



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

September 17, 2024

Re: Docket No. FDA-2024-P-1440

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 March 22, 2024, and submitted on behalf of pH-D Feminine Health, LLC and Vireo Systems, Inc. Your petition requests that the Agency “issue a guidance stating that OTC vaginal suppositories containing boric acid, that are marketed solely with deodorant claims, or claims to reduce vaginal odor, are ‘cosmetics’ and not also drugs.” In the alternative, if FDA “deem[s] these products to be ‘drugs,’” your Petition requests that the Agency (1) “promulgate a regulation re-classifying any affected products as ‘drugs’; 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 due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

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