UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MEHVA ROFFMAN, et al.,

Plaintiffs,

v.

PERFECT BAR, LLC,

Defendant.

Case No. 22-cv-02479-JSC

ORDER RE: MOTION TO DISMISS

Re: Dkt. No. 18

Plaintiffs are consumers who challenge Defendant's claims on its product labels about the amount of protein they contain. (Dkt. No. 1.)[1] Before the Court is Defendant's motion to dismiss. (Dkt. No. 18.) Having carefully considered the parties' briefing, and with the benefit of oral argument on August 31, 2022, the Court GRANTS the motion.

COMPLAINT ALLEGATIONS

Defendant makes claims on the front labels of its food products about the amount of protein they contain. The front label of the Perfect Bar in Dark Chocolate Chip Peanut Butter flavor says "15G PROTEIN," and the front label of the Perfect Peanut Butter Cups Dark Chocolate flavor says "7G PROTEIN." (Dkt. No. 1 ¶¶ 2, 18.) Plaintiff Ms. Chong bought the Perfect Bar in Dark Chocolate Chip Peanut Butter flavor at stores around the Bay Area between 2018 and 2022. (*Id.* ¶ 15.) Plaintiff Ms. Roffman bought Perfect Peanut Butter Cups in Dark Chocolate and Milk Chocolate flavors at stores around the Bay Area between 2019 and 2022. (*Id.* ¶ 59.)

Each Plaintiff "read[]" and "relied on" the "front labels that promised" "7G PROTEIN,"

[1] Record citations are to material in the Electronic Case File ("ECF"); pinpoint citations are to the ECF-generated page numbers at the top of the documents.

"8G PROTEIN," and "15G PROTEIN," "believ[ing] . . . that the product would actually provide her the specific amount of protein on the front label in a form her body could utilize as protein." (*Id.* ¶¶ 56, 60; *see id.* ¶ 2.) But "not all proteins are the same in their ability to meet human nutritional requirements, so a simple statement about the number of grams does not actually inform consumers about how much usable protein they are receiving." (*Id.* ¶ 3.)

> Some proteins are deficient in one or more of the nine amino acids essential to human protein synthesis and/or are not fully digestible within the human gut. When a human body uses up the least prevalent essential amino acid from a food product, protein synthesis shuts down and all of the remaining amino acids from that protein source degrade mostly into waste. Likewise, whatever portion of a protein source is not digestible is similarly unavailable for protein synthesis. A protein's ability to support human nutritional requirements is known as its "quality."

(*Id.*; *see id.* ¶¶ 25–28.) The "Protein Digestibility Corrected Amino Acid Score" ("PDCAAS"), also known as the "corrected amount of protein per serving," is a method for measuring protein quality. (*Id.* ¶ 4.) PDCAAS "combines a protein source's amino acid profile and its percent digestibility into a discount factor ranging from 0.0 to 1.0 that, when multiplied by the total protein quantity, shows how much protein in a product is actually available to support human nutritional requirements." (*Id.*) For example, nuts, the primary protein source in Defendant's products, have a PDCAAS score of 0.4–0.5, meaning that only 40–50% of the protein is "actually available to support human protein needs." (*Id.* ¶ 5.) PDCAAS can also be expressed as a percent daily value, meaning "the corrected amount of protein per serving divided by the daily reference value for protein of 50 grams." (*Id.* ¶ 4.) For example, a product with 10 grams of protein and a PDCAAS score of 0.5 would have a percent daily value of 10%: 10 grams multiplied by 0.5, divided by 50 grams. (*See id.*)

Plaintiffs allege Defendant's front-label claims, like "15G PROTEIN," are misleading because they provide only a quantitative amount without any information about protein quality. They also challenge Defendant's failure to include, in the nutrition facts panel on the back of its products, information about protein quality in the form of a percent daily value. (*See id.* ¶ 19.) Defendant's protein claims caused Plaintiffs "to pay a price premium for the products." (*Id.* ¶ 7.) Had Defendant not misrepresented the products, Plaintiffs "would not have purchased them or, at

a very minimum, [they] would have paid less." (*Id.* ¶¶ 57–58, 61–63.)

Plaintiffs filed suit on behalf of a nationwide class and California subclass. (*Id.* ¶ 64.) They bring claims under California law for violations of the Consumers Legal Remedies Act ("CLRA"), False Advertising Law ("FAL"), and Unfair Competition Law ("UCL"); fraud; and unjust enrichment. Plaintiffs disclaim any causes of action under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its regulations, relying on them only to the extent they are also enacted under state law or provide a predicate for liability under state law. (*See id.* at 21.)

DISCUSSION

Plaintiffs have three theories of liability. Defendant argues that each theory is expressly or impliedly preempted by the FDCA, and that Plaintiffs do not sufficiently allege reliance on the product labels.

I. Are the Front-Label Protein Claims Unlawful Without Corresponding Figures on the Nutrition Facts Panel?

Plaintiffs' first theory is that Defendant's front-label protein claims do not comply with 21 C.F.R. §§ 101.9(c)(7)(i) and 101.13(n), Food and Drug Administration ("FDA") regulations implementing the FDCA. These allegations serve as a predicate for violating California laws, including the Sherman Law, which in turn serve as a predicate for violating the "unlawful" prong of the UCL. (Dkt. No. 20 at 12–13; Dkt. No. 1 ¶¶ 100–01); *see Morgan v. Wallaby Yogurt Co., Inc.*, No. 13-cv-00296-WHO, 2013 WL 5514563, at *5 (N.D. Cal. Oct. 4, 2013) (noting that California's Sherman Law incorporates the FDCA and can form the basis for a UCL unlawful prong claim).

A. Express Preemption

The FDCA, as amended, expressly preempts state claims that are "not identical to" its own requirements. 21 U.S.C. § 343-1(a); *see Hawkins v. Kroger Co.*, 906 F.3d 763, 769–70 (9th Cir. 2018); *Reid v. Johnson & Johnson*, 780 F.3d 952, 959–60 (9th Cir. 2015). Thus, if the FDCA or FDA regulations do not prohibit Defendant's conduct as alleged in the complaint, then Plaintiffs' state law claims are expressly preempted. *See Hawkins*, 906 F.3d at 769–70; *see also Durnford v. MusclePharm Corp.*, 907 F.3d 595, 602 (9th Cir. 2018) (noting that "FDA regulations . . . have the

same preemptive effect as a statute"); *Gitson v. Trader Joe's Co.*, No. 13-1333, 2015 WL 9121232, at *1 (N.D. Cal. Dec. 1, 2015) ("[W]hen it comes to food labels, state law may only impose liability for what the federal statute proscribes.").

Section 101.9 regulates the information that appears in the nutrition facts panel on the back or side of a food product's packaging. With respect to protein:

> (c) The declaration of nutrition information on the label and in labeling of a food shall contain information about the level of the following nutrients . . .
>
> (7) "Protein": A statement of the number of grams of protein in a serving, expressed to the nearest gram . . . . Protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food . . . .
>
> (i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, . . . expressed as Percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product . . . . When such a declaration is provided, it should be placed on the label adjacent to the statement of grams of protein and aligned under the column headed "Percent Daily Value," and expressed to the nearest whole percent.

21 C.F.R. § 101.9(c)(7)(i). Thus, "the number of grams of protein in a serving" "shall" appear on the nutrition facts panel. *Id.* §§ 101.9(c)(7), 101.9(c). That figure "may" be calculated using what the parties call the nitrogen method. *Id.* § 101.9(c)(7); *see Durnford*, 907 F.3d at 603. An alternative figure "may" be calculated using the PDCAAS, referred to in the regulations as "the corrected amount of protein per serving," expressed as a percent daily value. 21 C.F.R. § 101.9(c)(7)(i). But if "a protein claim is made," then a figure calculated using the PDCAAS, expressed as a percent daily value, "shall" appear on the nutrition facts panel. *Id.* § 101.9(c)(7).

Section 101.13 regulates the information that appears elsewhere on the food product's packaging. As relevant to Section 101.9, Section 101.13 explains what a "protein claim" is:

> Information that is required or permitted by § 101.9 or § 101.36, as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

21 C.F.R. § 101.13(c); *see Reid*, 780 F.3d at 959 ("[T]he general rule is that 'nutrient content

claims' are not permitted on food labels. . . . However, the regulations do authorize some nutrient content claims. . . . While a required statement inside a nutrition [facts panel] escapes regulations reserved for nutrient content claims, the identical statement outside of the nutrition [facts panel] is still considered a nutrient content claim and is therefore subject to section 101.13."). Thus, information about protein that is required or permitted by Section 101.9, but that appears somewhere other than the nutrition facts panel, is a "protein claim" "subject to the requirements for nutrient content claims." 21 C.F.R. §§ 101.9(c)(7)(i), 101.13(c); *see id.* § 101.13(n) ("Nutrition labeling in accordance with § 101.9 . . . shall be provided for any food for which a nutrient content claim is made.").

Plaintiffs allege that Defendant states the amount of protein, calculated using the nitrogen method, on the front label of its products. (Dkt. No. 1 ¶ 18.) The amount of protein, calculated using the nitrogen method, is "permitted by § 101.9 . . . to be declared in nutrition labeling," meaning the nutrition facts panel. 21 C.F.R. § 101.13(c). Because Plaintiffs allege it appears "elsewhere"—on the front label—"it is a nutrient content claim and is subject to the requirements for nutrient content claims." *Id.* One such requirement is that "if a protein claim is made," then the amount of protein, calculated using the PDCAAS and expressed as a percent daily value, "shall" appear on the nutrition facts panel. *Id.* § 101.9(c)(7). Plaintiffs allege no such information appears on the nutrition facts panel of Defendant's products. (Dkt. No. 1 ¶ 19.) Thus, Plaintiffs plausibly allege Defendant's conduct does not comply with Section 101.9(c)(7) because it puts nitrogen-method protein claims on the front label without the corresponding PDCAAS figures on the nutrition facts panel. (*See id.* ¶¶ 74 ("Defendant had a duty to disclose the corrected amount of protein per serving for all the Products in the [nutrition facts panel] as calculated by the PDCAAS method, which Defendant failed to do."), 80, 90, 101.)

Courts in this District have not yet considered this particular theory. The closest case is *Brown v. Van's International Foods, Inc.* ("*Van's*"), No. 22-cv-00001-WHO, 2022 WL 1471454 (N.D. Cal. May 10, 2022), in which the court initially granted the defendant's motion to dismiss:

> [Plaintiff] contends that a protein claim unadjusted for digestibility is inherently misleading, but this legal theory is preempted by the [FDCA]. Her claims based on this first theory are dismissed with

> prejudice. . . . During the hearing, [Plaintiff] advanced a third theory that the front-label protein claim is unlawful because it violates 21 C.F.R. § 101.13(n). While at a first glance this argument appears plausible, I will not discuss it in this Order.

Id. at *1. The plaintiff then filed an amended complaint, which advanced the latter theory of unlawfulness. *See Van's*, 2022 WL 3590333 (N.D. Cal. Aug. 22, 2022). The defendant moved to dismiss for failure to plead reliance; the court denied the motion on those grounds, and had no occasion to analyze whether the plaintiff's unlawfulness theory stated a viable claim for relief. *See id.*

Defendant argues it is illogical to interpret the FDA regulations to allow one protein figure on the front label and require a different figure on the nutrition facts panel. But that is precisely what the regulations do. *See* 21 C.F.R. § 101.13(c) (allowing a nitrogen-method figure for a front-label protein claim); *id.* § 101.9(c)(7) (requiring a PDCAAS figure on the nutrition facts panel). Courts considering other theories have noted in passing that the regulations require that if a product has a front-label protein claim, it must have a corresponding PDCAAS figure on the nutrition facts panel. *See Chong v. Kind LLC*, No. 21-cv-04528-RS, 2022 WL 464149, at *3 (N.D. Cal. Feb. 15, 2022) ("If a producer makes a protein nutrient claim, however, it must also provide a '% Daily Value' in the Nutrition Facts panel. That '% Daily Value' must be calculated using the PDCAAS . . . ."); *Nacarino v. Kashi Co.* ("*Nacarino*"), No. 21-cv-07036-VC, 2022 WL 390815, at *4 (N.D. Cal. Feb. 9, 2022) ("[T]he FDA recognizes that in situations where consumers are drawn to a product for its protein content—those situations in which a manufacturer is touting its product's protein on its packaging—consumers deserve additional information in the Nutrition Facts label."), *appeal filed*, No. 22-15377 (9th Cir. Mar. 14, 2022).

Accordingly, Plaintiffs plausibly allege that the front-label protein claims are unlawful without corresponding PDCAAS figures on the nutrition facts panel. Because the alleged conduct is prohibited by FDA regulations, state law claims based on that conduct are not expressly preempted. *See Hawkins*, 906 F.3d at 769–70.

B. Implied Preemption

As for implied preemption, Defendant relies on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). *Buckman* held that there may be conflict preemption, a

"subcategor[y] of implied preemption," where there is an actual conflict between state law claims and the FDCA, as amended. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc); *see McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039–40 (9th Cir. 2015). Thus, the *Buckman* plaintiffs' state law claims that the defendant "made fraudulent representations to the FDA, resulting in improper market clearance for bone screws," conflicted with the FDCA's scheme for deterring fraud in the market clearance process. *McClellan*, 776 F.3d at 1039; *see Buckman*, 531 U.S. at 348 ("The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law."). *Buckman* "left the door open to state-law claims parallel to federal requirements." *McClellan*, 776 F.3d at 1040 (cleaned up).

Plaintiffs' theory parallels federal requirements. Plaintiffs assert that Defendant's front-label protein claims, without corresponding figures on the nutrition facts panel, violate California laws including the Sherman Law, and thus violate the "unlawful" prong of California's UCL. Therefore, their theory parallels the requirements of Sections 101.9(c)(7)(i) and 101.13(n). *See Stengel*, 704 F.3d at 1228 ("[The FDCA, as amended,] does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the [FDCA]."); *Morgan*, 2013 WL 5514563, at *5 ("[T]he state law mirrors the federal law, so a private party would not find it impossible to comply with both . . . ."). And because it parallels federal requirements, it presents no obstacle to Congress's objectives in enacting the FDCA. *See Morgan*, 2013 WL 5514563, at *5 ("Congress has expressly allowed state laws regulating food labeling so long as they are not expressly preempted; thus, the Sherman Law is not an obstacle to Congress's purpose and objectives.").

Buckman also held that claims that directly seek to enforce the FDCA are impliedly preempted. The FDCA contains no private right of action, so a plaintiff cannot sue directly to enforce its requirements. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013). But there is a "narrow gap" that avoids preemption: claims challenging "conduct that *violates* the FDCA,"

"but not *because* the conduct violates the FDCA." *Id.* at 1120 (cleaned up). Plaintiffs' theory fits through that narrow gap. They disclaim any cause of action under the FDCA, (*see* Dkt. No. 1 at 21), but challenge conduct that violates it. *Cf. Van's*, 2022 WL 1471454, at *7 ("In other words, [Plaintiff] is suing because the protein statements at issue are allegedly misleading under California law, not because the protein statements allegedly violate FDA regulations.").

Finally, there is a strong general presumption against preemption: "[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (cleaned up). That presumption applies here, because the states' historic police powers have included "the power to protect their citizens from fraud and deception in the sale of food." *Clancy v. The Bromley Tea Co.*, 308 F.R.D. 564, 573 (N.D. Cal. 2013); *see Stengel*, 704 F.3d at 1228 (noting that states' power "to protect the health and safety of their citizens" is "primarily, and historically, [a] matter[] of local concern" (cleaned up)). Defendant has not overcome that presumption.

Accordingly, Plaintiffs' state law claims based on the theory that Defendant's front-label protein claims are unlawful without corresponding PDCAAS figures on the nutrition facts panel are not impliedly preempted under *Buckman*. *See Van's*, 2022 WL 1471454, at *6–8 (finding no implied preemption of plaintiffs' protein labeling claims, and collecting cases).

C. Reliance

Finally, Defendant argues that this theory is not supported by plausible allegations of reliance.

As a matter of statutory standing for misrepresentation or fraud claims under the CLRA, UCL, and FAL, a plaintiff must have "actually relied on whatever defect in a product label allegedly makes it actionable when making her decision to buy the product." *Shaeffer v. Califia Farms, LLC*, 258 Cal. Rptr. 3d 270, 283 (Cal. Ct. App. 2020) (cleaned up); *see Moore v. Mars Petcare US, Inc.*, 966 F.3d 1007, 1020 (9th Cir. 2020) ("Since the passage of Proposition 64, a plaintiff must allege actual reliance in order to have standing to pursue UCL and FAL claims."). "To satisfy this requirement, she must truthfully allege that she would not have bought the product

but for the allegedly actionable misrepresentation or omission." *Shaeffer*, 258 Cal. Rptr. 3d at 283 (cleaned up). The requirement also applies for a claim under the UCL's unlawful prong if the underlying conduct is a misrepresentation or fraud. *See Kwikset Corp. v. Superior Court*, 246 P.3d 877, 888 n.9 (Cal. 2011); *Van's*, 2022 WL 3590333, at *4 (collecting cases); *see generally Cel-Tech Comms., Inc. v. L.A. Cellular Telephone Co.*, 973 P.2d 527, 539–40 (Cal. 1999) ("By proscribing 'any unlawful' business practice, [the UCL] borrows violations of other laws and treats them as unlawful practices that the [UCL] makes independently actionable." (cleaned up)).

Here, Plaintiffs' first theory is that the front-label protein claims are unlawful without corresponding PDCAAS figures—whether or not they are misleading. *See Cel-Tech*, 973 P.2d at 540 ("Because [the UCL] is written in the disjunctive, it establishes three varieties of unfair competition—acts or practices which are unlawful, or unfair, or fraudulent. In other words, a practice is prohibited as unfair or deceptive even if not unlawful and vice versa." (cleaned up)). The Court concludes that the reliance requirement also applies to a claim under the UCL's unlawful prong where the underlying conduct is not a misrepresentation or fraud. *See Van's*, 2022 WL 3590333, at *4–5 (analyzing issue but declining to rule on it because the plaintiff sufficiently alleged reliance regardless); *Nacarino v. Chobani, LLC*, No. 20-cv-07437-EMC, 2022 WL 344966, at *6 (N.D. Cal. Feb. 4, 2022) ("[The reliance requirement] appears true of all UCL claims, regardless of whether they are brought under the unfair, unlawful, or fraudulent prong."). While *Kwikset* declined to reach this issue, *see* 246 P.3d at 888 n.9, there is no reason to limit its principle—that reliance is a matter of causation—to misrepresentation or fraud. *See Kane v. Chobani, Inc.*, No. 12–CV–02425–LHK, 2013 WL 5289253, at *8–10 (N.D. Cal. Sept. 19, 2013) ("Were the Court to hold that Plaintiffs, who never viewed the No Sugar Added Representations, have standing to bring claims based solely upon allegations that they would not have purchased a product that was misbranded, purchasers who never viewed the defendant's advertising or misleading labeling would have standing to sue. Such a holding is inconsistent with Proposition 64 and *Kwikset*." (cleaned up)); *see also Moore*, 966 F.3d at 1020 (stating that reliance is a requirement for UCL claims, but applying the requirement specifically to a misrepresentation claim).

Thus, Plaintiffs must allege actual reliance. And because their theory is that the front-label protein claim is unlawful *without* a corresponding figure on the nutrition facts panel, they must allege they relied on the nutrition facts panel's omission. Under Plaintiffs' theory, the front-label protein claim may have been lawful if there was a corresponding figure on the nutrition facts panel. Therefore, without an allegation that Plaintiffs ever looked at the nutrition facts panel—and thus ever knew one way or the other if the nutrition facts panel had a corresponding figure—there is no causal link between the allegedly unlawful front-label protein claim and Plaintiffs' alleged harm. *See Shaeffer*, 258 Cal. Rptr. 3d at 278 (explaining that reliance is a matter of causation).

The complaint alleges each Plaintiff "read[]" and "relied on" the "front labels that promised" "7G PROTEIN," "8G PROTEIN," and "15G PROTEIN," "believ[ing] . . . that the product would actually provide her the specific amount of protein on the front label in a form her body could utilize as protein." (Dkt. No. 1 ¶¶ 56, 60; *see id.* ¶ 2.) It does not allege that Plaintiffs looked at or relied on the nutrition facts panel, only that the nutrition facts panel failed to include a PDCAAS figure. (*See id.* ¶ 19.) As such, the complaint does not plausibly allege reliance on the nutrition facts panel. *See Brown v. Natures Path Foods, Inc.*, No. 21-cv-05132-HSG, 2022 WL 717816, at *4 (N.D. Cal. Mar. 10, 2022) ("the Complaint does not allege that Plaintiffs ever reviewed the nutrition facts labels before buying the Products and therefore fails to allege that they relied on the absence of the 'percent daily value' figure to their detriment"). Accordingly, the complaint does not establish Plaintiffs' standing to pursue claims based on this theory.

Plaintiffs acknowledge they have not alleged reliance on the nutrition facts panel, but say they could amend their complaint to do so. Defendant's argument that the defects could not be cured by amendment does not make sense; that Plaintiffs relied on the front-label protein claims does not mean that they could not also have read and relied on the nutrition facts panel and its omission.

* * *

Plaintiffs' claims based on the theory that Defendant's front-label protein claims do not comply with Sections 101.9(c)(7) and 101.13(n) are not expressly or impliedly preempted. However, Plaintiffs have not established their standing to pursue those claims because they have

not adequately alleged reliance on the nutrition facts panel and its omission. Accordingly, Defendant's motion to dismiss is GRANTED as to claims based on this theory, with leave to amend so that Plaintiffs may allege what they read and relied on, if anything, in the nutrition facts panel. *See Van's*, 2022 WL 1471454, at *9–10 (dismissing for failure to allege reliance and granting leave to amend).

II. Are the Front-Label Protein Claims Misleading?

Plaintiffs separately allege that Defendant's front-label protein claims are misleading, deceptive, and fraudulent. The FDCA prohibits food labeling that is "false or misleading," and FDA regulations specifically prohibit nutrient claims that are "false or misleading in any respect." 21 U.S.C. 343(a); 21 C.F.R. § 101.13(i)(3). Plaintiffs' allegations serve as a predicate for violating the CLRA, the FAL, and the fraud prong of the UCL, as well as for common law fraud and unjust enrichment. (Dkt. No. 1 ¶¶ 74, 80, 90, 101, 115.) In turn, some of those violations also serve as predicates for the unlawful prong of the UCL. (*Id.* ¶ 100.) Plaintiffs characterize these as "two distinct deception/fraud theories":

> First, the Complaint alleges that Perfect Bar's front label claims, which omit a statement of the corrected amount of protein in the [nutrition facts panel], are deceptive because they lead consumers to believe that all the advertised protein will be bioavailable. Second, the Complaint alleges that Perfect Bar's standalone, nitrogen-based protein quantity claims on the front label are misleading by virtue of the low quality protein in Perfect Bar's products.

(Dkt. No. 20 at 19.)

A. Misleading Because of Omitted PDCAAS Figure on the Nutrition Facts Panel

Plaintiffs' first deception theory is that Defendant's nitrogen-method front-label protein claims are misleading because, without the required PDCAAS figures on the nutrition facts panel, consumers will believe that the full amount of protein is "bioavailable" or digestible.

1. Express Preemption

Defendant has met its burden of showing that Plaintiffs' claim that the omission of PDCAAS figures is misleading is expressly preempted. It is preempted because the FDA regulations expressly allow a manufacturer to put a nitrogen-method figure on the nutrition facts panel without any other information about protein anywhere on the product. *See* 21 C.F.R. §

101.9(c)(7); *see also Durnford*, 907 F.3d at 603 ("[F]ederal regulations allow nitrogen to be used on the nutrition panel as a proxy for protein content."). Since the regulations allow a nitrogen-method figure on the nutrition facts panel without any other information, Plaintiffs' claim that the nitrogen-method figure on the front label without any other information is misleading conflicts with and is not identical to FDA regulations and is thus preempted. To put it another way, since FDA regulations prohibit misleading labeling, *see* 21 C.F.R. § 101.13(i)(3), and FDA regulations permit a nitrogen-method figure, *see id.* § 101.9(c)(7), the nitrogen-method figure is not misleading under the FDA regulations. Thus, to find that the nitrogen-method figure is misleading would conflict with FDA regulations. *See Nacarino*, 2022 WL 390815, at *4. *But see Van's*, 2022 WL 1471454, at *6 (concluding this theory is plausible and not expressly preempted).

Accordingly, because this theory challenges conduct permitted by the FDCA and FDA regulations, it is expressly preempted. *See Hawkins*, 906 F.3d at 769–70.

* * *

Plaintiffs' claims based on the theory that Defendant's front-label protein claims are misleading without the corresponding PDCAAS figures on the nutrition facts panel are expressly preempted. Accordingly, Defendant's motion to dismiss is GRANTED as to claims based on this theory. The dismissal is without leave to amend because the defect is in the legal theory, not the factual allegations.

B. Misleading In and Of Themselves

Plaintiffs' second deception theory is that Defendant's nitrogen-method front-label protein claims are misleading in and of themselves. Plaintiffs say their position is limited to low-quality protein products like Defendant's, because nitrogen-method protein claims for high-quality protein products are less apt to mislead about the product's protein digestibility. (Dkt. No. 20 at 28.)

1. Express Preemption

For the reasons thoroughly explained by other courts in this District, the FDCA expressly preempts any claim that Defendant's nitrogen-method front-label protein claims are misleading in and of themselves.

Because the FDCA regulations allow protein claims to be calculated with the nitrogen

method, such claims cannot be misleading in and of themselves as a matter of law. *See* 21 C.F.R. § 101.13(o) ("compliance with requirements for nutrient content claims . . . will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9"); *id.* § 101.9(c)(7) (providing that the nitrogen method and PDCAAS may be used to determine compliance with nutrition labeling). "[T]o find that an FDA-approved protein measurement technique is inherently misleading . . . is not a plausible interpretation of the regulations." *Nacarino*, 2022 WL 390815, at *4. Thus, the FDCA preempts Plaintiffs' attempt to use state law to impose requirements that the FDCA does not. *See Van's*, 2022 WL 1471454, at *5–6 (finding preempted theory that "the claim misleadingly advertises a specific amount of protein per serving without adjusting for digestibility"); *Chong*, 2022 WL 464149, at *2–3 (same); *Nacarino*, 2022 WL 390815, at *3–5 (finding preempted theory that "the nitrogen-content method [] overstates the amount of protein per serving" and that it is "misleading to use a figure . . . that has not been adjusted for protein digestibility").

A few cases from other district courts that have held the FDCA does not preempt this theory. *See Ulrich v. Probalance, Inc.*, No. 16 C 10488, 2017 WL 3581183, *5 (N.D. Ill. Aug. 18, 2017) ("[E]ven if the regulations do not *require* manufacturers to calculate protein content by the PDCAAS-adjusted method, it may nevertheless be misleading in a particular context to use the nitrogen method, and misleading labeling violates the FDCA and accompanying regulations."); *Porter v. NBTY, Inc.*, No. 15 CV 11459, 2016 WL 6948379, *6 (N.D. Ill. Nov. 28, 2016) ("Because defendants were required to calculate the corrected amount of protein (so they could comply with the protein-claim regulation), they knew that the statement '60g Premium Protein' was not accurate. This is sufficient to state a claim that the front-label statement is false or misleading . . . ."). These cases are not persuasive because the FDA regulations allow the nitrogen method for front-label protein claims, with no distinction based on low- or high-quality protein. That the regulations simultaneously prohibit "misleading" labeling, 21 C.F.R. § 101.13(i)(3), shows that nitrogen-method protein claims are not inherently misleading under the FDA regulations.

Finally, the FDA recently issued guidance stating that, under Section 101.9(c)(7), "either"

the nitrogen method or the PDCAAS method may be used "when calculating protein values for use in protein nutrient content claims." (Dkt. No. 19-1 at 13.)[2] Thus, the guidance indicates that the FDA does not consider nitrogen-method front-label protein claims to be misleading in and of themselves. The guidance is persuasive authority on this point, but it is not necessary to the Court's conclusion. *See Van's*, 2022 WL 1471454, at *5 & n.2; *Nacarino*, 2022 WL 390815, at *4 & n.4.

* * *

Plaintiffs' theory that the nitrogen-method front label protein claims are misleading in and of themselves is expressly preempted by the FDCA. Accordingly, Defendant's motion to dismiss is GRANTED as to Plaintiffs' claims based on the theory that the nitrogen-method front-label protein claims are misleading in and of themselves and/or because of the low-quality protein contained in the products. The dismissal is without leave to amend because the defect is in the legal theory, not the factual allegations.

CONCLUSION

Defendant's motion is GRANTED.

Plaintiffs' claims based on (1) the theory that Defendant's front-label protein claims do not comply with Sections 101.9(c)(7) and 101.13(n) are dismissed WITH leave to amend. Plaintiffs' claims based on (2) the theory that Defendant's front-label protein claims are misleading without the corresponding PDCAAS figures on the nutrition facts panel and (3) the theory that

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[2] Defendant's request for judicial notice is GRANTED in part and DENIED in part. (Dkt. No. 19.)

The Court takes judicial notice of the 2022 FDA guidance, (Dkt. No. 19-1). *See King v. County of Los Angeles*, 885 F.3d 548, 555 (9th Cir. 2018) (noting that courts may take judicial notice of "undisputed and publicly available information displayed on government websites"); *see also Van's*, 2022 WL 1471454, at *5 n.2 (taking judicial notice of 2022 FDA guidance); *Nacarino*, 2022 WL 390815, at *4 n.3 (same).

However, the Court declines to take judicial notice of emails between FDA representatives and attorneys for manufacturers who make protein claims on their products. (Dkt. Nos. 19-2, 19-3.) The emails are private responses to private inquiries; they are not matters of public record and do not give the FDA's official interpretation of the FDCA or its regulations. *See Lee v. City of Los Angeles*, 250 F.3d 668, 689–90 (9th Cir. 2001); *cf. Von Koenig v. Snapple Beverage Corp.*, 713 F. Supp. 2d 1066, 1073 (E.D. Cal. 2010) (taking judicial notice of FDA letters that were issued as public records).

Defendant's front-label protein claims are misleading in and of themselves and/or because of the low-quality protein contained in the products are dismissed WITHOUT leave to amend. Plaintiffs may file an amended complaint on or before October 3, 2022.

The Court will hold an initial case management conference on November 3, 2022 at 1:30 p.m. via Zoom video. An updated joint case management conference statement with a proposed schedule with actual dates through class certification is due one week in advance.

This Order disposes of Docket No. 18.

IT IS SO ORDERED.

Dated: September 2, 2022

JACQUELINE SCOTT CORLEY
United States District Judge

United States District Court
Northern District of California