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

March 4, 2024

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

Dear Ms. Seymour and Mr. Faulkner:

This letter responds to the citizen petition (Petition) submitted to the Food and Drug Administration (FDA or Agency) by Vireo Systems, Inc. and pH-D Feminine Health, LLC (Petitioners) and received on October 17, 2022. In the Petition, you request that the Agency "issue a guidance for industry and FDA staff reiterating the Agency's position, since 1994, that [over-the-counter (OTC)] vaginal products marketed solely as deodorants, or to reduce vaginal odor, are 'cosmetics' and not also 'drugs.'"[1] In the alternative, if FDA "deem[s] these products (or any subset of these products) to be 'drugs,'" your Petition requests that the Agency (1) "promulgate a regulation re-classifying 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."[2]

We have carefully reviewed the arguments in the Petition. For the reasons stated below, we deny your requests.

I. BACKGROUND

A. Definitions of *Drug* and *Cosmetic* in the Federal Food, Drug, and Cosmetic Act

Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(g)(1)) defines a *drug* as:

(A) articles recognized in the official United States Pharmacopeia, official Homeopathic

[1] Petition at 2 (emphasis omitted).
[2] *Id.*

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> Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and
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> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
>
> (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
>
> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

Section 201(i) of the FD&C Act (21 U.S.C. 321(i)) defines a *cosmetic* as:

> (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and
>
> (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

A product may meet the definitions of both a drug and a cosmetic; the definitions are not mutually exclusive.

II. DISCUSSION

A. FDA Declines Your Request for the Agency to Make a Class-Wide Determination

In your Petition, you request that FDA issue a guidance "reiterating" that OTC vaginal products marketed solely as deodorants or to reduce vaginal odor are "cosmetics" and not also "drugs."[3] You assert that it is your understanding that "it is lawful for companies to market OTC vaginal products . . . as 'cosmetics' if the products are marketed solely with reduced odor claims."[4] You state that your understanding is based on (1) the definition of *cosmetic* under the FD&C Act, (2)

[3] *Id.* at 3.
[4] *Id.*

FDA's *Cosmetic Labeling Guide*, (3) FDA's statements made in the course of the OTC vaginal products rulemaking process, and (4) certain interactions with the Agency.[5, 6]

For the reasons discussed below, the information you have provided does not support the class-wide determination requested in this Petition about the product classification of OTC vaginal products marketed with solely deodorant or odor-reduction claims—including whether such products meet the definition of a drug, cosmetic, or both a drug and a cosmetic. This determination is necessarily fact-specific, requiring an analysis of the intended use of a particular product.

As discussed above, section 201(g)(1) of the FD&C Act defines *drug*, in part, as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" or an article "intended to affect the structure or any function of the body of man or other animals."[7] Accordingly, to determine whether a product meets this definition, FDA considers the intended use of the particular product.[8]

FDA regulations describe the types of evidence that can inform whether a product is intended for use as a drug under the FD&C Act. Such evidence is not limited to the stated claims in the label affixed to the product. Rather, FDA also considers information such as labeling claims, advertising matter, and oral or written statements by the persons legally responsible for the labeling of the article, or their representatives, as well as the design or composition of the article, and the circumstances surrounding its distribution.[9] Because all available evidence bearing on a product's intended use is relevant to its product classification, the information in this Petition does not support the determination requested in this Petition that all vaginal products marketed solely as a deodorant or to reduce vaginal odor are cosmetics and not also drugs.

B. This Response Does Not Reflect a "Change [to] the Regulatory Classification of [a] Product Class"

Your Petition presupposes that FDA classified vaginal deodorant products as cosmetics in the

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[5] *Id.* at 1–3. Your Petition references FDA's *Cosmetics Labeling Guide*. *See* FDA, *Cosmetics Labeling Guide*, available at https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide. The Cosmetics Labeling Guide states that "[i]f cosmetic claims, e.g., moisturizing, deodorizing, skin softening etc., are made on a label, the product is a cosmetic." *Id*. at 4. Importantly, this guide does not state that the product is *solely* a cosmetic; there might be other evidence that the product is intended for use as a drug, as well. As discussed above, a product can meet the statutory definitions of both a drug and a cosmetic. In contrast, if the available evidence bearing on the intended use of a product labeled with deodorizing claims shows that the product is solely intended for use as a cosmetic, then the product may meet the definition of a cosmetic and not also a drug. As discussed in this response, product classification inquiries are necessarily product-specific.

[6] Your Petition also references "certain interactions with the Agency" but does not provide any specific information or documentation about those interactions (Petition at 3). Without more information, we are unable to address this point.

[7] Section 201(g)(1)(B), (C) of the FD&C Act.

[8] *See, e.g., Federal Register* notice, "Vaginal Drug Products for Over-the-Counter Human Use; Withdrawal of Advance Notice of Proposed Rulemaking," published Feb 3, 1994 (59 FR 5226 at 5231) (explaining that "the [A]gency will consider the intended use in determining whether [a product] is a cosmetic, a drug, or both").

[9] 21 CFR 201.128.

course of the OTC vaginal products rulemaking. FDA disagrees with the Petitioners' implied assertion that the Agency made such a product classification determination.

In 1983, as part of the OTC drug review process, the Agency issued an advance notice of proposed rulemaking (ANPR) describing the recommendations of the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products (Panel) concerning establishment of a monograph that would describe conditions under which OTC vaginal drug products are generally recognized as safe and effective and not misbranded.[10]

As discussed in the ANPR, the Panel stated that it considered the definitions of *drugs* and *cosmetics* under the FD&C Act and decided that "certain labeling claims for vaginal products," including deodorant claims, "more properly fall within the cosmetic category, while other claims fit more accurately into the drug category."[11] The ANPR does not discuss whether vaginal *products* marketed with deodorant claims are necessarily cosmetics and not drugs; rather, the Panel stated only that a "deodorant *claim* for a vaginal preparation constitutes a cosmetic claim."[12]

In 1994, FDA announced by *Federal Register* notice that it was withdrawing the ANPR after reviewing public comments and the Panel's report and recommendations.[13] In that 1994 withdrawal notice, FDA explained that it had "determined that specific claims and ingredients for use in and around the vagina will be included in other appropriate OTC drug rulemakings."[14] FDA further explained that its withdrawal decision was made in part because the Agency concluded that some of the labeling claims evaluated in the context of vaginal products, including "deodorizing," were cosmetic claims only and were, therefore, "outside the scope of the OTC drug review."[15] As in the ANPR, FDA's 1994 withdrawal notice addressed the odor-reduction *claim* and not the product classification of all vaginal products labeled with that claim.

In withdrawing the ANPR, the Agency reiterated that, with respect to the OTC vaginal products described in the notice, "the intended use of a product is the primary determining factor as to whether a product is a drug, a cosmetic, or both," and that "[t]his intended use may be inferred from the product's labeling, promotional material, advertising, and any other relevant factor."[16]

In sum, the ANPR describes the Panel's determination that vaginal deodorizing claims are cosmetic claims, and FDA made a similar assessment in the notice withdrawing the ANPR.[17] Contrary to the Petitioners' assertion, FDA did not conclude or propose to conclude in these notices that any vaginal product marketed solely as a deodorant or to reduce vaginal odor is a

[10] *Federal Register* notice, "Vaginal Drug Products for Over-the-Counter-Human-Use; Establishment of a Monograph," published Oct 13, 1983 (48 FR 46694).
[11] *Id.* at 46701.
[12] *Id*. (emphasis added).
[13] 59 FR 5226.
[14] *Id.* at 5234, 5226, 5229, 5233.
[15] *Id*. at 5226–27, 5231–32, 5234.
[16] *Id.* at 5227 (emphasis added) (citing *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977)).
[17] 48 FR 46694 at 46701; 59 FR 5226 at 5227, 5231.

cosmetic (and not also a drug) without regard to other evidence of intended use.[18]

C. FDA Need Not Address Your Request to Promulgate a New Rule

You argue that "FDA cannot change the regulatory classification of the product class without issuing a new regulation."[19] Because FDA has not made such a class-wide determination regarding vaginal products marketed as a deodorant or to reduce vaginal odor, and declines your request to make such a class-wide determination, FDA need not address your requests to "promulgate a regulation re-classifying any affected products" and to "announce a policy of enforcement discretion over any potentially affected products."[20]

III. CONCLUSION

For the reasons stated above, your Petition is denied.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2024.03.04 09:03:21 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[18] The Petition also states that none of the design, composition, circumstances of sale, or distribution of OTC vaginal products marketed solely with deodorizing or odor reduction claims provides evidence of an intended use other than a cosmetic use and that, therefore, these products should not be regulated as drugs. *See* Petition at 4-5. However, as stated above, the determination of whether a product meets the definition of a drug, cosmetic, or both is a fact-specific inquiry. The information in the Petition does not support a class-wide determination about the classification of these OTC vaginal products.

[19] Petition at 5.

[20] *Id.* at 2.