ‘cosmetics’ and not also ‘drugs.’” Your petition further requests that if FDA “deem[s] these products (or any subset of these products) to be ‘drugs,’” that the Agency (1) “promulgate a regulation reclassifying any affected products; and (2) at least until such time as that regulation is final, announce a policy of enforcement discretion over any potentially affected products.”

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
Date: 2023.04.10
12:09:04 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research