UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

PHYLLIS GUSTAVSON, individually and on behalf of all others similarly situated Plaintiff, v. MARS, INC. and MARS CHOCOLATE NORTH AMERICA, LLC, Defendants.	Case No.: 13-CV-04537 ORDER DENYING DEFENDANTS' MOTION TO DISMISS

Plaintiff Phyllis Gustavson ("Plaintiff" or "Gustavson") brings this putative class action against Defendants Mars, Inc. and Mars Chocolate North America, LLC (collectively, "Defendants" or "Mars"), alleging that Defendants' package labeling is "misbranded" because it is unlawful and misleading under federal and state law. Defendants move to dismiss Plaintiff's Complaint. ("Mot.") ECF No. 18. Plaintiff opposes, ("Opp'n") ECF No. 22, and Defendants replied, ("Reply") ECF No. 28.

Pursuant to Civil Local Rule 7-1(b), the Court finds this matter appropriate for resolution without oral argument and hereby VACATES the Hearing scheduled for June 19, 2014. ECF No. 29. Having considered the submissions of the parties and the relevant law, the Court DENIES Defendants' motion to dismiss.

I. BACKGROUND

A. Factual Allegations

Mars Chocolate North America, LLC is one of the nation's leading producers of chocolate candy and other types of confectionary. ("Compl.") ECF No. 1 ¶ 13. Mars, Inc. is the parent company of Mars Chocolate North America, LLC. *Id*. Defendants sell their products to consumers through grocery and other retail stores throughout California and promote their products throughout California through their websites. *Id.* ¶ 25.

Plaintiff is a resident of California who "cares about the nutritional content of food and seeks to maintain a healthy diet." *Id.* ¶¶ 22, 191. Gustavson purchased more than $25.00 worth of Defendants' products between April 13, 2008 and the present. *Id.* ¶¶ 1, 22. Specifically, Plaintiff contends that she purchased the following food products: (1) M&M Chocolate Candy, 1.69 oz., (2) Twix Cookie Bar, 1.79 oz., (3) Dove Bar—Dark Chocolate, 3.3 oz., (4) Dove Bar—Milk Chocolate, 3.3 oz., and (5) Snickers Bar, 11.8 oz. *Id.* ¶ 2. Plaintiff contends that these products are "misbranded" in violation of federal and California law, and are deceptively packaged and labeled. *Id.* ¶¶ 6-7.

Plaintiff alleges that she read and relied on the claims on the labels of the products in making her purchasing decisions. *Id.* ¶ 143. Plaintiff further alleges that she relied on Defendants' package labeling, "based and justified the decision to purchase Defendants' products in substantial part on Defendants' package labeling," and "would have foregone purchasing Defendants' products and bought other products readily available at a lower price." *Id.* ¶ 195. Plaintiff claims that she "did not know, and had no reason to know, that Defendants' products were misbranded" and states that she would not have purchased the products "had she known the truth about them." *Id.* ¶ 196.

The Complaint alleges that Defendants' mislead consumers: (1) by making unlawful and misleading "nutrient content claims" regarding flavanols, *id.* ¶¶ 57-71; (2) by making unlawful and misleading calorie claims, *id.* ¶¶ 72-124; and (3) by failing to identify the ingredient "polyglycerol polyricinoleic acid" ("PGPR") by its common name, *id.* ¶¶ 125-142. Defendants do not seek to

dismiss Plaintiff's claim related to PGPR, *see* Mot. at 1 n.1, and thus the Court will not discuss this claim further for purposes of the instant Motion to Dismiss.

1. "Flavanol Claims"

Plaintiff alleges that Defendants' packaging for the 3.3 ounce dark chocolate Dove Bar includes statements that the chocolate bar is a "natural source of cocoa flavanols" and that the Defendants' COCOAPRO process "helps retain much of the naturally occurring cocoa flavanols" in cocoa beans. *Id.* ¶¶ 57, 60, 65. Plaintiff alleges that these statements are "nutrient content claims" that are subject to federal regulation under 21 U.S.C. § 343(r). *Id.* ¶ 59 (citing 21 C.F.R. §§ 101.13, 101.54 (identifying the requirements for making lawful nutrient content claims)).

According to Plaintiff, Defendants' flavanol statements are unlawful because under federal regulations, a nutrient content claim may only use particular terms defined in FDA regulations and the term "source" is not among these defined terms unless preceded by the modifier "good". *Id.* ¶ 63. Additionally, Plaintiff alleges that to the extent the term "source" is an acceptable synonym for an FDA-defined term, Defendants' statements are unlawful because a nutrient content claim may be made only where the food product contains some fixed percentage of the established daily value for the nutrient in question. *Id.* ¶¶ 58-60. Defendants' Dove chocolate bar cannot possibly contain adequate flavanols to meet these requirements, Plaintiff alleges, because the FDA has not established a recommended daily value for flavanols. *Id.* ¶¶ 65-66.

2. "Calorie Claims"

Plaintiff further alleges that all five of the Mars chocolate products she purchased make unlawful and misleading "calorie related nutrient content" claims on their labels. *Id.* ¶ 72. Plaintiff notes that the front labels on the products she purchased all make a claim about the number of calories contained in the product, as well as the percentage of one's "daily value" of calories the product supplies. *See* Def. Request for Judicial Notice ("Def. RJN"), ECF No. 19-4, Exs. A-E. The Complaint alleges that these calorie statements are unlawful and misleading nutrient content claims, because the statements are not accompanied by an FDA-mandated disclosure directing consumers to consult the full nutrition information panel (located on the back of the package) for further information regarding the levels of fat and saturated fat contained in the products. Compl.

¶¶ 74, 83-90. Plaintiff claims that Defendants' calorie statements are deceptive for the additional reason that the statements refer to a "daily value" for calories, when, in fact, the FDA has not established a daily value for calories. *Id.* ¶ 119. Finally, Plaintiff alleges that even if a daily value for calories did exist, Defendants' percentage statements would still be misleading because recent U.S. Dietary Guidelines recommend that individuals strictly limit the amount of calories they consume in the form of sugar and fat, both of which are present at high levels in Defendants' products. *Id.* ¶¶ 120-124.

Plaintiff alleges that by manufacturing, advertising, distributing, and selling misbranded products, Defendants have violated California Health & Safety Code Sections 109885, 110390, 110395, 110398, 110660, 110665, 110670, 110705, 110760, 110765, and 110770. *See id.* ¶¶ 173-183. In addition, Plaintiff asserts that Defendants have violated the standards set by 21 C.F.R. §§ 101.2, 101.3, 101.4, 101.9, 101.12, 101.13, 101.18, 101.22, 101.54, 101.60, 102.5, and 105.66, which have been adopted by reference into the Sherman Food, Drug, and Cosmetic Act ("Sherman Law"), Cal. Health & Safety Code §§ 109875 *et seq*. *See* Compl. ¶¶ 184-187. Consequently, Plaintiff's Complaint alleges the following causes of action: (1) violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200 *et seq*., for unlawful, unfair, and fraudulent business acts and practices (claims 1, 2, and 3); (2) violation of California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500 *et seq*., for misleading, deceptive, and untrue advertising (claims 4 and 5); and (3) violation of the Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750 *et seq*. (claim 6). *See* Compl. ¶¶ 211-267.

B. Procedural History

Plaintiff originally asserted her claims against Mars in a separate action, *Gustavson v. Wrigley Sales Co.*, Case No. 12-1861 ("Wrigley case"), which also included claims against Wrigley Sales Company and Wm. Wrigley Jr. Company. *See Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1112-13 (N.D. Cal. 2013). Wrigley and Mars filed motions to dismiss the complaint in the Wrigley case, which the Court granted in part and denied in part on September 16, 2013. *See id.* In the order on the motion to dismiss, the Court directed Gustavson to file her claims

against Mars as a separate case. *Id.* at 1133. Accordingly, Plaintiff filed the instant Complaint as a new case on October 1, 2013. ECF No. 1.

Defendants moved to dismiss the Complaint on November 15, 2013. ECF No. 18. Gustavson opposed the Motion on December 23, 2013, ECF No. 22, and Defendants replied on January 17, 2014, ECF No. 28. Both Defendants' Motion and Gustavson's Opposition were accompanied by Requests for Judicial Notice. ECF Nos. 19, 23.[1]

II. LEGAL STANDARDS

A. Rule 8(a)

Rule 8(a)(2) of the Federal Rules of Civil Procedure requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." A complaint that fails to meet this standard may be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6). The Supreme Court has held that Rule 8(a) requires a plaintiff to plead "enough facts to state a

[1] Defendants request that the Court take judicial notice of: (1) images of the packaging for the five products Gustavson purchased, Def. RJN at 1-3, Exs. A-E; (2) a letter from the FDA to the Grocery Manufacturers Association ("GMA") and Food Marketing Institute ("FMI") regarding the GMA/FMI's "Nutrition Keys" front-of-package labeling program, *id.* at 3-4, Ex. F; (3) an FDA press release regarding a "Front-of-Package Labeling Initiative," *id.* at 3-4, Ex. G; (4) an FDA Warning Letter sent to Jonathan's Sprouts, Inc., *id.* at 3-4, Ex. H; and (5) a GMA/FMI "Style Guide" for the Nutrition Keys program, *id.* at 4, Ex. I.

The Court GRANTS Defendants' Request for Judicial Notice as it relates to the images of product packaging, both because the packaging is incorporated into the SAC by reference, *see, e.g.*, *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005) (court may take judicial notice of documents referenced in a complaint), and because the package images Gustavson provided are not fully legible. *Accord Gustavson*, 961 F. Supp. 2d at 1113 n.1 (taking judicial notice of product packaging). The Court also GRANTS Defendants' Request for Judicial Notice as it relates to the FDA letter to GMA/FMI, the FDA press release, and the FDA Warning Letter because these documents are readily available on a government agency website. *See, e.g.*, *Hansen Beverage Co. v. Innovation Ventures, LLC*, No. 08-1166, 2009 WL 6597891, at *2 (S.D. Cal. Dec. 23, 2009) (courts may take judicial notice of documents available through government agency websites); *accord Gustavson*, 961 F. Supp. 2d at 1113 n.1 (taking judicial notice of FDA documents). However, the Court DENIES Defendants' Request for Judicial Notice as it relates to the GMA/FMI Style Guide. Federal Rule of Evidence 201(b) provides for judicial notice only when the subject of the request is "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." At this stage in the litigation, the Court is not convinced that the Style Guide, which apparently comes from the internet, satisfies either of these criteria, and thus it declines to take judicial notice of this document. In any event, the Court notes that considering the GMA/FMI Style Guide would not have impacted its decision.

Plaintiff, for her part, asks the Court to take judicial notice of several FDA Warning Letters, ("Pl. RJN") ECF No. 23, Exs. A-C, as well as an FDA Advanced Notice of Proposed Rulemaking, *id.* Ex. D. The Court GRANTS Plaintiff's Request for Judicial Notice as to all of these documents because these documents are readily available on a government agency website. *See, e.g.*, *Hansen Beverage*, 2009 WL 6597891 at *2.

claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (internal quotation marks omitted). For purposes of ruling on a Rule 12(b)(6) motion, a court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008).

However, a court need not accept as true allegations contradicted by judicially noticeable facts, *Shwarz v. United States*, 234 F.3d 428, 435 (9th Cir. 2000), and the "[C]ourt may look beyond the plaintiff's complaint to matters of public record" without converting the Rule 12(b)(6) motion into one for summary judgment, *Shaw v. Hahn*, 56 F.3d 1128, 1129 n.1 (9th Cir. 1995). Nor is the court required to "'assume the truth of legal conclusions merely because they are cast in the form of factual allegations.'" *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011) (per curiam) (quoting *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981)). Mere "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss." *Adams v. Johnson*, 355 F.3d 1179, 1183 (9th Cir. 2004); *accord Iqbal*, 556 U.S. at 678. Furthermore, "a plaintiff may plead herself out of court" if she "plead[s] facts which establish that [s]he cannot prevail on h[er] . . . claim." *Weisbuch v. Cnty. of L.A.*, 119 F.3d 778, 783 n.1 (9th Cir. 1997) (internal quotation marks and citation omitted).

III. DISCUSSION

Defendants seek to dismiss Plaintiff's Flavanol and Calorie Claims for two reasons: (1) both the Flavanol and Calorie Claims are expressly preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"); and (2) the Calorie Claims implicate technical and policy questions that are under active consideration by the FDA and thus are committed to the primary jurisdiction of the FDA. *See* Mot. at i. For the reasons stated herein, the Court DENIES Defendants' Motion to Dismiss.

A. Express Preemption

Defendants contend that Plaintiff's Flavanol and Calorie Claims are both expressly preempted by the Nutritional Labeling and Education Act of 1990 ("NLEA"). Pub. L. No. 101-535, 104 Stat. 2353. *See* Mars Mot. at 10-11. The NLEA amended the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, which prohibits the misbranding of food in interstate commerce and sets forth conditions under which food is considered "misbranded." Among other things, the NLEA contains an express preemption, which provides that "no State . . . may directly or indirectly establish . . . any requirement . . . made in the label or labeling of food that is not identical to" certain FDA requirements, such as 21 U.S.C. § 343(q), which applies to nutrition information, and 21 U.S.C. § 343(r), which applies to "Nutrition levels and health-related claims." 21 U.S.C. § 343-1(a)(4)-(5). Per FDA regulations, "'[n]ot identical to' . . . means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (i) [a]re not imposed by or contained in the applicable provision . . . or (ii) [d]iffer from those specifically imposed by or contained in the applicable provision." 21 C.F.R. § 100.1(c)(4).

Gustavson responds that she seeks only to enforce labeling requirements identical to those imposed by the FDA. *See* Opp'n at 5. The Court discusses whether Plaintiff's Flavanol and Calorie Claims are subject to express preemption below. The Court then discusses whether Plaintiff's Calorie Claims should be dismissed under the doctrine of primary jurisdiction.

1. Flavanol Claims

Under the FDCA, any statement on a food product label is a "nutrient content claim" if the statement "expressly or by implication . . . characterizes the level of any nutrient which is of the type required" by the FDCA to be listed on the nutrition label. 21 U.S.C. § 343(r)(1)(A). Such a nutrient content claim may use only certain defined terms pursuant to 21 U.S.C. § 343(r)(2)(A)(i). Whether Defendants' statement that the Dove dark chocolate bar is a "natural source" of flavanols characterizes the level of flavanols in the product is thus the decisive question before this Court.

The Court confronted this same question in its September 16, 2013 Order in the Wrigley case. The Court held that flavanols are a type of antioxidant governed by 21 C.F.R. § 101.54(g),

and noted that the only authority then before the Court—an FDA warning letter sent to Jonathan Sprouts Inc. ("Sprouts Letter"), in which the FDA stated that the term "source" is a nutrient content claim that characterizes the level of a nutrient in a food[2]—suggested that the FDA viewed the term "source" as a nutrient content claim. *See Gustavson*, 961 F. Supp. 2d at 1120-22. Accordingly, the Court was not persuaded that Plaintiff sought to impose requirements not identical to federal law and declined to find Plaintiff's Flavanol Claims preempted. *Id.*

In the instant Motion, Defendants present new authority to support their view that the flavanol statements on Dove dark chocolate do not constitute nutrient content claims. *See* Mot. at 12. Defendants further argue that FDA regulations requiring a product labeled as a "good source" of a nutrient to contain at least 10% of the established daily value for that nutrient do not apply, as only the small set of FDA-defined synonyms for "good source" trigger this requirement. *See id.* at 13. Finally, Defendants urge this Court not to defer to the FDA's position reflected in the Sprouts Letter that a "source of" claim qualifies as a nutrient content claim. *See id.* at 13-15. Defendants assert that an informal letter such as the Sprouts Letter is only entitled to deference proportional to its power to persuade, and that the interpretation in the Sprouts Letter is unpersuasive because it would render language in the regulations superfluous and is inconsistent with more reasoned FDA statements. *See id.*

Plaintiff responds by urging the Court not to reconsider its prior refusal to dismiss these claims as preempted, arguing that Defendant's flavanol statements violate the FDA requirements for nutrient content claims both by using non-defined terms and by making nutrient content claims for a nutrient (flavanols) for which there is no established daily value. *See* Opp'n at 17-18.[3] For the

[2] Specifically, the Sprouts Letter stated: "Your Organic Clover Sprouts products label bears the claim 'Phytoestrogen Source[.]' . . . These claims are nutrient content claims subject to [21 U.S.C. § 343(r)(1)(A)] because they characterize the level of nutrients of a type required to be in nutrition labeling . . . by use of the term 'source.'" *See* Compl. ¶ 62 (quoting Sprouts Letter).

[3] Plaintiff urges the Court to disregard Defendant's motion to dismiss with regard to these claims entirely, arguing that the Court's prior ruling should be considered "law of the case" and that Civil Local Rule 7-9(c) prohibits parties from relitigating issues already decided by the Court. Opp'n at 16. However, Local Rule 7-9(c) does not apply when a motion to dismiss is made pursuant to an amended complaint, because a defendant is not seeking to relitigate an issue but rather responding to a new complaint. *See Lacey v. Maricopa Cnty.*, 693 F.3d 896, 927 (9th Cir. 2012) (en banc) (noting that "an amended complaint supercedes the original complaint and renders it without legal effect"). As such, Defendants' arguments pertaining to the Flavanol Claims are properly before the Court.

proposition that Defendants' statements are nutrient content claims, Gustavson continues to rely on the Sprouts Letter. *See id.* at 18.

The Court remains unpersuaded by Defendants' express preemption arguments regarding the Flavanol Claims. While Defendants argue that the statement "natural source of cocoa flavanols" simply notifies consumers that flavanols are naturally present in the chocolate, without in any way characterizing the level at which the flavanols are found, the Court finds that Plaintiff's position that this "natural source" language *does* characterize the level of flavanols is sufficiently plausible to survive a motion to dismiss. At the very least, stating that a food product is a "source" of a given nutrient indicates that the nutrient is present at a level higher than zero, and the fact that the manufacturer chooses to note that its product is a "source" of that nutrient arguably implies that the nutrient is present in substantial quantities.

The published record of the FDA's reasoning on this point supports an inference that the agency considered the word "source" alone to characterize the level of nutrients in a product. Defendants cite a single sentence from the FDA's explanation of its final rule on nutrient content claims in support of the proposition that the term "source" indicates only "that a nutrient is present but does not signify the quantity present." Mot. at 14 (quoting 58 Fed. Reg. 2302, 2345 (Jan. 6, 1993)). The FDA's full reasoning, however, makes clear that the FDA was, in fact, concerned that the term "source" might lead consumers to conclude that a nutrient was present in a product at significant levels. After initially proposing to allow "source of" statements on food packaging (provided a nutrient was present at certain prescribed levels), the FDA reversed course and decided to permit only "good source of" statements after comments to the proposed rule highlighted the potentially confusing nature of "source" standing alone. *See* 58 Fed. Reg. at 2345 ("The agency agrees that consumers may not be able to understand the distinction between the meanings of 'high' and 'source.'"). The final regulation includes only "good source" as a defined term, the FDA explained, because without the modifier "good," the word "source" would "not enable the consumer to conclude that the level of nutrient present is less than 'high.'" *Id.* This reasoning indicates that the FDA was concerned that "source of" claims would suggest a certain level of nutrients to consumers.

The Sprouts Letter further supports Plaintiff's claim that the FDA considers "source of" claims to characterize the level of nutrient in a product. While Defendants dispute whether the Sprouts Letter is an official, binding statement of the FDA's position on the term "source," *see* Mot. at 14, Defendants fail to identify any contrary statements made by the agency. Even if, as Defendants argue, the Sprouts Letter is entitled to deference only "proportional to its power to persuade," the Sprouts Letter's persuasiveness is bolstered by its status as the only FDA pronouncement on this topic known to the Court. Furthermore, Defendants' argument that the Sprouts Letter's interpretation is unpersuasive because it conflicts with more reasoned FDA statements lacks merit. As noted above, the Federal Register entry Defendants cite as a supposedly conflicting regulatory interpretation is, when read in context, consistent with the position taken in the Sprouts Letter.

Finally, the majority of courts in this District have agreed with Plaintiff's position that claims challenging "source of" or similar statements about antioxidants are not preempted because such statements are regulated nutrient content claims.

Defendants rely heavily on *Trazo v. Nestlé USA, Inc.*, No. 12-2272, 2013 WL 4083218 (N.D. Cal. Aug. 9, 2013). In *Trazo*, the plaintiff challenged use of the statement "natural source of antioxidants" on chocolate products. *Id*. at *9. The court held that the statement was not a nutrient content claim because "[t]he qualifier 'natural,' unlike 'good,' 'excellent,' and 'fine,' does not modify the word 'source' to indicate the level of the ingredient." *Id*. The court went on to conclude that because the term "source" was not within the "specific, finite list" of defined terms contemplated in the regulations on nutrient content claims, the plaintiff's claims that the statement was unlawful went "beyond the boundaries of the regulation" and were expressly preempted. *Id*. at *6.

While *Trazo* does present a situation factually analogous to the present case, this Court is not persuaded by its reasoning. As noted above, a manufacturer's decision to highlight the fact that its product is a "source" or "natural source" of a given nutrient arguably does suggest that the nutrient is present in meaningful quantities. Moreover, *Trazo* did not discuss the FDA's

interpretation of its regulations as reflected in either the Federal Register entry or the Sprouts Letter.

By contrast, the other three courts in this District to confront similar claims have all discussed this FDA interpretive authority, and all have allowed claims such as Plaintiff's to survive motions to dismiss based on preemption. *See Clancy v. The Bromley Tea Co*., No. 12-3003, 2013 WL 4081632, at *9-10 (N.D. Cal. Aug. 9, 2013) (statements that tea was a "natural source of antioxidants" were nutrient content claims as reflected by the Sprouts Letter, and plaintiff's claims challenging such statements were accordingly not preempted); *Lanovaz v. Twinings N. Am., Inc*., No. 12-2646, 2013 WL 675929, at *4-5 (N.D. Cal. Feb. 25, 2013) (relying on Sprouts Letter to conclude that "natural source of antioxidants" was a nutrient content claim and could be challenged as such without running afoul of the NLEA's express preemption provision); *see also Victor v. R.C. Bigelow, Inc*., No. 13-2976, 2014 WL 1028881, at *15 (N.D. Cal. Mar. 14, 2014) (statement "delivers healthful antioxidants" was plausibly a nutrient content claim based on the position taken in various FDA warning letters). Accordingly, *Trazo* does not persuade the Court to change its previous decision that Plaintiff's Flavanol Claims are not preempted.

The Court, being persuaded that "natural source of cocoa flavanols" is plausibly a nutrient content claim governed by the FDA regulations, concludes that Plaintiff's claims based on alleged violations of those regulations do not seek to impose requirements beyond what federal law requires.[4] Accordingly, the Court DENIES Defendants' Motion to Dismiss Gustavson's Flavanol Claims under the doctrine of express preemption.

2. Calorie Claims

As described above, Gustavson contends that Defendants' Calorie Claims are unlawful and misleading because the calorie statements on the front of Defendants' product labels are not accompanied by a disclosure statement directing consumers to consult the full nutrition information on the back of the package for information regarding the levels of fat and saturated fat found in the

[4] Because the Court concludes that Defendants' statements constitute nutrient content claims and because Defendants concede that "source of" is not among the FDA-approved defined terms for such claims, *see* Mot. at 13, at this time the Court need not consider Plaintiff's argument that Defendants' flavanol statements are unlawful for the additional reason that there is no established daily value for flavanols.

products. *See supra* Part I.A.2. 21 C.F.R. § 101.13(h)(1) requires that if a product bearing a nutrient content claim on its label contains more than "13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium . . . per labeled serving," then the product label must also include the disclosure, "[s]ee nutrition information for __ content." This disclosure generally must appear immediately adjacent to the nutrient content claim. 21 C.F.R. § 101.13(h)(4)(ii). Plaintiff alleges that Defendants' products contain sufficiently high levels of fat and/or saturated fat to trigger this disclosure requirement, and thus that Defendants' failure to include such a disclosure adjacent to the calorie statements on the front of the product packaging violates FDA regulations. Compl. ¶¶ 84-91.

Defendants respond by citing to a different subsection of 21 C.F.R. § 101.13, subsection (i), arguing that this provision governs their calorie statements in lieu of subsection (h). *See* Mot. at 8. 21 C.F.R. § 101.13(i)(3) provides that "the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if . . . [t]he statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect." Because subsection (i) makes no mention of a disclosure requirement when the product contains sufficiently high levels of fat, saturated fat, cholesterol, or sodium, Defendants assert that no such disclosure is required. *See* Mot. at 8.

The Court is not convinced.[5] Even assuming that 21 C.F.R. § 101.13(i)(3) applies to Defendants' front-of-package calorie statements, nothing in the language or structure of the regulation indicates that package statements subject to subsection (i) are exempt from the requirements of subsection (h). Rather, the requirements appear to be cumulative. 21 C.F.R. § 101.13(b) states that nutrient content claims must be "made in accordance with this regulation," and the remaining subsections of Section 101.13 list various requirements for the wording and placement of nutrient content claims. These subsections, including subsections (h) and (i), are not

[5] The Court acknowledges that it accepted this argument when it appeared as part of the motion to dismiss in the Wrigley case. *See Gustavson*, 961 F. Supp. 2d at 1122-23. The Calorie Claims that were part of the operative complaint in the Wrigley Case, however, were extremely vague and Plaintiff failed to respond to Defendants' argument that 21 C.F.R. § 101.13(i) governed and did not require a disclosure statement. *See id.* In the instant Complaint, Plaintiff has clarified her claims considerably, and also addressed Defendants' argument regarding 21 C.F.R. § 101.13(i). Accordingly, the Court concludes that a different result is warranted here.

separated by disjunctive language (such as "or") that would suggest that a food manufacturer need only comply with portions of the regulation. Moreover, the purposes of subsections (h) and (i) appear to differ. Subsection (i) lists the circumstances under which a manufacturer may make a "statement about the amount or percentage of a nutrient" and imposes requirements for the presentation of such a statement. *See* 21 C.F.R. § 101.13(i). By contrast, subsection (h) is concerned with informing consumers about the presence of *other* nutrients in the product, apart from whatever nutrient the manufacturer has chosen to highlight. *See* 21 C.F.R. § 101.13(h). Finally, there is no apparent conflict between the subsections that would preclude a manufacturer from complying with them both. That is, there is nothing to prevent Defendants from: (1) making a calorie statement on the front of their product packages that "does not in any way implicitly characterize the level of the nutrient in the food and [] is not false or misleading in any respect," in accord with subsection (i); and (2) accompanying that statement with a disclosure directing consumers to consult the full nutrition information on the back of the packages for information regarding other nutrients, in accord with subsection (h).

Plaintiff additionally challenges Defendants' calorie statements on the ground that the statements list a percent of the daily value of calories (based on a 2,000-calorie diet) supposedly supplied by the products. Compl. ¶ 119. Plaintiff alleges that the FDA has not established a daily value for calories and that Defendants are prohibited from listing a percent daily value where no FDA-defined daily value exists. *Id.* Plaintiff further alleges that listing a percent daily value for calories is misleading because individual calorie needs differ such that many individuals require far fewer than 2,000 calories per day. *Id.* Defendants' respond that Plaintiff's allegation is expressly preempted because the FDA itself uses a 2,000-calorie diet to calculate percent daily values for other nutrients. Mot. at 6-7. According to Defendants, "[n]othing prohibits a food manufacturer from doing basic math and providing a similar percentage of calories." *Id.* at 7.

At this stage of the litigation, the Court cannot conclude that Plaintiff's allegations regarding Defendants' use of a percent daily value for calories are expressly preempted. Although the FDA does calculate percent daily values for other nutrients using a 2,000-calorie diet as a baseline, this is not the same as having established a daily value for calories. The FDA has to use

some caloric baseline in order to ensure consistency in the way manufacturers report nutrient percentages on nutrition labels, and it has chosen a baseline of 2,000 calories. One need not necessarily conclude from this that the FDA therefore considers 2,000 calories to be an appropriate number of calories for all or most people to consume on a daily basis. Indeed, other portions of the FDA's labeling regulations suggest that the FDA does *not* mean to imply that individuals should generally consume 2,000 calories per day. Specifically, the FDA requires that the nutrition information panel on a food product include the statement: "Percent Daily Values are based on a 2,000 calorie diet. *Your daily values may be higher or lower depending on your calorie needs.*" 21 C.F.R. 101.9(d)(9)(i) (emphasis added). Moreover, Defendants offer no authority in support of their argument that FDA regulations permit them to list a percent daily value for calories as a matter of "basic math." The Court concludes that Plaintiff's allegations that FDA regulations prohibit Defendants from listing a percent daily value for calories are at least plausible and that these allegations can therefore withstand an express preemption challenge at the motion to dismiss stage.[6]

Ultimately, the Court is not persuaded either that 21 C.F.R. § 101.13(i) relieves Defendants of the obligations imposed by 21 C.F.R. § 101.13(h), or that FDA regulations permit Defendants to list a percent daily value for calories on their products. Consequently, the Court concludes that Plaintiff has plausibly alleged that Defendants' calorie statements violate FDA regulations and thus that Plaintiff is not attempting to impose labeling requirements beyond those imposed by federal law. The Court therefore DENIES Defendants' Motion to Dismiss Plaintiff's Calorie Claims on the ground that they are expressly preempted.

B. Primary Jurisdiction

Defendants additionally argue that Gustavson's Calorie Claims are subject to dismissal under the doctrine of primary jurisdiction. The primary jurisdiction doctrine "allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within

[6] Because the Court finds that Plaintiff has sufficiently alleged that Defendants' use of a percent daily value for calories where no such daily value exists is unlawful and misleading, the Court need not consider Plaintiff's additional argument that the percent daily value for calories is misleading because it overstates the quantity of calories in an individual's diet that should derive from sugar and fat.

the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). The doctrine applies when: "(1) [there is a] need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek Semiconductor Co. v. Microchip Tech., Inc.*, 307 F.3d 775, 781 (9th Cir. 2002). However, the doctrine of primary jurisdiction "does not require that all claims within an agency's purview be decided by the agency. Nor is it intended to secure expert advice for the courts from regulatory agencies every time a court is presented with an issue conceivably within the agency's ambit." *Brown v. MCI WorldCom Network Servs., Inc.*, 277 F.3d 1166, 1172 (9th Cir. 2002) (internal quotation marks omitted). Rather, "[p]rimary jurisdiction is properly invoked when a claim is cognizable in federal court but requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Id.*

Defendants assert that dismissal on primary jurisdiction grounds is warranted because "[f]ront-of-pack calorie-related labeling is an issue of first impression that is currently under active consideration by the FDA." Mot. at 15. In support of the claim that the FDA is actively considering whether to allow front-of-package calorie statements of the sort at issue in this case, Defendants point to: (1) a December 13, 2011 FDA Guidance Letter sent to the Grocery Manufacturer's Association ("GMA") and Food Marketing Institute ("FMI") discussing the conditions under the FDA would exercise enforcement discretion toward manufacturers employing the GMA/FMI's "Nutrition Keys front-of-pack labeling program," ("GMA/FMI Letter") Def. RJN Ex. F; (2) an FDA press release announcing a "Front-of-Package Labeling Initiative," *id.* Ex. G; (3) two Advanced Notices of Proposed Rulemaking ("ANPRM"), from 2005 and 2007, in which the FDA requested comments and data on the possibility of creating a daily value for calories, *see* 72 Fed. Reg. 62,149, 62,167-62,168 (Nov. 2, 2007); 70 Fed. Reg. 17,008, 17,008-17,010 (Apr. 4, 2005); and (4) two recent statements of the FDA's regulatory agenda in which the FDA indicated its intent to amend its nutrition labeling requirements in general, *see* 79 Fed. Reg. 896, 957 (Jan. 7, 2014); 78 Fed. Reg. 44,252, 44,254 (July 23, 2013).

Defendants also observe that this Court previously dismissed, on primary jurisdiction grounds, a claim in the Wrigley case related to the serving size for breath mints. *See* Mot. at 16 (citing *Gustavson*, 961 F. Supp. 2d at 1127-28). In the Wrigley case, the Court reasoned that the FDA was actively considering changing the serving size for breath mints and thus that it would be "more prudent to step back and allow the FDA regulatory process to play out." *Id.* at 1128. Defendants contend that the same result should apply here.

The Court concludes that the FDA's regulatory process with regard to front-of-package calorie statements is not sufficiently concrete or advanced as to warrant dismissal of Plaintiff's Calorie Claims. In spite of Defendants' attempts to analogize this case to the breath mint serving size regulation at issue in the Wrigley case, closer examination of the FDA materials cited by Defendants reveals that the FDA's plans for regulating front-of-package calorie statements in a manner that would affect the outcome of this case are far less apparent than they were in the Wrigley case. In the Wrigley case, the FDA had issued a Notice of Proposed Rulemaking ("NPRM") that would have changed the very same serving size rule that Plaintiff sought to enforce, *see* 62 Fed. Reg. 67,775, 67,776 (Dec. 30, 1997), and had placed that proposal on its 2013 regulatory agenda, *see* FDA, *Food Labeling: Serving Sizes; Reference Amount and Serving Size Declaration for Hard Candies and Breath Mints*, *available at* http://federalregister.gov/r/0910-AG82 (accessed June 6, 2014). Crucially, the FDA had expressed clear dissatisfaction with the existing rule, which indicated that the rule Plaintiff accused Wrigley of violating no longer reflected the FDA's views on the proper serving size for breath mints. *See* 62 Fed. Reg. at 67,776. Even so, the Court stated in the Wrigley case that it viewed its decision to dismiss Plaintiff's serving size claim on primary jurisdiction grounds as a "close question." *See Gustavson*, 961 F. Supp. 2d at 1128.

Here, by contrast, although the FDA has indicated that it intends to consider changing labeling requirements for calories generally, it has provided little detail concerning what form those changes might take. The 2005 ANPRM requested comments and data concerning the possibility of establishing a daily value for calories, *see* 70 Fed. Reg. at 17,009, but subsequent FDA statements have only discussed an intent to "provide updated nutrition information on the label," *e.g.*, 79 Fed.

Reg. at 957; *see also* 78 Fed. Reg. at 44,254; Def. RJN Ex. G. Furthermore, the FDA's discussion of its regulatory agenda with regard to calorie statements has made no mention of an intent to alter the disclosure requirements of 21 C.F.R. § 101.13(h). The FDA's expressions of intent to regulate calorie statements similar to those at issue in this case have simply been too vague and tentative for the Court to conclude, as it did in the Wrigley case, that it was prudent not to interfere with an active and ongoing regulatory process.[7]

Nor is dismissal on primary jurisdiction grounds warranted because this case raises issues of first impression or particular technical complexity. *See Brown*, 277 F.3d at 1172. As evidenced by this Court's discussion of 21 C.F.R. § 101.13(h) above, the FDA has already spoken as to at least one of the reasons why Defendants' product labels are allegedly misleading—namely, Defendants' failure to accompany their front-of-package calorie statements with a disclosure directing consumers to consult the nutrition information panel for information about fat and/or saturated fat. *See supra* Part II.A.2. Similarly, Gustavson's claims do not raise highly technical issues uniquely within the FDA's expertise. As with so many of the other food misbranding cases filed within this district, Plaintiff's case is "far less about science than it is about whether a label is

[7] Defendants' citation to the GMA/FMI Letter as evidence that the FDA intends to allow, or at least to tolerate, front-of-package calorie statements similar to those at issue here is similarly unavailing. The GMA/FMI Letter refers to a labeling program which concededly differs from the front-of-package calorie statements that appear on Defendants' labels. *See* Mot. at 9; *compare* Def. RJN Ex. F ("Products labeled with Nutrition Keys include four 'Basic Icons' on the principal display panel [*i.e.*, the front of the package]. The four 'Basic Icons' provide information from the Nutrition Facts panel on calories, saturated fat, sodium and total sugar content."), *with* Def. RJN Ex. A (front of the M&Ms package bears only a single icon listing calorie content). The GMA/FMI Letter's conclusion that the FDA will exercise enforcement discretion is expressly limited to "firms that participate in and comply with the terms of the Nutrition Keys program." Def. RJN Ex. F. This conclusion does not extend to firms using alternative labeling schemes, and indeed the GMA/FMI Letter warns that "FDA does not intend to exercise enforcement discretion with respect to companies that misuse the Nutrition Keys labeling system in a manner that misleads consumers or otherwise violates the FDCA." *Id.* Moreover, the Court notes that the GMA/FMI Letter states that a "key consideration" in the FDA's decision to exercise enforcement discretion with respect to the Nutrition Keys program "is that the disclosure statement referring consumers to the Nutrition Facts panel of the food label will continue to be required." *Id.* This refers to the very same disclosure statement that is conspicuously absent from Defendants' front-of-package calorie statements. *See supra* Part II.A.2.

The Court does not view the GMA/FMI Letter as providing a clear indication as to how the FDA would view the calorie statements at issue here; to the extent the Letter does shed light on the FDA's thinking on this issue, it suggests that the FDA would not look favorably on Defendants' isolated use of a calorie icon on the front of their packaging without an accompanying disclosure regarding fat and/or saturated fat.

misleading." *Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889, 898 (N.D. Cal. 2012). "'[E]very day courts decide whether conduct is misleading,'" and the "'reasonable-consumer determination and other issues involved in Plaintiff's lawsuit are within the expertise of the courts to resolve.'" *Id.* at 899 (quoting *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1035 (N.D. Cal. 2009), and *Delacruz v. Cytosport, Inc.*, No. 11-3532, 2012 WL 2563857, at *10 (N.D. Cal. June 28, 2012)). Accordingly, the Court DENIES Defendants' Motion to Dismiss Gustavson's Calorie Claims on the basis of primary jurisdiction.

V. CONCLUSION

For the foregoing reasons, the Court DENIES Defendants' Motion to Dismiss in its entirety.

IT IS SO ORDERED.

Dated: June 10, 2014

LUCY H. KOH
United States District Judge