UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ASHLEY FRANZ, individually and on behalf of others similarly situated, Plaintiff, vs. BEIERSDORF, INC., Defendant.	CASE NO. 14cv2241-LAB (AGS) **ORDER DENYING DEFENDANT'S MOTION TO DISMISS [Dkt. 62]**

Currently before the Court is Defendant Beiersdorf, Inc.'s Motion to Dismiss Plaintiff's Second Amended Complaint. The parties are familiar with the procedural history of the case, so the Court doesn't repeat it here. In short, Plaintiff Ashley Franz purchased a $10 bottle of Nivea "Skin Firming Hydration Body Lotion" from a San Diego CVS in the summer of 2012. Although her original complaint contained multiple claims related to Beiersdorf's marketing of this lotion, Franz has whittled those claims down to one: that the sale of the lotion was "unlawful" under California's Unfair Competition Law ("UCL") because Beiersdorf did not receive FDA approval prior to selling the lotion, which she alleges is a drug. Beiersdorf now moves to dismiss.

To state a cause of action based on an "unlawful" business practice under California's UCL, "a plaintiff must allege facts sufficient to show a violation of some underlying law." Perez v. Wells Fargo Bank, N.A., 929 F. Supp. 2d 988, 1003 (N.D. Cal. 2013) (citing People v. McKale, 25 Cal.3d 626, 635 (Cal. 1979). Here, Franz alleges that the Nivea lotion was a

"drug" within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, et seq., and the California Sherman, Food, Drug, and Cosmetic Law ("Sherman Law"), Cal. Health & Safety Code §§ 109875, et seq.[1] She further alleges that Beiersdorf sold that drug without first obtaining approval from the Food and Drug Administration ("FDA"), in violation of both statutes. This motion therefore turns on a single question of law: has Franz plausibly pled that the Nivea lotion was a drug? The Court finds that she has and therefore denies Defendant's motion.

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). It defines "cosmetic" as "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." Id. § 321(i). If a product qualifies as a drug under the FDCA, the seller must first seek approval from the FDA before selling that product. See id. § 355. There is no such requirement if the product is a cosmetic.

When deciding whether a product is a drug under the FDCA, "[t]he intended use of [the] product is determined by the vendor's objective intent," United States v. Kasz Enters., Inc., 855 F. Supp. 534, 539 (D.R.I. 1994) (citing 21 C.F.R. § 201.128) (emphasis in original), which "may be derived or inferred from labeling, promotional material, advertising, or any other relevant source." United States v. Storage Spaces Designated Nos. 8 & 49 Located at 277 E. Douglas, Visalia, Cal., 777 F.2d 1363, 1366 (9th Cir. 1985); see also United States v. Article ... Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734, 739 (2d Cir. 1969) ("[A product] will be deemed a drug for purposes of the [FDCA]

[1] The California Sherman Law's definition of "drug" is identical to the FDCA's, and it likewise requires that a company seeking to market a drug first seek approval from the FDA. See Cal. Health & Safety Code §§ 109925 (defining "drug"), 111550(a)(1) (requiring FDA approval for any drug). Because the relevant provisions of each statute are identical, this opinion cites only the FDCA provisions for simplicity.

where the labeling and promotional claims show intended uses that bring it within the drug definition.").

Franz points to the lotion's label as support for her argument that Beiersdorf intended the product to be used as a drug. Among the claims on the lotion bottle—which can be seen in more detail in Appendix 1—are that the lotion provides "skin firming hydration," "improves skin's firmness in as little as 2 weeks," and is "proven to firm and tighten skin's surface in as little as two weeks." Because "firming skin" and "tightening skin" suggest the product will "affect the structure of the body," Franz argues that she has plausibly pled the lotion is a drug.

The parties have submitted several FDA enforcement letters in support of their arguments.[2] In October 2012, for example, the FDA sent a "warning letter" to Avon Products regarding its line of face creams. See SAC ¶16; Dkt. 62-4. Among the claims the FDA found objectionable, Avon advertised that the face creams would "fortify damaged tissue with new collagen. In just 3 days, see tighter, firmer, more lifted skin." Id. Avon also advertised that the creams would "help tighten the connections between skin's layers." Id. In a 2015 letter to StriVectin, the FDA likewise warned that the company's "neck cream" was being improperly marketed because it claimed to contain "potent elastin-stimulating peptides [to] help enhance skin structure" and provide "even more tightening, lifting." Dkt. 62-5. A third enforcement letter, sent to Bioque Technologies, warned that the company's anti-wrinkle products were drugs because the products claimed to "de-stress[] 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

[2] The parties request that the Court take judicial notice of various documents, including FDA warning letters, FDA guidance, website screenshots, and news articles. See Dkts. 62-2, 65-1, 68-1. The Court **GRANTS** the requests for judicial notice as to the FDA warning letters and FDA guidance, but the rest of the material is irrelevant to the Court's decision, so those requests are **DENIED AS MOOT**. Gustavson v. Wrigley Sales Co., 961 F. Supp. 2d 1100, 1113 n.1 (N.D. Cal. 2013) ("The Court may take judicial notice of materials available on government agency websites.").

skin into wrinkles." Dkt. 62-6. Franz suggests that the Nivea lotion is a drug because its "skin firming" claims are similar to those the FDA has previously found objectionable.

Beiersdorf counters that "skin firming" representations are not per se violations of the FDCA and that the Court must instead look to the claimed mechanism by which the product firms skin. In a guidance document on Wrinkle Treatments and Other Anti-Aging Products, for example, the FDA states that "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." FDA, Wrinkle Treatments and Other Anti-Aging Products, Dkt. 62-3 (emphasis added). Because Franz has not plausibly pled any facts to show that the lotion "affects the structure or function of the body" in any way other than by moisturization or hydration, Beiersdorf argues she has failed to state a claim.

But FDA guidance, as helpful as it may be, doesn't necessarily determine what is and isn't a drug under the FDCA. Indeed, FDA guidance is simply a reflection of the "current thinking" of the agency—it's not binding on the FDA, the public, or this Court. See FDA, Cosmetics Guidance & Regulation ("Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public."); see also Christensen v. Harris Cty., 529 U.S. 576, 587 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant Chevron-style deference."). The Court is, of course, bound by the language of the FDCA. It is likewise bound by the FDA's promulgated regulations to the extent those regulations are permissible constructions of the FDCA. See Christopher v. SmithKline Beecham Corp., 635 F.3d 383, 392 (9th Cir. 2011), aff'd, 567 U.S. 142 (2012) (citing Auer v. Robbins, 519 U.S. 452, 457 (1997)) ("We defer to the [agency's] regulation 'so long as it is 'based on a permissible construction of the statute.'"). But the parties have not identified a provision of the FDCA or any applicable agency regulation—see, e.g., 21 C.F.R. §§ 200.5, et seq. (Drugs), id. §§ 300.50, et seq. (Drugs for Human Use), id. §§ 700.3, et seq. (Cosmetics)—that would exclude a product that "affects the structure or function of

the body" from the definition of "drug" simply because it does so through moisturization. Nor have the parties identified the statutory or regulatory basis for the FDA's Wrinkle Treatments and Other Anti-Aging Products guidance, so the Court is unable at this juncture to determine whether the agency's interpretation excluding moisturizing products from the definition of "drug" is persuasive. See Christensen, 529 U.S. at 587 ("[I]nterpretations contained in formats such as opinion letters are 'entitled to respect'. . ., but only to the extent that those interpretations have the 'power to persuade.'") (citations omitted). Accepting as true the allegations in the complaint, which the Court is required to do at this stage, Franz has stated a plausible claim that the lotion is a drug and that it was sold unlawfully. Given this finding, Franz's secondary claim that the lotion's ingredients are listed in an improper order on the label—a requirement that applies only if the product is a "drug"—is also plausible.

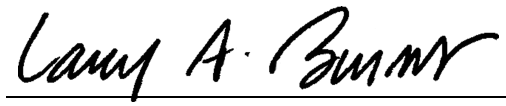
This is a limited holding. The Court is not deciding that the lotion is a drug.[3] That's a factual question not suitable for resolution at this stage of the litigation. It is simply determining that Franz's claims clear the relatively low bar of plausibility. See, e.g., Reid v. GMC Skin Care USA Inc., 2016 WL 403497, at *9 (N.D.N.Y. 2016) ("Because the complaint characterizes the products as both drugs and cosmetics, and any categorization hinges on the perceived intended use, it would be inappropriate to resolve the issue at this early pleading stage.") (quotation marks omitted). Given the straightforward facts and questions of law presented, this might be the rare case in which a summary judgment motion would be appropriate before addressing class certification. See Wright v. Schock, 742 F.2d 541, 543–44 (9th Cir. 1984) ("Under the proper circumstances—where it is more practicable to do so and where the parties will not suffer significant prejudice—the district court has

[3] Indeed, the Court finds it significant that the FDA has declined to take any action with respect to the lotion in the seven-plus years it has been on the market. As evidenced by the numerous FDA warning letters the parties have submitted in support of their arguments, the FDA actively polices drugs that are improperly sold as cosmetics. In this case, Franz filed a citizen petition with the FDA asking it to step in, but the agency declined to do so. To the extent agency action (or lack thereof) is relevant to whether Beiersdorf should have first sought agency approval before marketing the lotion, this deliberate inaction is instructive.

discretion to rule on a motion for summary judgment before it decides the certification issue."). For now, though, Defendant's motion is **DENIED**. Dkt. 62.

IT IS SO ORDERED.

Dated: May 20, 2019



HONORABLE LARRY ALAN BURNS
Chief United States District Judge

APPENDIX 1

Figure 1 (SAC ¶ 9)

Figure 2 (SAC ¶ 10)