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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ASHLEY FRANZ, On Behalf of Herself and All Others Similarly Situated,

Plaintiff,

v.

BEIERSDORF, INC. a Delaware Corporation,

Defendant.

Case No. 3:14-cv-02241-LAB-RBB

DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT

JUDGE: Hon. Larry A. Burns

DATE: March 18, 2019

TIME: 11:30 a.m.

PLACE: Courtroom 14A (14th Fl.)

*Oral Argument Requested
DEMAND FOR JURY TRIAL

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Six years ago, Plaintiff purchased a $10 bottle of NIVEA Skin Firming Hydration Body Lotion (the "Lotion"), which she now alleges was "misbranded" and "illegal[ly]" sold. Plaintiff's claim is based solely on the premise that the "Lotion" is a drug that had not been approved by the U.S. Food and Drug Administration ("FDA") prior to sale. According to Plaintiff, because the Lotion label makes statements about improving firmness and tightening the skin's appearance, the Lotion is both a *cosmetic* (as it is currently sold), and a *drug* that should have been approved by the FDA (Second Amended Complaint ("SAC") [Dkt. 46] ¶¶ 2-3). In particular, the SAC says that the Lotion is a drug based on the cherry-picked label statements that the Lotion "improves skin firmness within 2 weeks," and is "proven to firm and tighten skin's surface in as little as two weeks" (collectively referred to as the "skin-firming representations"), while ignoring all other representations on the label (SAC [Dkt. 46] ¶¶ 2, 10).

Despite two amended complaints, Plaintiff still has not put forth any factual or legal allegations to support her theory. From the face of her SAC, Plaintiff has failed to plead a key statutory element underlying her allegation that the Lotion is a drug: that Defendant *intended* the Lotion to be used as a drug (*i.e.*, to affect the structure or function of the body). She has also failed to plead facts that plausibly show the Lotion is a drug in light of the context of the full label, which her SAC ignores. FDA guidance and relevant case law further undermine her claim because they establish that the Lotion is properly marketed as a cosmetic – and not a drug – because moisturizing is a cosmetic claim. For all of these reasons, the Court should dismiss Plaintiff's SAC in its entirety pursuant to Fed. R. Civ. P. 8 and 12(b)(6).

I. BACKGROUND

A. First Amended Complaint And First Motion To Dismiss

On November 13, 2014, Plaintiff filed her Corrected First Amended Complaint ("FAC") [Dkt. 19], which made two claims: (1) the Lotion's skin-firming representations were false and misleading because they were not supported by

"reliable scientific evidence" (which Plaintiff defined as published, randomized, placebo-controlled, clinical trials subject to peer review) (*id.* ¶¶ 13-26, Count II (violation of the Consumer Legal Remedies Act)); and (2) the Lotion is not only a cosmetic but also a drug, which cannot be sold without an FDA-approved New Drug Application ("NDA") (*id.* ¶¶ 27-38, Count I (Violation of Business & Professions Code, UCL)).

Defendant filed a Motion to Dismiss the FAC on the grounds that (1) Plaintiff had not sufficiently alleged an actionable misrepresentation; and (2) the UCL cosmetic/drug classification claim should be dismissed or stayed based on the primary jurisdiction doctrine [Dkt. 22]. The Court agreed with Defendant, finding, first, that Plaintiff failed to state a cognizable claim for misrepresentation because she alleged only that the skin-firming representations lacked substantiation, not that they were actually false (Order [Dkt. 34] 4-5). The Court granted Plaintiff leave to re-plead her misrepresentation claim if she could adequately allege actual falsity (*id.* at 9). Second, the Court agreed that the FDA had primary jurisdiction to determine whether the Lotion was a drug or a cosmetic (*id.* 7), and stayed the case to allow Plaintiff an opportunity to seek relief from the FDA.

B. Citizen Petition

As to her cosmetic/drug classification claim, Plaintiff filed a "Citizen Petition" with the FDA on September 16, 2015, asking the FDA to take action by commencing the warning letter process on the ground that the Lotion is an unapproved new drug, or, alternatively, informing Plaintiff that it did not intend to take any action regarding the Lotion (*see* Plaintiff's Supplemental Report Regarding Order Staying Plaintiff's UCL Claims and Request for Telephonic Status Conference [Dkt. 37]). The FDA chose the latter. On March 14, 2016, the FDA denied Plaintiff's petition, stating that it did "not intend to take action regarding Nivea CoQ10" [Dkt. 37, 37-1]. In its denial letter, the FDA explained that the information Plaintiff provided was "helpful for [it] to identify problems with marketed products and possible violations of the laws and

regulations that [it] enforce[s]," but noted that initiating enforcement action is decided on a case-by-case basis and is within the discretion of the agency [*id.*]. In the more than three years since Plaintiff filed her petition, FDA could have taken action if it agreed with Plaintiff's interpretation, but it has not done so.

On October 3, 2016, this Court granted Plaintiff's motion for leave to file her SAC [Dkt. 45].

C. Second Amended Complaint And Second Motion To Dismiss

Plaintiff chose not to re-plead her claim for lack of substantiation and did not attempt to state a misrepresentation claim, so the SAC rests entirely on the conclusory allegation that the Lotion is an unapproved drug, and was therefore sold in violation of California's Unfair Competition Law ("UCL") "unlawful" prong. Without citing any guidance or statement from the FDA concluding that skin-firming statements make a cosmetic also a drug, Plaintiff alleges that Defendant violated the Federal Food, Drug, and Cosmetic Act ("FDCA") and California's Sherman Act by selling the Lotion without FDA drug approval. She now claims that she would not have purchased the Lotion (for $10 at a San Diego CVS) had she known it was an "illegal and misbranded drug" (SAC ¶ 7). Plaintiff asserts only one count: an Unfair Competition Law ("UCL") claim based on the "unlawful" prong of that statute (*id.* ¶¶ 56-77). Plaintiff seeks restitution (for the $10 purchase) on behalf of a California class of consumers who purchased the Lotion (*id.* ¶¶ 21, 33-34, p. 9).

Defendant moved to dismiss the SAC on grounds that Plaintiff had not plausibly shown the Lotion was a drug based on either FDA Guidance or relevant case law. This Court dismissed the SAC, finding that Plaintiff had failed to allege the causation or reliance necessary to establish standing and had failed to allege the minimum amount in controversy under the Class Action Fairness Act [Dkt. 54]. The Ninth Circuit reversed and remanded for this Court to consider in the first instance whether Plaintiff had stated a plausible claim to relief [Dkt. 52-1]. Because Plaintiff fails to do so, the SAC should be dismissed.

II. LEGAL STANDARD

Plaintiff's SAC does not satisfy Rule 8.[1] Under Rule 8, "[t]o survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain sufficient factual matter to 'state a claim to relief that is *plausible* on its face.'" *Sateriale v. R.J. Reynolds Tobacco Co.*, 697 F.3d 777, 784 (9th Cir. 2012) (emphasis added) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Plausibility requires that the allegations, taken as true, be "enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 559 (2007); Fed. R. Civ. P. 8. That standard "asks for more than a sheer *possibility* that a defendant has acted unlawfully." *Iqbal*, 129 S.Ct. at 1949.

"Mere conclusory statements," "naked assertions," and "formulaic recitation[s] of the elements of a cause of action" do not suffice and are not entitled to the presumption of truth. *Chavez v. U.S.*, 683 F.3d 1102, 1108 (9th Cir. 2012). To determine the plausibility of a claim, the court must draw on its judicial experience and common sense, and ask: (1) whether the allegations do more than recite the elements of a cause of action and contain sufficient allegations of underlying facts to give fair notice to enable the opposing party to defend itself, and (2) whether those allegations plausibly suggest an entitlement to relief, "such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Eclectic Properties East, LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 995-96 (9th Cir. 2014).

[1] Under Plaintiff's own allegations in the SAC, she claims that she would not have purchased the Lotion if she knew it had not been approved. Where a plaintiff's claim under the UCL "sounds in fraud," she must also comply with the heightened pleading requirements of Rule 9(b), requiring her to plead those allegations with particularity. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1122, 1124-27 (9th Cir. 2009) (emphasis in original) (finding that Rule 9(b)'s particularity requirement applies to UCL causes of action). "Averments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged," *id.* at 1124, and must state enough facts to raise '"a reasonable expectation that discovery will reveal evidence'" of the alleged misconduct. *Cafasso, U.S. ex rel. v. Gen. Dynamics C4 Systems, Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting *Twombly*, 550 U.S. at 556). Here, Plaintiff fails to meet even the lesser Rule 8 pleading standard, let alone Rule 9.

III. ARGUMENT

Plaintiff's SAC turns on her unsupported allegation that the Lotion is a drug that affects the structure or function of the body, and not just a cosmetic that merely affects the skin through moisturizing. But Plaintiff does not allege facts to plausibly show the Lotion is a drug, and the SAC must be dismissed in its entirety.

First, Plaintiff does not allege that the Lotion's intended use is to affect the structure or function of the body. Because Defendant's intended use of the product is an essential statutory element to determine whether a product is a drug or a cosmetic, this defect alone is fatal to her claim. Second, Plaintiff's conclusory allegations are not plausible because they are contradicted by the face of the Lotion label, which appears in the SAC. The label shows that the Lotion was intended to be a moisturizing cosmetic, which the FDA considers the quintessential example of a cosmetic (not a drug). And third, no other factual allegations support her position that the Lotion is a drug. In fact, other FDA guidance as well as case law refute her position.

A. FDCA Definitions

The FDCA defines "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 such articles." 21 U.S.C. § 321(i). The FDCA defines "drug" to include "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C) (2009); SAC ¶ 13, 15. Relevant here, FDA guidance explains that "[p]roducts intended to make people more attractive are generally cosmetics," so "moisturizing is a cosmetic claim." FDA, *Wrinkle Treatments and Other Anti-Aging Products, available at* http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm388826.htm, RJN Ex. A. Whereas "products intended to affect the structure or function of the body . . .

are drugs . . . even if they affect the appearance," so a product intended to, for example, "remove wrinkles or increase the skin's production of collagen," is a drug. *Id.*

"The vendor's intent is the key element in this statutory definition" of whether a product is considered a drug versus a cosmetic. *U.S. v. Storage Spaces . . . 277 East Douglas, Visalia, Cal.*, 777 F.2d 1363, at 1366 (9th Cir. 1985). The vendor's intent "may be derived or inferred from labeling, promotional material, advertising, or any other relevant source." *Id.; see also U.S. v. Article . . . "Sudden Change,"* 409 F. 2d 734, 739 (2d Cir. 1969) ("[A product] will be deemed a drug for purposes of the [FDCA] where the labeling and promotional claims show intended uses that bring it within the drug definition."). To be considered a drug, intended use must be fairly said "to constitute a representation that the product will affect the structure of the body in some medical- or drug-type fashion, i.e., in some way other than merely 'altering the appearance.'" *Sudden Change*, 409 F.2d at 742.

B. Plaintiff Does Not Allege That Defendant's Intended Use Of The Lotion Was To Affect The Body's Structure Or Function.

Defendant's intended use is an essential inquiry in determining whether a product is a drug. *Storage Spaces*, 777 F.2d at 1366. Yet Plaintiff alleges no facts concerning Defendant's intended use of the product whatsoever, let alone that Defendant intended that the Lotion be used to affect the structure or function of the body. This alone is fatal to her complaint. *See Eclectic Properties*, 751 F.3d at 1000 (dismissing complaint for failure to state a claim because complaint failed to allege plausible inference regarding defendant's requisite intent).

Plaintiff mentions intended use only when she quotes statutory and FDA guidance defining whether a product is a drug. SAC ¶¶ 12, 13, 15, 16. She makes no allegations about *Defendant's* intended use for the Lotion. This is insufficient to allege that the Lotion is an unapproved drug under Rule 8. *See Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 964 (N.D. Cal. 2013) (dismissing food labeling claim

because the complaint "provide[d] little more than a long summary of the FDCA and its food labeling regulations, a formulaic recitation of how the[] regulations appl[ied] to [the] [d]efendants' products, and conclusory allegations regarding [the] [d]efendants' 'unlawfulness.'").

C. Plaintiff Cannot Allege Facts That Plausibly Show Defendant's Intended Use Of The Lotion Was To Affect The Body's Structure Or Function Because Such Allegations Would Be Directly Contradicted By The Lotion Label.

As explained above, the FDA guidance Plaintiff herself cites in the SAC states that "moisturizing is a cosmetic claim[,] [s]o if a product is intended to make lines and wrinkles less noticeable, simply by moisturizing the skin, it's a cosmetic." *See* SAC ¶ 16 (citing Wrinkle Treatments and Other Anti-Aging Products, *available at* http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm388826.htm), RJN Ex. A. That is precisely the case here. Both the words and structure of the label, which appear in in the SAC ¶¶ 9-10, contradict Plaintiff's allegations and show she cannot prevail.

The label states: "Skin Firming Hydration Body Lotion." Basic interpretation principles instruct that "adjectives modify nouns," *see Weyerhaeuser Co. v. United States Fish & Wildlife Svc.*, 139 S. Ct. 361, 368 (2018), and thus "Skin Firming" necessarily describes the "Hydration" provided by the "Body Lotion." *See Carrea v. Dreyer's Grand Ice Cream, Inc.*, 475 F. App'x 113, 115 (9th Cir. 2012) (affirming dismissal with prejudice of allegations that "Original Sundae Cone," "Original Vanilla," and "Classic" implied an ice cream was natural or nutritious because 'Original Vanilla' is adjacent to the phrase 'Artificially Flavored.'"). The label expressly says that the Lotion provides moisture and hydration. In other words, the skin firming effect occurs *through* the hydration of the skin by the lotion. This practical reading of the label, which must frame the Court's analysis, reflects Defendant's intended use that the Lotion be a moisturizing, hydrating lotion.

Additionally, the Lotion label should be read as a whole, considering the structure and spatial relationships of the representations. *Avis Rent A Car System, Inc. v. Hertz Corp.*, 782 F.2d 381, 385 (2d Cir. 1986) ("a court must 'consider the advertisement in its entirety and not . . . engage in disputatious dissection."'). When considered in context, all of the "firming" or "tightening" claims on the label are structurally *subordinate to* and used to *modify* a claim of hydration, showing that Defendant objectively intended, and others would understand, the Lotion to be used for moisturizing. Specifically, Plaintiff points to two representations: the label states (1) that it "Improves Skin's Firmness in as little as two weeks" and (2) that it is "proven to firm and tighten skin's surface in as little as two weeks." *See* SAC ¶ 2. The label image itself shows that both representations appear underneath and in smaller font than a statement that the Lotion provides hydration or moisture. The first representation is below:

The words "Skin Firming Hydration" and "Body Lotion" appear at the top of the label in very large, all capital font. The phrase "Improves Skin's Firmness in as little as 2 weeks" appears in smaller font *immediately* below, and is, at best, a subheading. The second representation is below:

The words "Proven to firm and tighten skin's surface in as little as two weeks" appear in smaller font *immediately* under the words "NIVEA® Skin Firming Hydration." Plaintiff cannot ignore that the label repeatedly and prominently refers to hydration as the benefit to the Lotion. In fact, there are no alternative mechanisms specified by which the skin firming effects occur *other* than hydration and moisturization. Thus, read in context, both representations must be read as a description of the Lotion's moisturizing properties, and the label itself contradicts Plaintiff's tortured reading.[2] Plaintiff's unreasonable and factually unsupported inference that the Lotion is a drug should be rejected. *See In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008) ("The court need not . . . accept as true allegations that contradict matters properly [shown] . . . by exhibit. Nor is the court required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences."). Indeed, taking Plaintiff's allegations

[2] Plaintiff states that the "former label used during most of the class period is attached as Exhibit A." SAC fn. 1, 3. Exhibit A then inexplicably contains only a partial image of the Lotion label. Plaintiff has not alleged which label was affixed to the Lotion she purchased, which is insufficient to satisfy Rules 8 or 9(b). Nonetheless, Exhibit A also shows that all of the "firming" or "tightening" claims on the label are subordinate to and used to modify claims of hydration.

as true, it appears that even she believed the Lotion was a cosmetic when she bought it. She alleges that, had she known it was a drug, she would not have bought it (SAC ¶ 7), which implies that even she understood the product to be making cosmetic claims. Thus, to the extent a consumer's interpretation is relevant to the intended use of the product, her own experience supports that the product was intended to be a cosmetic.

D. Plaintiff Has Not and Cannot Put Forth Any Plausible Allegations That The Lotion Is A Drug.

Not only does the label refute Plaintiff's counter-factual reinterpretation of the Lotion, FDA guidance and case law do as well.[3]

1. FDA Guidance Shows That The Lotion Is Not A Drug.

Plaintiff cites in the SAC two FDA guidance documents, neither of which support her conclusory allegation that the Lotion is a drug.

First, Plaintiff cites FDA guidance regarding Wrinkle Treatments and Other Anti-Aging Products, which instructs that "[p]roducts intended to make people more attractive are generally cosmetics" and "moisturizing is a cosmetic claim," so if a product claims "to make lines and wrinkles *less noticeable*, simply by moisturizing the skin, it's a cosmetic." https://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm388826.htm (updated July 2, 2014), Request for Judicial Notice ("RJN") Ex. A.[4] (emphasis

[3] Plaintiff also alleges that the Lotion violates the FDCA and Sherman FD&C ingredient labeling requirements for drugs because the ingredients found on the back of the Product label are not listed in the required order. ¶ 20. But the SAC is devoid of any explanation of how or why Plaintiff was injured by any ingredient labeling, whether Plaintiff alleges this is a separate UCL violation, or any allegation she would have made a different decision had the ingredients been labeled differently. Moreover, federal law makes clear only the FDA is authorized to bring suit for violations of the FDCA, 21 U.S.C. § 337(a), and to the extent Plaintiff suggests otherwise, her claims seeking to enforce the FDCA must be dismissed as preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348-53 (2001).

[4] In ruling on a motion to dismiss, "courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v.*

added). The guidance further explains that if a product is intended to affect the structure or function of the skin by "remov[ing] wrinkles or increase[ing] the skin's production of collagen, it's a drug or a medical device." *Id.*

There can be no question that the Lotion was not intended to, and its labeling does not represent that it will, *remove* wrinkles or increase the *production* of collagen. To the contrary, it makes repeated claims about hydration and moisturization, including claims about "softer, smoother skin," which, taken as a whole, support that the product was intended to be a cosmetic. This FDA guidance cannot move Plaintiff's claim from possible to plausible.

Second, Plaintiff cites a 2012 Warning Letter to Avon, but that Warning Letter was concerned with Avon's use of "anti-wrinkle" claims, which have no relation to the Lotion label here. *See* Letter from M. Roosevelt (FDA) to A. Jung ("Avon") dated Oct. 5, 2012, *available at* https://wayback.archive-it.org/7993/20171115075932/https:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm323738.htm (last visited Jan. 22, 2019), RJN Ex. B. The FDA issued the Warning Letter after examining eight representations by Avon, including:

- "The at-home answer to wrinkle-filling injections. Start rebuilding collagen in just 48 hours."
- "4D WRINKLE-REVERSE TECHNOLOGY IS DESIGNED TO: Rebuild collagen to help plump out lines and wrinkles. Stimulate elastin to help improve elasticity and resilience. Regenerate hydroproteins to help visibly minimize creasing."
- "Formulated to boost shock-absorbing proteins to help strengthen skin's support layers."
- "Improve fine & deep wrinkles up to 50%. Immediately plumps out wrinkles and fine lines. Within 48 hours begins boosting collagen production."

Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2509 (2007). Courts routinely take judicial notice of documents that appear on FDA's website without converting motions to dismiss into motions for summary judgment. *See, e.g., Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1113 n.1 (N.D. Cal. 2013).

- "Designed to boost Activin, ANEW's Activinol Technology helps reactivate skin's repair process to recreate fresh skin & help dramatically reverse visible wrinkles."
- "[H]elp tighten the connections between skin's layers."
- "Formulated with pomegranate and fennel extracts to help boost production of collagen and elastin."

The FDA warning letter also highlighted one skin "firming" representation made by Avon: "Our effective lifting treatment is formulated to fortify damaged tissue with new collagen. In just 3 days, see tighter, firmer, more lifted skin." But Avon's "firming" statement was interwoven with its claim of fortifying damaged *tissue* with new *collagen* – claims that Defendant did not make. This "firming" representation also cannot be read in a vacuum; it was analyzed in the context of the other representations outlined above. Thus, viewing the above claims in context and in totality, the FDA concluded that Avon's products were drugs because the representations indicated the products were intended to affect the structure (damaged tissue) or function (new collagen) of the human body.

Unlike the Avon product, the Lotion at issue here claims to improve the appearance of skin through hydration and moisturization—it does not purport to *remove* wrinkles, *regenerate* hydroprotiens, *reactivate* skin's repair process, or boost collagen *production* like the Avon products. Each of the Avon phrases signals a physiological change to the skin structure "in some medical- or drug-type fashion, i.e., in some way other than merely 'altering the appearance.'" *Sudden Change*, 409 F. 2d at 742; *see also FTC v. Pantron I Corp.*, 33 F. 3d 1088 (9th Cir. 1994) (asking whether product carried "drug connotations"). The fact that the FDA has found products intended "to remove wrinkles or increase the skin's production of collagen" to be drugs (SAC ¶ 16), says nothing about this Lotion, which makes no physiological representations about removing wrinkles, increasing production of collagen, or changing the molecular structure of skin. In short, the Avon warning letter cannot

push Plaintiff's claim from the possible to the probable because it does not address what FDA would think of the very different representations made on the Lotion.

Plaintiff cited two other warning letters in her appeal to the Ninth Circuit, which similarly focus on representations signaling a physiological change to the skin structure in a medical or drug-type fashion and do not address any products that solely claim to improve skin's firmness. Compare:

- February 2015 Letter to StriVectin Operating Company, where the FDA classified the products as drugs based on the following physiological representations: "[c]linically proven to change the anatomy of a wrinkle," "potent elastin-stimulating peptides [to] help enhance skin structure," "[n]ow even more tightening, lifting . . .", "restore[s] the elastin fiber architecture, providing noticeable lift and improving resistance to gravity," and "contains a powerful blend of active ingredients that stimulates elastin synthesis." *See* Feb. 12, 2015 Letter from William Correll to Melisse Shaban ("StriVectin"), *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm436692.htm (last accessed Jan. 22, 2019), RJN Ex. C.

- October 2016 Letter to Bioque Technologies, Inc. & Vouray, Inc., where the FDA classified products as drugs based on the following physiological representations: "promotes the production of collagen and elastin," "activate[s] collagen and elastin and repairs damaged proteins," "[t]he BOTOX alternative that packs a peptide punch," "performs better than cosmetic injections," and "de-stresses facial muscles beneath the deepest layer of skin to reduce tightening around cavities caused by collagen and elastin deterioration, stopping the process that furrows and puckers the outer layer of skin into wrinkles." *See* Oct. 7, 2016 Letter from Evelyn Bonnin to Vittoria A. Bonomo ("Bioque"), *available at*

https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm524644.htm (last accessed Jan. 22, 2019), RJN Ex. D.

Other relevant FDA guidance has similarly classified products as drugs only where the representations evidenced an intent to effectuate a physiological change to the skin structure in a medical- or drug-type fashion. None of those letters were issued where, as here, the represented skin change was (1) a mere alteration to skin appearance, and (2) achieved through moisturizing.[5]

Tellingly, the SAC cites no guidance or regulation from the FDA (or any regulatory agency) concluding that appearance-based "tightening" or "firming"

[5] *See also* July 18, 2016 Letter from LaTonya M. Mitchell to John Robert Insigner ("Ageless Aesthetics"), *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm511929.htm (last accessed Jan. 22, 2019), RJN Ex. E (finding products to be drugs based on claims such as "[s]timulates production of collagen and elastin (fibroblasts)"); Sept. 20, 2016 Letter from William A. Correll to Christy Pair ("Face Naturals"), *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm525667.htm (last accessed Jan. 22, 2019), RJN Ex. F (finding products to be drugs based on claims such as "boosts collagen production," and "reduce bacteria, which greatly improves the skin's immunity against infection,"); Oct. 18, 2016 Letter from Craig W. Swanson to Dr. Mostafa M. Omar ("PhytoCeuticals, Inc."), *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm525938.htm (last accessed Jan. 22, 2019), RJN Ex. G (finding products to be drugs based on claims such as "stimulates cell-cell interaction, assists in the formation of collagen, and increases skin elasticity," "accelerates cell renewal," "assists the formulation of collagen and strengthens in structural proteins," "assists in skin regeneration," "stimulates cell reproduction and collagen," and "acts as a topical Botox"); May 26, 2017 Letter from Ingrid A. Zambrana to James W. Dukes ("Star Health & Beauty"), *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm563230.htm (last accessed Jan. 22, 2019), RJN Ex. H (finding products to be drugs based on claims such as "Natural Botox Alternative," "[S]timulate collagen growth . . . reduction of deep wrinkles," and "reduces wrinkles . .. Also has been shown to prevent aging of the skin"); Aug. 10, 2017 Letter from Evelyn Bonnon to Kathi Kirschner ("Skin 2 Spirit"), *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm571564.htm (last accessed Jan. 22, 2019), RJN Ex. I (finding products to be drug based on claims such as "has recently been used to create . . . an FDA Approved injectable material that aestheticians and plastic surgeons predict will replace collagen injections because the risk of reaction is lower . . . and the results last longer than those of collagen injections," and "supports the keratin migration cycle that is responsible for the natural regeneration of skin cells and can increase renewed cells in the epidermis.").

claims, in conjunction with hydration and moisturizing representations, such as ones made on the Lotion label, are sufficient to render a product a drug. Indeed, authoritative sources are to the contrary. *See Hutt, et al.*, Food and Drug Law, 4th ed. 2014, 114-15 ("a product that claims to improve or maintain temporarily the appearance or the feel of the skin" are cosmetics, not drugs) (quoting *Letter From John M. Taylor, FDA Associate Commissioner for Regulatory Affairs, to Various Attorneys Representing the Cosmetic Industry,* Nov. 19, 1987 ("Taylor Letter"), and explaining that the "letter represents the agency's view of the line between separating cosmetics from cosmetic drugs to the current day."). The Taylor Letter states that "claims that a product 'counteracts,' 'retards,' or 'controls' aging or the aging process, as well as claims that a product will 'rejuvenate,' 'repair,' or 'renew' the skin are drug claims because they can be fairly understood as claims that a function of the body, or that the structure of the body, will be affected by the product." *Id.* The Taylor Letter goes on to note, however, in no uncertain terms, that "a product that claims to moisturize or soften the skin is a cosmetic." *Id.*

This interpretation was reiterated in FDA's guidance for Alpha Hydroxy Acids ("AHA") used in both cosmetics and drugs. *See* https://www.fda.gov/cosmetics/productsingredients/ingredients/ucm107940.htm (last visited Jan. 22, 2019), RJN Ex. J. In that guidance, FDA notes that AHAs are cosmetics when they are marketed for "smoothing fine lines and surface wrinkles, improving skin texture and tone, unblocking and cleansing pores, and improving skin condition," but are considered drugs when they are marketed for "treating acne, removing scars, and lightening discolorations." *Id*.

These sources demonstrate that the FDA's interpretation of the FDCA is at odds with Plaintiff's theory. Plaintiff's theory appears to be that any representation that can arguably be read as affecting the structure or function of the body makes a product a drug. But, as outlined above, the FDA has clearly stated that a product that moisturizes or softens the skin, which by nature of moisturizing or softening also

affects or changes the skin in some way, is a cosmetic. So Plaintiff's theory cannot be correct, and she has nothing more than that theory to support her claim. Because her theory cannot take her claim from possible to plausible, it must be dismissed.

Finally, Plaintiff's theory also requires another unreasonable inference. As this Court pointed out, the SAC necessarily assumes that had Defendant consulted the FDA, the agency would have found that the Lotion was a drug and would have refused to allow Defendant to sell it [Dkt. 54 at 3]. But Plaintiff has not alleged that the FDA would have refused to allow Defendant to sell the Lotion. Nor could she: Franz petitioned the FDA to make those same findings and the agency refused to do so.

2. Case Law Also Establishes That The Lotion Is Not A Drug.

To date, Plaintiff has never cited any case concluding that "firming" claims akin to the ones made on the label of the Lotion are drug claims. To the contrary, the most analogous case involving claims of skin firming and tightening (along with additional claims that this Lotion does not make) held that such representations are clearly intended to be understood as cosmetic claims related to "altering the appearance," and are *not* representations "that the product will affect the structure of the body in some medical-or drug-type fashion." *U.S. v. An Article . . . "Helene Curtis Magic Secret,"* 331 F. Supp. 912, 917 (D. Md. 1971).

In *Helene Curtis*, the court reviewed a product called Magic Secret making the following claims: "pure protein," "smoothes away wrinkles in minutes, keeps them away for hours," "dramatic power to smooth away crows feet, puffy under eye circles, laugh, frown, and throat lines in just minutes," "see how smooth and young looking your skin can become," "skin should respond fully to Magic Secret's dramatic action," "does indeed firm the skin to smoother, younger-looking loveliness," "astringent sensation . . . indicating that the lotion is gently firming and toning your skin," "tightening and moisturizing tired skin," and "skin quickly responds to Magic Secret's dramatic astringent activity." 331 F. Supp. at 915.

Even in light of these claims – which were much closer to a physiological representation than the claims Plaintiff challenges here – the court held that Magic Secret was not a drug because "even the 'ignorant, unthinking and credulous' consumer would not be led . . . to believe that 'Magic Secret' would do other than alter their appearance." *Id.* at 917; *see also FTC v. Pantron I Corp.*, 33 F. 3d 1088, 1105 (9th Cir. 1994) (explaining that the *Helene Curtis* product was not a drug because a consumer would interpret the advertisement to cause only a temporary, superficial change in appearance for a short period, not affect the structure or function of the body). Here, by comparison, Defendant is alleged to have made only *one* of the many claims made about the Magic Secret, and it cannot be said that the ignorant, unthinking, and credulous consumer would plausibly believe the Lotion would do anything other than alter the appearance of skin.

Then in *FTC v. Pantron I Corp.*, 33 F. 3d 1088, 1105 (9th Cir. 1994), the Ninth Circuit considered claims made about a hair re-growth product and concluded it was a drug. The court contrasted *Helene Curtis*, explaining, "representations that the product will cause the body to generate new hair in parts of the scalp where no hair currently exists," were "far more likely to be understood as affecting the structure or function of the body, and thus carrying 'drug connotations,' than are Helene Curtis's representations regarding 'Magic Secret.'" *Id.* (citations omitted). The skin firming representations on the Lotion, like those in *Magic Secret*, simply do not promise to affect the structure or function of the body in the same physiological, drug-like way as the hair re-growth product in *Pantron*. Like *Pantron*, the only cases Plaintiff has relied on to support her claim (in appellate briefing) have involved very different representations suggesting physiological changes to the structure of the body in a medical- or drug-type fashion.[6]

[6] *See, e.g., U.S. v. An Article of Drug Consisting of 36 Boxes . . . "Line Away Temporary Wrinkle Smoother, Coty" ("Line Away")*, 415 F.2d 369, 371 (3d Cir. 1969) (finding product to be a drug because representations indicated it was "therapeutic," having a physiological effect on the skin itself: explanation that the user will feel a tingling sensation when they put the product on, meaning "Line Away

There is no need to check common sense at the door when deciding a motion to dismiss. *See Stuart v. Cadbury Adams USA, LLC*, F. App'x 689, 690 (9th Cir. 2011) (affirming dismissal of UCL claim because plaintiff's claims "def[ied] common sense"). This is a lotion product that is replete with references to hydration, body lotion, and moisturization, and there is simply no reason to believe anyone, let alone the authorities, would think it is a drug. *See Videtto v. Kellogg USA*, 2009 WL 1439086 (E.D. Cal., May 21, 2009) (dismissing without leave to amend UCL, FAL and CLRA claims based on allegations that consumers believed that "Froot Loops" cereal contained "real, nutritious fruit"); *Red v. Kraft*, 2012 WL 5504011, at *3 (C.D. Cal. Oct. 25, 2012) (rejecting that consumers could believe crackers were "made with real vegetables" noting that "[t]he fact remains that the product is a box of crackers, and a reasonable consumer would be familiar with the fact of life that a cracker is not composed of primarily fresh vegetables"); *Pelayo v. Nestle USA, Inc.*, 989 F. Supp. 2d 973, 978 (C.D. Cal. 2013) (granting motion to dismiss because allegations that pasta products were misleadingly labeled as "All Natural" were implausible; consumers are "aware that [the pasta products] are not springing fully formed from Ravioli trees and Tortellini bushes").

As a result, Plaintiff has not alleged facts, a coherent legal theory, or the existence of any case law to support her novel position that the Lotion is a drug. Her cause of action does not rise to the requisite level of plausibility demanded by Rule 8 and should be dismissed. Because Plaintiff's claim that Defendant violated FDA regulations would fail under FDA guidance and relevant case law, her UCL

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is at work – smoothing, firming, tightening" and it would "visibly smooth[] out fatigue lines, laugh lines, worry lines, frown lines, tiny age lines, and crows feet while *discouraging new lines from forming*") (emphasis added); *U.S. v. An Article . . . Consisting of . . . Sudden Change ("Sudden Change")*, 409 F.2d 734, 738-42 (2d Cir. 1969) (finding product to be a drug based on the following representations: "provide a *face lift* without surgery," and "smooth away crows feet, laugh and frown lines – even under-eye puffiness in minutes" and "keep [them] and 'that tired look' away for hours" (emphasis added)).

"unlawful" prong claim likewise fails as a matter of law. *See Cullen v. Netflix, Inc.*, 880 F. Supp. 2d 1017, 1028 (N.D. Cal. 2012).

IV. CONCLUSION

For the foregoing reasons, Defendant requests that the Court dismiss Plaintiff's SAC with prejudice pursuant to Fed. R. Civ. P. 8 and 12(b)(6). Despite two amended complaints, Plaintiff has not put forth any allegations to plausibly suggest an entitlement to relief sufficient to require Defendant to be subject to the expense of discovery and continued litigation.

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CERTIFICATE OF SERVICE VIA CM/ECF SYSTEM

The undersigned certifies that on **January 31, 2019**, a true and correct copy of the following document was electronically filed and served on all counsel of record who are deemed to have consented to electronic service via the Court's CM-ECF system:

DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT

Pursuant to the CM/ECF system, registration as a CM/ECF user constitutes consent to electronic service through the Court's transmission facilities. Any other counsel of record will be served by electronic mail and U.S. mail.

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