October 17, 2022

Division of Dockets Management
U.S. Food & Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned Petitioners respectfully submit this petition under 21 C.F.R. §§ 10.20 and 10.30 to request that the Commissioner of Food and Drugs issue guidance for industry and Food and Drug Administration ("FDA" or the "Agency") 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 decides to change its long-standing position—and to deem these products (or any subset of these products) to be "drugs"—Petitioners request that: (1) the Commissioner 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. An enforcement discretion policy is appropriate given that these types of products have been regulated as "cosmetics" and used safely for decades. Indeed, boric acid suppositories, for example, have been used safely for over 100 years.[2]

The undersigned Petitioners are Vireo Systems and pH-D Feminine Health, which together manufacture and market pH-D Boric Acid Vaginal Suppositories ("pH-D Suppositories") as "cosmetics." Our pH-D Suppositories are marketed solely with anti-odor cosmetic claims based on our understanding—reached in part, during our consultation with FDA staff—that, in the absence of any disease or structure/function claims in our labeling and advertising, pH-D Suppositories would be appropriately regulated as a "cosmetic" rather than as a "drug."[3] This

[1] *See, e.g.*, U.S. Food & Drug Admin., *Cosmetics Labeling Guide*, https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide (updated Feb. 25, 2022) (stating that "[i]f cosmetic claims, e.g., moisturizing, deodorizing . . . etc., are made on a label, the product is a cosmetic"); 59 Fed. Reg. 5226, 5227, 5231 (Feb. 3, 1994) (stating that deodorizing claims for OTC vaginal products are cosmetic claims and therefore will not be included in OTC drug rulemakings).
[2] Melinda Zeron Mullins and Konia M. Trouton, *BASIC study: is intravaginal boric acid non-inferior to metronidazole in symptomatic bacterial vaginosis? Study protocol for a randomized controlled trial*, 16 TRIALS 315 (2015), https://doi.org/10.1186/s13063-015-0852-5.
[3] 21 U.S.C. § 321(g), (i).

understanding is also supported by: (1) the definition of "cosmetic" in the Food, Drug and Cosmetic Act ("FD&C Act") itself;[4] (2) by FDA guidance;[5] and (3) by a statement made by FDA during notice-and-comment rulemaking in 1994 that deodorizing claims for OTC vaginal products are cosmetic claims, and therefore, such products will not be included in OTC drug rulemakings.[6]

Recently, however, we have become concerned that: (1) there is confusion within FDA about the regulatory status of our pH-D Suppositories and other similar products; (2) FDA staff is confused about the regulatory status of various products in the class; or (3) FDA has even quietly reversed its public position that these products are "cosmetics" when marketed solely with reduced odor claims.

ACTION REQUESTED

The undersigned Petitioners respectfully request that the Commissioner of Food and Drugs 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."[7]

In the alternative, if FDA intends to change its long-standing position—and to deem these products (or any subset of these products) to be "drugs"—Petitioners request that: (1) the Commissioner 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.

[4] *Id.* § 321(i) (defining "cosmetic" as (among other things) "articles intended to be . . . introduced into . . . the human body . . . for promoting attractiveness").
[5] U.S. Food & Drug Admin., *Cosmetics Labeling Guide* ("If cosmetic claims, e.g., moisturizing, deodorizing . . . etc., are made on a label, the product is a cosmetic"); *see also* U.S. Food & Drug Admin., *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap?fbclid=IwAR2dXKG1m1RrEOv_JAkX4XBOXBaM8ugAYwg-abUXURjXSoKSMJh2YSxv8Dc (updated Feb. 25, 2022) ("Among the products included in this definition [of cosmetics] are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants").
[6] 59 Fed. Reg. at 5231 ("The agency agrees that cosmetic claims should not be included in OTC drug rulemakings. Therefore, the cosmetic claims 'cleansing' … and 'deodorizing' will not be included in the OTC drug monographs.").
[7] *See, e.g.*, U.S. Food & Drug Admin., *Cosmetics Labeling Guide* (stating that "[i]f cosmetic claims, e.g., moisturizing, deodorizing . . . etc., are made on a label, the product is a cosmetic"); 59 Fed. Reg. at 5227, 5231 (stating that deodorizing claims for OTC vaginal products are cosmetic claims and therefore will not be included in OTC drug rulemakings).

STATEMENT OF GROUNDS

It has long been our understanding based on the definition of "cosmetic" in the FD&C Act,[8] based on FDA guidance, based on a 1994 statement made by FDA,[9] and based on certain interactions with the Agency, that it is lawful for companies to market OTC vaginal products (*e.g.*, lactic acid suppositories, vaginal gel products, and boric acid suppositories) as "cosmetics" if the products are marketed solely with reduced odor claims.

A change in this approach, particularly with regard to boric acid suppositories and particularly without giving stakeholders an opportunity to provide input, would be unjustified. As mentioned, boric acid suppositories have been marketed safely for over 100 years. Indeed, for years, FDA exercised enforcement discretion over these products, *even when they were marketed with "drug" claims (e.g., to treat yeast infections)*.[10]

I. Products Intended Only for the Reduction of Vaginal Odor Are "Cosmetics" Under the FD&C Act

The FD&C Act defines cosmetics, in relevant part, as "articles intended to be . . . introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, [or] promoting attractiveness . . . ."[11] By comparison, the Act defines drugs as articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body."[12]

FDA assesses a product's intended use by looking at the objective intent of the labeling, advertising and promotion, and any relevant source of evidence (direct and circumstantial).[13] Specifically, FDA will consider: (1) "expressions"—such as labeling claims and representations, advertising matter, and oral or written statements by persons responsible for the labeling, or their representatives; (2) the design or composition of the article; and (3) circumstances surrounding the sale or distribution of the article.[14]

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[8] 21 U.S.C. § 321(i) (defining "cosmetic" as (among other things) "articles intended to be . . . introduced into . . . the human body . . . for promoting attractiveness").
[9] U.S. Food & Drug Admin., *Cosmetics Labeling Guide* ("If cosmetic claims, e.g., moisturizing, deodorizing . . . etc., are made on a label, the product is a cosmetic"); 59 Fed. Reg. at 5227, 5231 (stating that deodorizing claims for OTC vaginal products are cosmetic claims and therefore will not be included in OTC drug rulemakings); U.S. Food & Drug Admin., *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, ("Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants").
[10] *See* U.S. Food & Drug Admin., *Compliance Policy Guide Sec. 400.400: Conditions Under Which Homeopathic Drugs May be Marketed* (1988) (withdrawn Oct. 2019).
[11] 21 U.S.C. § 321(i).
[12] *Id.* § 321(g).
[13] *See* 21 C.F.R. § 201.128.
[14] *Id.*

a. It Has Long Been FDA's Position that Claims for Vaginal Products Related to Reducing or Deodorizing Vaginal Odor Are "Cosmetic" Claims, Not "Drug" Claims

FDA has considered odor reduction and deodorant claims to be cosmetic claims, including specifically with respect to vaginal products. According to FDA's "Cosmetics Labeling Guide," a product labeled with a cosmetic claim such as "deodorizing" is a cosmetic product.[15] Moreover, FDA announced in 1994 that OTC vaginal products that were "limited to cosmetic purposes, e.g., cleansing, deodorizing, [and] mechanical flushing" are cosmetic in nature and not subject to OTC drug rulemaking—that is, the Agency deemed them to be "cosmetics."[16]

In other words, it has long been FDA's position that claims for OTC vaginal products related to reducing or deodorizing vaginal odor are "cosmetic" claims, not "drug" claims. The intended use of these products is clearly to "cleans[e]," "beautify[]," and "promot[e] attractiveness" of users—not to diagnose, cure, mitigate, treat, or prevent disease or to have any effect on the structure or function of the body.

b. Neither the Design and Composition of These Products Nor the Circumstances of Their Sale or Distribution Is Evidence of an Intended Use Other than a Cosmetic Use

As a general matter, we do not believe that there is any reason for FDA to regulate OTC vaginal products as "drugs" based on their design or composition. FDA did not believe that this was an issue in 1994, and there is no reason for it to reconsider that determination now. FDA itself has made clear that its revisions to the "intended use" regulations[17] in 2021 (*e.g.*, adding language regarding the design and composition of the product being indicia of "intended use") did not reflect a change in FDA's policies or practices, but rather codified, or made more express, FDA's existing practices.[18]

More specifically, there is no reason that OTC vaginal products containing boric acid are "drugs" based simply on the presence of boric acid alone. Boric acid has never been approved by FDA for use as an active pharmaceutical ingredient in any prescription or nonprescription drug. Moreover, it is our understanding that boric acid suppositories were historically regulated as homeopathic drugs *only when they were marketed with express "drug" claims* (*e.g.*, to treat yeast infections).

Further, to the extent that boric acid has physiological and/or antimicrobial effects, those effects alone cannot render the boric acid suppositories "drugs." If that were the case, FDA would have to regulate all products that contain ingredients with physiological and/or antimicrobial effects as

[15] U.S. Food & Drug Admin., *Cosmetics Labeling Guide*.
[16] 59 Fed. Reg. at 5227, 5231.
[17] *See* 21 C.F.R. § 201.128.
[18] 86 Fed. Reg. 41383, 41390 (Aug. 2, 2021).

"drugs," including many products marketed as cosmetics that contain lavender, tea tree, or lemon oils,[19] or certain acids, such as vinegar.[20]

Finally, we are not aware of any circumstances of sale or distribution regarding OTC vaginal deodorant products, generally, or OTC vaginal boric acid suppositories, specifically, that would render the class (or the product) "drugs." These products are typically sold to consumers at retail establishments that sell other cosmetics or online like many other cosmetics. As FDA recognized in its revisions to the "intended use" regulations, a "firm's knowledge that health care providers are prescribing or using its approved or cleared medical product for an unapproved use would not, by itself, automatically trigger obligations for the firm to provide labeling for that unapproved use."[21]

II. FDA Cannot Change the Regulatory Classification of the Product Class Without Issuing a New Regulation

To be clear, the *reclassification* from "cosmetic" to "drug" of any OTC vaginal product marketed solely with cosmetic claims would be a "rule" under the Administrative Procedure Act ("APA").[22] Such a reclassification also would be a *legislative* rule because it would have a compulsory effect and expose regulated entities to legal consequences.[23] Indeed, it would establish new standards of duty, such as premarket approval.[24] Therefore, any reclassification could only be effectuated in accordance with notice-and-comment rulemaking under the APA.[25]

Further, even if FDA could successfully argue that reclassifying any OTC vaginal product marketed solely with reduced odor or deodorant claims is not subject to notice-and-comment rulemaking under the APA (and we do not believe that it can), FDA would have to, at a minimum, issue guidance signaling that the Agency has changed its position—in accordance with the Agency's Good Guidance Practices.[26] Good Guidance Practices preclude FDA from "us[ing] documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public

[19] Alina Kunicka-Styczynska et al., *Antimicrobial activity of lavender, tea tree and lemon oils in cosmetic preservative systems*, 107 J. APPLIED MICROBIOLOGY 1903, 1905 (2009), https://sfamjournals.onlinelibrary.wiley.com/doi/10.1111/j.1365-2672.2009.04372.x.
[20] Darshna Yagnik et al., *Antimicrobial activity of apple cider vinegar against* Escherichia coli*,* Staphylococcus aureus *and* Candida albicans*; downregulating cytokine and microbial protein expression*, 8 SCI. REP. 1732 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5788933/.
[21] *See* 85 Fed. Reg. 59718, 59720 (Sept. 23, 2020).
[22] 5 U.S.C. § 551(5).
[23] *See Nat'l Mining Ass'n* v. *McCarthy*, 758 F.3d 243, 250 (D.C. Cir. 2014); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000).
[24] *See Gen. Motors Corp*. v. *Ruckelshaus*, 742 F.2d 1561, 1563 (D.C. Cir. 1984) (en banc).
[25] *See supra*, at note 23.
[26] 21 U.S.C. § 371(h); 21 C.F.R. § 10.115(e).

audience for the first time."[27] FDA has publicly communicated in numerous fora its intent to treat odor reduction claims as cosmetic only. Any policy change now would necessitate issuing guidance to communicate FDA's "new" and "different regulatory expectations."

III. FDA Should Exercise Enforcement Discretion in the Absence of Clear Guidance

To the extent that FDA intends to upset stakeholders' settled expectations and alter its position that these products are cosmetics, it should nevertheless announce a policy of enforcement discretion over any potentially affected products until such time as FDA has finalized necessary regulations and, as a practical matter, given affected parties sufficient time to conform to new legal requirements.

ENVIRONMENTAL IMPACT

Petitioners claim a categorical exclusion from the requirement of an environmental impact under 21 C.F.R. § 25.30(h).

ECONOMIC IMPACT

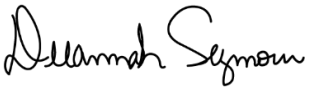
Petitioner will submit economic information upon request of the Commissioner. No information is required at this time.

[27] 21 U.S.C. § 371(h); 21 C.F.R. § 10.115(e).

CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition and all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



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