UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

REBECCA YUMUL, individually, and on behalf of all others similarly situated, Plaintiff, vs. SMART BALANCE, INC., Defendant.	CASE NO. CV 10-00927 MMM (AJWx) ORDER DENYING CLASS CERTIFICATION; DISMISSING COMPLAINT WITH LEAVE TO AMEND

Rebecca Yumul filed this putative class action against Smart Balance, Inc. ("Smart Balance" or "SBI") on February 8, 2010.[1] On May 24, 2010, the court granted defendant's motion to dismiss the complaint with leave to amend for failure to allege with particularity the facts upon which the claims were based.[2] On July 30, 2010, the court granted defendant's second motion to dismiss insofar as the complaint sought to plead claims that predated the limitations

[1]Complaint for Violations of Unfair Competition Law, False Advertising Law, and Consumer Legal Remedies Act ("Complaint"), Docket No. 1 (Feb. 8, 2010).

[2]Order Granting in Part and Denying in Part Defendant's Motion to Dismiss ("First Order"), Docket No. 18 (May 17, 2010).

period.[3] The court directed Yumul to file a second amended complaint alleging the facts on which she based her invocation of the delayed discovery rule. On August 12, 2010, plaintiff filed a second amended complaint pleading three causes of action: (1) violation of California's unfair competition law ("UCL"), California Business & Professions Code §§ 17200 et seq.; (2) violation of California's false advertising law ("FAL"), California Business & Professions Code §§ 17500 et seq.; and (3) violation of California's Consumer Legal Remedies Act ("CLRA"), California Civil Code § 1750 et seq.[4]

On November 22, 2010, Yumul filed a motion for class certification,[5] seeking to certify two classes under Rules 23(a), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure: (1) a proposed CLRA and FAL class consisting of "[a]ll persons (excluding officers, directors, and employees of SBI) who purchased, on or after January 1, 2000 [ ] Nucoa Real Margarine in the United States for their own use, rather than resale or distribution[;]"[6] and (2) a proposed UCL class, consisting of "[a]ll persons (excluding officers, directors, and employees of SBI) who purchased, on or after February 8, 2006 [ ] Nucoa Real Margarine in the United States for their own use, rather than resale or distribution."[7] Defendant opposes certification of the classes.[8]

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[3]Order Granting in Part and Denying in Part Defendant's Motion to Dismiss ("Second Order"), Docket No. 29 (July 30, 2010).

[4]Second Amended Complaint ("SAC"), Docket No. 30 (August 12, 2010).

[5]Motion to Certify Class ("Motion"), Docket No. 54 (November 22, 2010); Declaration of Jack Fitzgerald ("Fitzgerald Decl"), Docket No. 55 (November 22, 2010); Declaration of Gregory Weston ("Weston Decl"), Docket No. 56 (November 22, 2010).

[6]Motion at 2.

[7]*Id.* at 2-3.

[8]Opposition ("Opp."), Docket No. 57 (December 20, 2010); Declaration of Robert Harris ("Harris Decl"), Docket No. 57 (December 20, 2010); Declaration of Peter Draw ("Dray Decl."), Docket No. 57 (December 20, 2010); Declaration of Victoria Ianni ("Ianni Decl."), Docket No. 58 (December 20, 2010); Declaration of Yoram Wind ("Wind Decl."), Docket No. 59 (December 20, 2010).

I. FACTUAL BACKGROUND

Smart Balance is a Delaware corporation with its principal place of business in New Jersey.[9] Yumul alleges that she purchased Nucoa Real Margarine ("Nucoa"), a product distributed by Smart Balance, repeatedly during the class period.[10] Specifically, Yumul asserts that she purchased one package of Nucoa approximately every two weeks and that, in the aggregate, she purchased Nucoa 200 and 300 times between January 1, 2000 and January 24, 2010.[11]

Yumul alleges that Nucoa contains artificial trans fat, which raises the risk of coronary heart disease by raising the level of "bad" LDL blood cholesterol and lowering the level of "good" HDL blood cholesterol.[12] Yumul also alleges that trans fat causes cancer and type 2 diabetes.[13] Despite the ill effects of trans fat, she contends that at all times relevant to this action,

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[9]SAC, ¶ 10; Dray Decl., ¶ 10. There appears to be a dispute about the location of Smart Balance's principal place of business. Plaintiff alleges that defendant's principal place of business is in California. (SAC, ¶ 10). Defendant, however, has proffered evidence that its principal place of business is in New Jersey. Peter Dray, the Executive Vice President of Operations and Product Development of GFA Brands, Inc., a wholly owned subsidiary of Smart Balance, has submitted a declaration stating that "[t]he combined principal office of both Smart Balance and GFA-Delaware is in Paramus, New Jersey. GFA-Ohio, GFA-Delaware, and Smart Balance always have had their principal offices in New Jersey, and have never had offices or any place of business in California. Sales to customers always have been made from, and continue to be made and invoiced from, these New Jersey offices. There are two employees who have marketing responsibilities throughout a number of western states who have chosen to reside in California, but not by company direction or request. These two employees have no advertising or labeling responsibilities and do not work out of a company office in California." (Dray Decl., ¶¶ 10-11). As Yumul has proffered no evidence contradicting this testimony, the court considers New Jersey to be defendant's principal place of business for purposes of this motion.

[10]SAC, ¶ 3

[11]*Id.*, ¶ 12.

[12]*Id.*, ¶¶ 4-5.

[13]*Id.*, ¶¶ 6–7. See also *id.*, ¶ 61 ("SBI's Nucoa Real Margraine contains substantial and dangerous levels of artificial *trans* fat, which increases LDL cholesterol and decreases HDL cholesterol levels. SBI capitalizes on a common misperception of the relative importance of dietary cholesterol to fool consumers who are concerned about heart health, leading them to

Nucoa packages bore the label "No Cholesterol" or "Cholesterol Free."[14] Smart Balance appears to concede that Nucoa was labeled as "No Cholesterol" or "Cholesterol Free"; it contends, however, that the product was labeled this way because until mid-2010, it was made of 80% vegetable oil and water, and thus contained no cholesterol.[15]

Smart Balance has proffered evidence that, at all relevant times, the label carried an ingredient declaration disclosing that Nucoa contained partially hydrogenated soybean oil as well as the legend "Cholesterol Free."[16] Beginning in late 2005, a Nutrition Facts panel was added disclosing that each serving contained 1.5g of trans fat.[17] The label continued to represent that the product was "Cholesterol Free," however,[18] Since late 2005, the product label has continuously identified the presence and amount of trans fat per serving,[19] and to list partially hydrogenated soy bean oil – the source of the trans fat – in the ingredient declaration.[20] In late November 2009, the word "healthy" was added to the printed text on the back panel of the Nucoa label.[21] Prior to this time, the label had never included the word "healthy."[22]

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purchas[e] a produce that increases their LDL serum cholesterol, lowers their HDL serum cholesterol, and raises their risk for heart disease, diabetes, and cancer"). Much of the complaint recites scientific research establishing that trans fat has adverse physical health effects. (*Id.*, ¶¶ 16–57.)

[14]SAC, ¶ 60.

[15]Dray Decl., ¶¶ 15, 18. Smart Balance also proffers evidence that competing vegetable oil products, such as I Can't Believe It's Not Butter, Imperial, Parkay, Blue Bonnet, Fleischmann's, and Shedd's, are labeled "cholesterol free." (*Id.*, ¶¶ 17, 19).

[16]*Id.*, ¶ 27.

[17]*Id.*, ¶ 28.

[18]*Id.*, ¶¶ 28-29.

[19]*Id.*, ¶ 30.

[20]*Id.*

[21]*Id.*, ¶ 30.

[22]*Id.*, ¶¶ 27-29.

Yumul alleges that Nucoa's "Cholesterol Free" label is "false and highly misleading," since consumption of Nucoa in fact raises the level of LDL blood cholesterol.[23] She contends that inclusion of the word "healthy" on the product packaging is also misleading because of the negative health effects of trans fat.[24]

Smart Balance proffers evidence that in March 2010, trans fat was eliminated from Nucoa, and thus from the label.[25] It contends that Nucoa was reformulated in March 2010 for several reasons. First, as the cost of vegetable oil rose, most competitive products had reduced amounts of vegetable oil.[26] Most competitors also eliminated trans fat in reaction to the negative public image trans fat developed.[27] To ensure competitive pricing, Smart Balance made similar changes in Nucoa; these included a reduction in the percent of vegetable oil in the product to 65%.[28] Smart Balance deleted the reference to "healthy" from the back label in March 2010, when the product was reformulated.[29]

Yumul contends she did not discover that Smart Balance's labeling of Nucoa was allegedly false, deceptive, or misleading until late January 2010, when she learned of the causal link between Nucoa and coronary heart disease, type-2 diabetes, and cancer during a conversation she had with an acquaintance who was highly knowledgeable about the subject.[30] Until that time, she did not know that Nucoa posed a risk to her health, and was unaware of the facts supporting her

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[23]SAC, ¶ 8. See also *id.*, ¶ 62 ("Nucoa Real Margarine is anything but 'healthy.' To the contrary, Nucoa Real Margarine is extremely high in *trans* fat, which causes heart disease, cancer, and type-2 diabetes, and therefore harms rather than benefits human health").

[24]*Id.*, ¶ 62.

[25]Dray Decl., ¶ 33.

[26]*Id.*

[27]*Id.*

[28]*Id.*

[29]*Id.*, ¶ 30.

[30]SAC, ¶ 79.

claims against Smart Balance.[31] Yumul asserts that she is a reasonably diligent consumer who exercised reasonable diligence in purchasing, using, and consuming Nucoa.[32] She maintains that, like nearly all consumers, she is not a nutrition expert and lacked the means to discover Smart Balance's deceptive practices.[33] She also argues that Smart Balance's labeling – in particular its representation that Nucoa was "healthy" and "Cholesterol Free" – actively impeded her ability and the ability of similarly situated consumers to discover the alleged fraud.[34]

Plaintiff seeks an order compelling Smart Balance to (1) cease using the allegedly misleading tactics to market and sell Nucoa; (2) conduct a corrective advertising campaign; (3) make restitution to consumers of the amounts by which it was unjustly enriched; (4) destroy all allegedly misleading and deceptive materials and products; and (5) award class members actual damages, restitution, punitive damages, costs, expenses, and reasonable attorneys' fees.[35]

II. DISCUSSION

A. Legal Standard Governing Class Certification

"Class actions have two primary purposes: (1) to accomplish judicial economy by avoiding multiple suits, and (2) to protect the rights of persons who might not be able to present claims on an individual basis." *Haley v. Medtronic, Inc.*, 169 F.R.D. 643, 647 (C.D. Cal. 1996) (citing *Crown, Cork & Seal Co. v. Parker*, 462 U.S. 345 (1983)). A district court may certify a class only if

> "(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the

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[31] *Id.*

[32] *Id.*, ¶ 80.

[33] *Id.*

[34] *Id.*

[35] *Id.*, ¶ 9.

> representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class." FED.R.CIV.PROC. 23(a).

In addition, the district court must also find that at least one of the following three conditions is satisfied:

> "(1) the prosecution of separate actions would create a risk of: (a) inconsistent or varying adjudications, or (b) individual adjudications dispositive of the interests of other members not a party to those adjudications; (2) the party opposing the class has acted or refused to act on grounds generally applicable to the class; or (3) questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of the controversy." *Dukes v. Wal-Mart Stores, Inc.*, 603 F.3d 571, 580 (9th Cir. 2010) (en banc) (citing FED.R.CIV.PROC. 23(b)), cert. granted, 131 S.Ct. 795 (Dec. 6, 2010)

"The party seeking certification bears the burden of showing that each of the four requirements of Rule 23(a) and at least one requirement of Rule 23(b) have been met." *Id.* (citing *Zinser v. Accufix Research Institute, Inc.*, 253 F.3d 1180, 1186 (9th Cir.), amended by 273 F.3d 1266 (9th Cir. 2001)).

In deciding whether to certify a class under Rule 23, an inquiry regarding "the merits of the claims is [generally] inappropriate." 7A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, FEDERAL PRACTICE AND PROCEDURE: CIVIL 2D § 1759 (2006); see also *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177-78 (1974); *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1232 (9th Cir. 1996). Nonetheless, the court may find it necessary to look beyond the pleadings and examine plaintiffs' substantive claims to determine whether the elements of Rule 23 have been satisfied. See *Dukes*, 603 F.3d at 581 ("When considering class certification under Rule 23, district courts are not only at liberty to, but must, perform a rigorous analysis to ensure that the prerequisites of Rule 23(a) have been satisfied," citing *General Telephone Co. of Southwest v. Falcon*, 457 U.S. 147, 160-61 (1982)). See also *Coopers & Lybrand v. Livesay*, 437 U.S. 463,

469 (1978) (determining whether to certify a class "generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action" (internal quotation marks omitted)); *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 509 (9th Cir. 1992) (holding that the court can consider evidence regarding the merits of the claims to determine whether Rule 23 has been satisfied); *In re Unioil Secs. Litig.*, 107 F.R.D. 615, 618 (C.D. Cal. 1985) ("[N]otwithstanding its obligation to take the allegations in the complaint as true, the Court is at liberty to consider evidence which goes to the requirements of Rule 23 even though the evidence may also relate to the underlying merits of the case").

As the Ninth Circuit has emphasized, this "does not mean that a district court must conduct a full-blown trial on the merits prior to certification." *Dukes*, 603 F.3d at 581. Nonetheless, "[a] district court's analysis will often, though not always, require looking behind the pleadings, even to issues overlapping with the merits of the underlying claims," since "district courts [must] ensure that Rule 23 requirements are actually met, not simply presumed from the pleadings." *Id.* at 581–82.

B. Whether Plaintiff's Claims Are Preempted by Federal Law

Smart Balance asserts that the court cannot certify the classes Yumul proposes because her state law claims are preempted by federal law. Specifically, Smart Balance contends that Yumul's claims that Nucoa's label was false and misleading are preempted by the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301, et seq., and the Nutrition Labeling and Education Act of 1990 ("NLEA"), 21 U.S.C. § 343(r), et seq.

1. Whether Smart Balance Waived Any Argument That the Claims Are Preempted

Yumul contends that Smart Balance waived any preemption defense because it failed to raise the argument in its prior motions to dismiss. While the court agrees with Yumul that Smart Balance's argument could have been more easily addressed in the context of a motion to dismiss, it cannot conclude the argument has been waived.

Rule 12(g) provides that "[e]xcept as provided in Rule 12(h)(2) or (3), a party that makes a motion under this rule must not make another motion under this rule raising a defense or

objection that was available to the party but omitted from its earlier motion." See FED.R.CIV.PROC. 12(g)(2). This well-established principle prevents litigants from taking a "second bite at the apple." See *Doe v. White*, No. 08-1287, 2010 WL 323510, *2 (C.D. Ill. Jan. 20, 2010) ("The Court agrees with the Magistrate that principles of waiver, as expressed in Rule 12(g)(2), should be enforced in order to prevent a second bite at the apple, and to prevent piecemeal litigation"); *FRA S. p. A. v. Surg-O-Flex of America, Inc.*, 415 F.Supp. 421, 426 (S.D.N.Y. 1976) ("It is clear that the practice contemplated by Rule 12 is one which avoids a series of motions resulting in delay and dilatory tactics").

Rule 12(h), however, governs the waiver of defenses. Under Rule 12(h)(1), "[a] party waives any defense listed in Rule 12(b)(2)-(5) by: (A) omitting it from a motion in the circumstances described in Rule 12(g)(2); or (B) failing to either: (i) make it by motion under this rule; or (ii) include it in a responsive pleading or in an amendment allowed by Rule 15(a)(1) as a matter of course." This rule applies only to waiver of the following defenses, none of which is applicable here: Rule 12(b)(2) – lack of personal jurisdiction; rule 12(b)(3) – improper venue; Rule 12(b)(4) – insufficient process; and Rule 12(b)(5) – insufficient service of process.

Rule 12(h)(2) provides that defenses such as "[f]ailure to state a claim upon which relief can be granted, to join a person required by Rule 19(b), or to state a legal defense to a claim may be raised: (A) in any pleading allowed or ordered under Rule 7(a);[36] (B) by a motion under Rule 12(c); or (C) at trial." Rule 12(h)(3) provides that the defense that the court lacks subject matter jurisdiction can be raised at any point in the litigation. See FED.R.CIV.PROC. 12(h)(3) ("If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action").

If a claim is preempted by federal law, it fails to state a claim upon which relief can be granted under Rule 12(b)(6). See *Stewart v. U.S. Bancorp*, 297 F.3d 953, 987 (9th Cir. 2002) ("Plaintiffs contend that if we look past the 12(b)(6) label, the dismissal [ ] for failure to plead a

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[36]Rule 7(a) establishes which pleadings are allowed, including, "(1) a complaint; (2) an answer to a complaint. . . ."

cognizable ERISA claim was a dismissal for lack of jurisdiction. . . . We respectfully disagree. In preemption cases the district court must analyze the complaint to determine if a federal preemption defense applies. A district court's analysis of whether the complaint is federally preempted is a question of law and fact; it is a decision on the merits of the pleadings"); *Aguayo v. U.S. Bank*, 658 F.Supp.2d 1226, 1230-31 (S.D.Cal. 2009) (dismissing a complaint on preemption grounds for failure to state a claim on which relief could be granted); *Gordon v. Impulse Marketing Group, Inc.*, 375 F.Supp.2d 1040, 1045-46 (E.D. Wash. 2005) (considering a federal preemption defense in the context of a motion to dismiss under Rule 12(b)(6)).

Smart Balance was, therefore, entitled to raise its preemption defense in its answer, in a motion for judgment on the pleadings under Rule 12(c), or at trial. See FED.R.CIV.PROC. 12(h)(2). As Smart Balance preserved the defense in its answer,[37] there can be no argument that it failed to raise the defense in a pleading under Rule 7(a). Because Smart Balance is entitled to raise the defense any time prior to or during trial, moreover, it would promote efficient resolution of the case to consider it in the context of the currently pending motion for class certification. See *Coleman v. Pension Ben. Guar. Corp.*, 196 F.R.D. 193, 196-97 (D.D.C. 2000) ("[T]he Court will allow PBGC to assert that defense [in the context of motions to strike a jury demand and to certify a class]. As indicated, PBGC's preemption defense is not waived because PBGC may still raise it in a motion for judgment on the pleadings or at trial. '[G]iven the lack of waiver and the fact that defendant's defense . . . will . . . require adjudication in any event, many courts permit the defense of failure to state a claim upon which relief can be granted to be asserted in a subsequent motion as a means of preventing unnecessary delay in the proceedings.' *In re Westinghouse Securities Litigation*, [No. Civ.A. 91-354,] 1998 WL 119554, *6 (W.D. Pa. Mar. 12, 1998). . . ; see also *Vega v. State University of New York Board of Trustees*, [No. 97 Civ.

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[37]See Answer to Second Amended Complaint, Docket No. 50 (September 21, 2010) at 20 ("**TWENTY-NINTH AFFIRMATIVE DEFENSE (Federal Preemption)** Plaintiff's claims are expressly or impliedly preempted by federal law, including but not limited to, the Food, Drug, and Cosmetic Act, the Nutrition Labeling and Education Act of 1990, and the Federal Drug Administration's regulations").

5767(DLC),] 2000 WL 381430, *2 (S.D.N.Y. Apr. 13, 2000) (allowing successive motion to dismiss asserting Rule 12(b)(6) defense omitted from first motion). Moreover, there is no reason to believe that PBGC is seeking to delay the litigation or inconvenience plaintiffs by asserting preemption at this stage. See *Federal Express Corp. v. United States Postal Service*, 40 F.Supp.2d 943, 948-49 (W.D. Tenn. 1999) (emphasizing defendant's lack of intent to delay action or inconvenience plaintiff in allowing [a] successive Rule 12(b)(6) motion); *Sharma v. Skaarup Ship Management Corp.*, 699 F.Supp. 440, 444 (S.D.N.Y.1988) (emphasizing lack of intent to delay). In the absence of any apparent bad faith, and in the interest of promoting the efficient resolution of this case, the Court will consider PBGC's preemption argument").[38] Consequently,

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[38]Plaintiff cites several cases that she contends support her view that the preemption defense has been waived. Each case, however, addresses whether preemption can be raised for the first time on appeal, i.e., whether a party's failure to raise preemption as a defense in the trial court precludes the court of appeals from considering the argument. See *Williams v. Gerber Products Co.*, 523 F.3d 934, 937-38 (9th Cir. 2008) ("In Gerber's answering brief, it argues for the first time that some of Appellants' claims were preempted by the Federal Food Drug and Cosmetic Act ("FDCA"). Because Gerber did not argue this below, the district court did not address the issue, and we decline to decide this issue in the first instance based on arguments made in an answering brief, particularly where nothing in Appellants' complaint suggested that they were attempting to directly enforce violations of the FDCA"); *Gilchrist v. Jim Slemons Imports, Inc.*, 803 F.2d 1488, 1496-97 (9th Cir. 1986) (rejecting petitioner's assertion that "its preemption argument is a question of subject matter jurisdiction that may be raised at any time," and concluding that because petitioner did not assert preemption as a defense in the district court, ithe court would not consider it on appeal); see also *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 336 (3d Cir. 2009) ("We conclude that Snapple has waived its express preemption argument with regard to Holk's HFCS claims. Though Snapple contended in its two motions to dismiss that Holk's juice content claims were expressly preempted by 21 U.S.C. § 343-1(a)(3), it did not raise this provision with regard to Holk's HFCS claim. In fact, it did not raise any express preemption argument in response to the HFCS claim and explicitly disclaimed the applicability of express preemption to this claim. This clearly demonstrates that the issue was not before the District Court. For this reason, we conclude that the issue is waived"); *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 11 (1st Cir. 1995) ("[A]lthough Dyonics pleaded preemption as an affirmative defense in its answer, it neither developed a record on the issue nor pressed it in any fashion before the district court. Merely mentioning an issue in a pleading is insufficient to carry a party's burden actually to present a claim or defense to the district court before arguing the matter on appeal. . . . Dyonics had ample opportunity and incentive to assert preemption below. It chose, however, neither to file a motion to dismiss nor to press for summary judgment on the issue. . . . To allow Dyonics to resurrect the issue here would undermine the logic behind our refusal to consider issues not

the court finds that Smart Balance's defense of federal preemption has not been waived and may properly be considered in the context of the present motion.

2. Federal Preemption under the FDCA and NLEA

The Supremacy Clause of the United States Constitution empowers Congress to enact legislation that preempts state law. See *Gibbons v. Ogden*, 22 U.S. 1, 82 (1824) ("In every such case, the act of Congress, or the treaty, is supreme; and the law of the State, though enacted in the exercise of powers not controverted, must yield to it."); *Law v. General Motors Corp.*, 114 F.3d 908, 909 (9th Cir. 1997) ("The Supremacy Clause empowers Congress to supplant decentralized, state-by-state regulation with uniform national rules"). "Federal preemption occurs when: (1) Congress enacts a statute that explicitly pre-empts state law; (2) state law actually conflicts with federal law; or (3) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field." *Chae v. SLM Corp.*, 593 F.3d 936, 941 (9th Cir. 2010) (quoting *Tocher v. City of Santa Ana*, 219 F.3d 1040, 1045 (9th Cir. 2000), abrogated on other grounds by *City of Columbus v. Ours Garage and Wrecker Service, Inc.*, 536 U.S. 424 (2002)).

In assessing Smart Balance's argument that Yumul's claims are preempted, the court must be mindful of the presumption against preemption. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("In all preemption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' we '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'"); see also *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005) ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action"); *Law*,

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presented below: Dyonics 'cannot evade the scrutiny of the district court . . . on appeal with a new claim in order to create essentially a new trial,'" citing *G.D. v. Westmoreland School Dist.*, 930 F.2d 942, 950 (1st Cir. 1991)). As none of these cases addresses the issue here – whether a preemption is waived if it is not raised in a Rule 12(b)(6) motion but is alleged in an answer – the citations are inapposite.

114 F.3d at 909-10 ("Given the importance of federalism in our constitutional structure, however, we entertain a strong presumption that federal statutes do not preempt state laws; particularly those laws directed at subjects – like health and safety – 'traditionally governed' by the states. 'Thus, pre-emption will not lie unless it is the clear and manifest purpose of Congress'" (citations omitted)); see also *In re Farm Raised Salmon Cases*, 42 Cal.4th 1077, 1088 (2008) (noting that consumer protection laws such as the UCL, false advertising law and CLRA, are within the states' historic police powers and therefore subject to the presumption against preemption). Where Congress has expressly preempted state law, the presumption against preemption requires the court to read the federal statute narrowly. See *Lohr*, 518 U.S. at 485 (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992)).

The FDCA was enacted in 1938 as a successor to the 1906 Pure Food and Drugs Act, which was the first comprehensive federal legislation designed to protect consumers from fraud or misrepresentation in the sale of food and drugs. See James T. O'Reilly, FOOD AND DRUG ADMINISTRATION § 3:1-13 (3d ed. 2009). The FDCA empowers the Food and Drug Administration ("FDA") (a) to protect the public health by ensuring that "foods are safe, wholesome, sanitary, and properly labeled," 21 U.S.C. § 393(b)(2)(A); (b) to promulgate regulations to implement the statute; and (c) to enforce its regulations through administrative proceedings. See 21 C.F.R. § 7.1 et seq. The FDCA deems a food "misbranded" if its labeling "is false or misleading in any particular." 21 U.S.C. § 343(a).[39]

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[39]There is no private right of action under the FDCA. See *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) (noting that "the FDCA forbids private rights of action under that statute "). See also *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 810-11 (1986) ("In this case, both parties agree with the Court of Appeals' conclusion that there is no federal cause of action for FDCA violations. For purposes of our decision, we assume that this is a correct interpretation of the FDCA. . . . In short, Congress did not intend a private federal remedy for violations of the statute that it enacted); *Cabazon Band of Mission Indians v. Wilson*, 124 F.3d 1050, 1063 (9th Cir. 1997) ("The Supreme Court, holding that the district court did not have removal jurisdiction, found that the lack of a private right of action under the FDCA was dispositive . . . ," citing *Merrell Dow*; *Utley v. Varian Associates, Inc.*, 811 F.2d 1279, 1282 (9th Cir. 1987) ("The Court, in rejecting the district court's reasoning and holding that it did not have removal jurisdiction, found that the lack of a private right of action under the FDCA disposed of

In 1990 Congress amended the FDCA by enacting the NLEA "to 'clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.'" *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 223 (2d Cir.1998) (citing H.R.Rep. No. 101-538, at 7 (1990)). "The NLEA amended the FDCA in several significant respects: it expanded the coverage of nutrition labeling requirements; it changed the form and substance of ingredient labeling on packages; it imposed limitations on health claims; it standardized the definitions of all nutrient content claims; and it required more uniform serving sizes." *Ackerman v. Coca-Cola Co.*, No. CV-09-0395 (JG)(RML), 2010 WL 2925955, *3 (E.D.N.Y. July 21, 2010) (citing *The Impact of the Nutrition Labeling and Education Act of 1990 on the Food Industry*, 47 ADMIN.L.REV. 605, 606 (1995)). The NLEA also added an express preemption provision to the FDCA. See 21 U.S.C. § 343-1(a)(5) ("Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . (5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title").

Section 343(r)(1) of the NLEA governs claims on food labels that – "expressly or by implication," – "characterize[ ] the level of any nutrient" or "characterize[ ] the relationship of any nutrient . . . to a disease or health related condition. . . ." 21 U.S.C. § 343(r)(1). The FDA has promulgated regulations concerning three different kinds of such claims: express nutrient-content claims, implied nutrient-content claims, and health claims. See 21 C.F.R. § 101.13 (defining express and implied nutrient-content claims); *id.*, § 101.14 (defining health claims). "An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., 'low sodium' or 'contains 100 calories.'" 21 C.F.R. § 101.13(b)(1). An "implied nutrient content claim is any claim that: (i) Describes the food or

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the issue of whether a state claim based on its violation arose under federal law," citing *Merrell Dow Pharmaceuticals*, 478 U.S. 804).

an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., 'high in oat bran'); or (ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., 'healthy, contains 3 grams (g) of fat')." 21 C.F.R. §§ 101.13(b)(2). "A claim that a product is 'healthy' is generally an implied nutritional content claim." *Ackerman*, 2010 WL 2925955 at *3.[40] Finally, a "[h]ealth claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, . . . characterizes the relationship of any substance to a disease or health-related condition." 21 C.F.R. § 101.14.

The issue in this case is whether § 343-1(a)(5), which prohibits states from establishing any "requirement" that is "not identical" to the requirements of 21 U.S.C. § 343(r), expressly preempts Yumul's state law consumer protection claims.

a. "Cholesterol Free" and "No Cholesterol" Claims

Smart Balance asserts that FDA regulations expressly permit use of the phrases "No Cholesterol" and "Cholesterol Free," and that Yumul's claims, which seek to prohibit the use of these terms when a product contains trans fat, seek to impose requirements that are not identical to the FDA regulations. 21 C.F.R. § 101.62(d) permits terms such as "Cholesterol Free"[41] to be

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[40] *Id.* at *3 n. 8 ("The FDA has explained that while use of the term 'healthy' typically constitutes an implied nutrient content claim, it could, in some circumstances, constitute a health claim where it is used in reference to a disease or health-related condition. See Final Rule, Food Labeling; General Requirements for Health Claims for Food: In the case of the word 'healthy,' the agency does not believe that the use of this word would normally be a health claim. 'Healthy' has a wide variety of meanings in addition to ones that would satisfy the second basic element of a health claim. For example, 'healthy' can certainly imply general nutritional well-being. Thus, while a claim such as 'Eat a diet low in fat for a healthy heart' may be a health claim, 'Eating five fruits or vegetables a day is a good way to a healthy lifestyle' is not. Moreover . . . [the] FDA may also regulate the term 'healthy' . . . as an implied nutrient content claim. 58 Fed.Reg. 2478-01, 2483-84 (Jan. 6, 1993)").

[41] See 21 C.F.R. § 101.62(d) (discussing "[t]he terms 'cholesterol free,' 'free of cholesterol,' 'zero cholesterol,' 'without cholesterol,' 'no cholesterol,' 'trivial source of cholesterol,' 'negligible source of cholesterol,' or 'dietarily insignificant source of cholesterol'").

used anywhere on a product label under certain circumstances. The court addresses below whether those circumstances are present in this case; to the extent they are, however, courts in this circuit have repeatedly dismissed claims under California's consumer protection laws that challenge labels such as these as false and misleading on preemption grounds. See, e.g., *Peviani v. Hostess Brands, Inc.*, __ F.Supp.2d __, 2010 WL 4553510, *6 (C.D. Cal. Nov. 3, 2010) (NLEA and FDCA preempted state law claims alleging that a manufacturer's representation on a 100-calorie dessert pack that the dessert contained "0 Grams of Trans Fat" was deceptive and misleading, under the UCL, FAL, and CLRA, since the claims sought to impose a state law obligation regarding trans fat disclosure that was not required by federal law); *Chacanaca v. Quaker Oats Co.*, ___ F.Supp.2d ___, 2010 WL 4055954, *5-7 (N.D. Cal. Oct. 14, 2010) (consumers' state law claims against a manufacturer of granola bars, which sought to prohibit use of the allegedly misleading statement "0 grams trans fat" on a side label of the bars' boxes, were preempted because they sought to impose burdens that were not identical to those imposed by the FDCA and the NLEA); *Red v. The Kroger Co.* ("*Kroger*"), No. CV 10-01025 DMG (MANx), 2010 WL 4262037, *4-7 (C.D. Cal. Sept. 2, 2010) (state law claims alleging that a manufacturer's representation on Kroger ChurnGold Margarine, Kroger Soft Margarine, and Kroger Value Graham Crackers that the products were "Cholesterol Free" and contained "0g Trans Fat" were preempted by NLEA and FDCA, since they sought to impose a state-law obligation that was not required by federal law); see also *Red v. Kraft Foods, Inc.* ("*Kraft*"), __ F.Supp.2d __, 2010 WL 5000717, *2 (C.D. Cal. Nov. 18, 2010) (noting that "[p]reviously, this Court found that Defendants' labeling claims of 'no cholesterol' and specific quantities of 'whole grain' per serving were not actionable on the ground that they [were] preempted by federal law. . .").

As cases such as these recognize, the statement that a product contains "No Cholesterol" is an express nutrient claim because it is a "direct statement about the level" of cholesterol in the food. See *Kroger*, 2010 WL 4262037 at *4 n. 4 ("The parties do not dispute that the phrases 'cholesterol free' and '0g Trans Fat' per serving are nutrient content claims, which are subject to 21 U.S.C. § 343(r) and to regulations promulgated by the FDA in connection therewith"); see also *Peviani*, 2010 WL 4553510 at *6 ("Defendants' use of the phrase '0 Grams of Trans Fat' outside

the Nutrition Facts Panel constitutes an express nutrient content claim."); *Chacanaca*, 2010 WL 4055954 at *5 ("The threshold question is whether the '0 grams trans fat' statement that appears on the side label of the Chewy Bars box (but outside the nutrition box) is a nutrient content claim. The answer is yes, subsection (r) (and its regulations) controls, and the express preemption provision of section 343-1 is implicated. Specifically, the statement is an express nutrient content claim, or a 'direct statement about the level (or range) of a nutrient in [a] food . . . .' 21 C.F.R. § 101.13(b)(1)").

If Smart Balance complied with the regulatory requirements for labeling a product "Cholesterol Free", then its label is not "false and misleading" under 21 C.F.R. § 101.13(i)(3). See *Kroger*, 2010 WL 4262037 at *4 ("The undisputed fact that the products at issue comply with the requirements under which 'cholesterol free' can be used directly undermines Plaintiffs' argument that Defendant's use of 'cholesterol free' in this case is 'false and misleading.' Given that federal regulations specify when the terms 'cholesterol free' can be used, Defendant's compliance with those regulations cannot be deemed to be 'false or misleading.'"); *id.* at *5 ("While both 21 U.S.C. § 343(a) and 21 C.F.R. § 101.13(i)(3) prohibit labels from being 'false or misleading' or from characterizing nutrient levels in a 'false or misleading' way, 21 U.S.C. § 343(r) and accompanying regulations describe, in detail, nutrient content claims that are permitted under federal law and, therefore, by definition, are not considered 'false or misleading' under federal law. As a general matter, courts do not construe statutory phrases in isolation, but instead, must read statutes as a whole to avoid interpretations that would produce absurd results. In this case, because the terms 'cholesterol free' and '0g Trans Fat' are either expressly defined or permitted under federal regulations, the Court must reject Plaintiffs' argument that nutrient content claims using these same terms in a regulation-compliant manner are nonetheless 'false and misleading' and beyond the NLEA's express preemption provision" (citations omitted)).

Because Yumul seeks to enjoin Smart Balance from placing a "No Cholesterol" label on its product – something the FDA regulations expressly permit Smart Balance to do – a liability finding in this action would impose a requirement "that is not identical" to federal law. As a consequence, so long as Smart Balance's product meets the conditions imposed by the FDCA and

accompanying regulations, plaintiff's claims are expressly preempted by the FDCA and the NLEA. See *Peviani*, 2010 WL 4553510 at *6 ("The FDA regulations explicitly define the term '0 Grams of Trans Fat' and the NLEA expressly prohibits any state from directly or indirectly establishing any requirement that is not identical to the relevant federal requirements. 21 U.S.C. § 343-1(a)(5). Plaintiff's claims seek to enjoin the use of the very term permitted by the NLEA and its accompanying regulations. Plaintiff's claims must therefore fail because they would necessarily impose a state-law obligation for trans fat disclosure that is not required by federal law"); *Kroger*, 2010 WL 4262037 at *7 ("Insofar as Plaintiffs seek to enjoin Defendant's use of the very terms permitted by 21 U.S .C. § 343(r) and regulations promulgated by the FDA in connection therewith, it is difficult for this Court to imagine, and Plaintiffs also have not identified for the Court, a situation in which resolution of Plaintiffs' claims could result in requirements that are 'identical to' FDA regulations. Because Plaintiffs challenge the use of terms that the FDA, through its regulations, has defined and permitted, Plaintiffs' claims fall within the scope of the FDA's preemption clause. The Court therefore finds that Plaintiffs' state law claims are expressly pre-empted by the NLEA"); see also *Turek v. General Mills, Inc.*, __ F.Supp.2d __, 2010 WL 3527553, *6 (N.D. Ill. Sept. 1, 2010) ("Clearly, new requirements that direct manufacturers to label certain fiber nutrients as 'non-natural' and to disclose alleged lack of health benefits are non-identical to and materially different from the current NLEA requirements that do allow inulin to be labeled simply as 'fiber' and do not require manufacturers to disclose any lack of health benefits. Defendants in the instant case have overcome the presumption against preemption due to the particularly strong preemptive language of the NLEA, its thorough regulation of fiber, and the inconsistent labeling that plaintiff's claim would require").

b. "Healthy" Claims

The FDA regulations deem use of the term "healthy" on a food label an implied nutrient claim if it "[s]uggest[s] that a food because of its nutrient content may help consumers maintain healthy dietary practices; and [if the claim is] made in connection with an explicit or implicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams of fat")." 21 C.F.R. § 101.65. Yumul alleges that Smart Balance used "healthy" in the following sentence: "Because it's Lactose

Free and Cholesterol Free, it's the healthy and delicious way to make your favorite dishes come to life."[42] As this statement both suggests that Nucoa "may help consumers maintain healthy dietary practices" and is made in "connection with an explicit . . . statement about" the amount of cholesterol and lactose in the product, it is an implied nutrient claim under 21 C.F.R. §§ 101.13(b)(2). 21 C.F.R. § 101.65(d)(2) permits "the term 'healthy' or related terms (e.g., 'health,' 'healthful,' 'healthfully,' 'healthfulness,' 'healthier,' 'healthiest,' 'healthily,' and 'healthiness') as an implied nutrient content claim on the label or in labeling of a food" so long as the "food meets [certain] conditions for fat, saturated fat, cholesterol, and other nutrients[.]"

Because Yumul seeks to enjoin Smart Balance from labeling its product "healthy" – something the FDA regulations expressly permit Smart Balance to do – a liability finding in this case would impose a requirement "that is not identical" to federal law requirements. As a result, so long as Smart Balance's product meets the conditions imposed by the FDCA and accompanying regulations, the claim is expressly preempted by the FDCA and the NLEA.

3. Whether Plaintiff's Claims Escape Preemption Because Nucoa's Labels Violate the FDCA

Yumul asserts that her claims are not preempted because Nucoa's labels violate the FDCA; consequently, she contends she intends only to *enforce* federal food labeling regulations, not to impose different or non-identical conditions on Smart Balance.[43] Specifically, Yumul maintains that Nucoa labels fail to disclose the product's fat content as required by the FDA regulations.[44] She cites 21 C.F.R. § 101.13(h)(1), which states, in pertinent part, that "[i]f a food . . . 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 reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g . . . , then that food must bear a statement disclosing that the nutrient exceeding the specified level is

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[42]SAC at 15.

[43]Reply, Docket No. 60 (January 10, 2011) at 18-19.

[44]*Id.* at 20.

present in the food as follows: 'See nutrition information for __content' with the blank filled in with the identity of the nutrient exceeding the specified level, e.g., 'See nutrition information for fat content.'"

Plaintiff contends that Nucoa's label violates this provision because it contains more than 13.0g of total fat per 50g, but its label does not bear the statement "See nutrition information for total fat content."[45] Plaintiff contends that this *per se* violation of the FDCA means that her claim that the label is false and misleading is not preempted.

Yumul contends that labeling Nucoa "Cholesterol Free" violated FDA regulations because such a label can only be used if "[t]he label or labeling discloses the level of total fat in a serving . . . of the food. Such disclosure shall appear in immediate proximity to such claim preceding any disclosure statement required under § 101.13(h) in type that shall be no less than one-half the size of the type used for such claim." 21 CFR § 101.62(d)(1). She asserts that the label did not disclose the total fat per serving in proximity to the "Cholesterol Free" claim, i.e., on the same panel of the packaging, and that the Nucoa label violates the FDA regulations as a consequence.[46]

Yumul also maintains that the Nucoa packaging violated the FDA regulations because it included a "No Cholesterol" label without disclosing that cholesterol is not usually present in the food.[47] See 21 CFR § 101.62(d)(1)(ii)(E) ("As required in § 101.13(e)(2), if the food contains less than 2 mg of cholesterol per reference amount customarily consumed . . . without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., 'canola oil, a cholesterol-free food, contains 14 g of fat per serving')").

Finally, Yumul contends that Smart Balance's use of the term "healthy" from November 2009 to June 2010 violated the FDCA because it contained more total fat, saturated fat, and

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[45] *Id.*

[46] *Id.* at 21.

[47] *Id.* at 21-22.

sodium than permitted by 21 C.F.R. § 101.65(d)(2).[48]

Plaintiff argues that based on these *per se* violations of the FDCA, she can state a claim under the California Food, Drug, and Cosmetic Law ("Sherman Law"), California Health & Safety Code §§ 109875-111915. California's Sherman Law "incorporates '[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the [FDCA]' as 'the food labeling regulations of this state.' Thus, California has adopted as its own the FDA regulations" regarding food labeling. See *In re Farm Raised Salmon Cases*, 42 Cal.4th at 1087 (citing CAL. HEALTH & SAF. CODE § 110100). As a result, the California Supreme Court has held that the Sherman Law imposes requirements that are identical to those under the FDCA; thus, claims brought under the Sherman Law are not expressly preempted. See *id.* at 1090, 1094 ("The words of section 343-1 clearly and unmistakably evince Congress's intent to authorize states to establish laws that are 'identical to' federal law. That is precisely what California did in enacting the Sherman Law. The Sherman Law provision prohibiting misbranding with regard to the use of color additives is identical to section 343(k), the parallel federal requirement specifically listed in section 343-1 as one of the federal statutes covered by the express preemption provision. . . . Accordingly, in light of the plain statutory language of section 343-1, and the high court's construction of similar preemption language, we conclude that Congress intended to allow states to establish their own requirements so long as they are identical to those contained in section 343(k), which California has done in the form of the Sherman Law"); see also *Ackerman*, 2010 WL 2925955 at *6 ("Because [the FDCA] preempts any state requirement that is different than FDCA's regulation in Section 343(r)(1), . . . plaintiffs may escape its preemptive force . . . if the plaintiffs' claims seek to impose requirements that are identical to those imposed by the FDCA; . . . [A] state statute mirroring its federal counterpart does not impose any additional requirement merely by providing a damage remedy for conduct that would otherwise violate federal law . . . . Accordingly, claims under state laws that parallel the FDCA's requirements are not preempted").

In a footnote in her reply brief, plaintiff argues that "[a]lthough the [second amended

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[48] *Id.* at 23-24.

complaint's] UCL count does not expressly reference the Sherman Law, the Court should nevertheless construe the [complaint] 'so as to do justice,' FED.R.CIV.PROC. 8(e), and find that Plaintiff's allegations (i.e., that SBI's statements are false and misleading under FDA regulations) state Sherman Law violations supporting Plaintiff's UCL claim. This is especially true because preemption is being raised for the first time in opposition to class certification. Alternatively, if the Court were to find [that] the [second amended complaint] insufficiently alleges direct violations of the FDCA and Sherman Law, Plaintiff would respectfully request leave to amend."[49]

The second amended complaint failed to put Smart Balance on notice that Yumul contended it had violated California's Sherman Law. Yumul's new allegations, raised for the first time in her reply in support of class certification, identify specific FDA regulations that she now contends were violated. While the claim is factually related to the UCL claim pled in the second amended complaint – e.g., plaintiff still appears to argue that defendant's use of the terms "Cholesterol Free" and "healthy" was false and misleading – the foundation of the claim is entirely different. Yumul for the first time asserts that Smart Balance engaged in unfair business practices by labeling its product as it did because the label does not comport with the FDCA and accompanying regulations. This claim, which can only be based on the FDCA or California's Sherman Law, is not pled in the second amended complaint. The complaint alleges that Smart Balance violated California's UCL by using "'unlawful' business acts and practices in that SBI's conduct violates the False Advertising Law and the Consumer Legal Remedies Act."[50] The complaint does not allege, as Yumul does contends, that Smart Balance's actions were unlawful because they violated the Sherman Law.

"A plaintiff alleging unfair business practices under [the UCL] must state with reasonable particularity the facts supporting the statutory elements of the violation." *Khoury v. Maly's of California, Inc.*, 14 Cal.App.4th 612, 619 (1993). Because the 'unlawful' prong of the UCL "'borrows' violations of other laws and makes them independently actionable as unfair competitive

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[49]Reply at 19 n.14.

[50]SAC, ¶ 83.

practices," see *Theme Promotions, Inc. v. News America Marketing FSI*, 546 F.3d 991, 1008 (9th Cir. 2008), "to state a claim for an 'unlawful' business practice under the UCL, a plaintiff must assert the violation of [an]other law." *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal.4th 163, 180 (1999); *Berryman v. Merit Property Management, Inc.*, 152 Cal.App.4th 1544, 1554 (2007) ("Thus, a violation of another law is a predicate for stating a cause of action under the UCL's unlawful prong"); see also *Vega v. JPMorgan Chase Bank, N.A.*, 654 F.Supp.2d 1104, 1117 (E.D. Cal. 2009) (dismissing a UCL claim where "[t]he unfair competition claim identifies no borrowed violated law. . ."); *Lisnawati v. Bank of New York Mellon*, No. C-09-0609 RMW, 2009 WL 1468793, *2 (N.D. Cal. May 26, 2009) (granting "dismissal of the Business and Professions Code § 17200 claim [where] it fail[ed] to identify the purported 'unlawful business activity' that underlie[ ] the claim, [rendering] . . . the claim . . . so uncertain that it is impossible for defendants to respond"). Because the complaint failed to put Smart Balance on notice of Yumul's intent to assert a Sherman Law claim or a UCL claim based on the Sherman Law or the FDCA, she cannot use alleged violations of those statutes to avoid federal preemption of her state law claims.

III. CONCLUSION

For the reasons stated, the court concludes that Yumul's complaint, as currently pled, is preempted by federal law. The court therefore dismisses the complaint for failure to state a claim on which relief can be granted. Because it appears that Yumul may be able to allege violations of the FDCA or the Sherman Law, the dismissal is without prejudice. See *Dumas v. Kupp* , 90 F.3d 386, 389 (9th Cir. 1996) (explaining that dismissal with prejudice is only "appropriate when it is clear that the complaint cannot be saved by further amendment"); *Doe v. United States* , 58 F.3d 494, 497 (9th Cir. 1995) ("'[A] district court should grant leave to amend . . . unless it determines that the pleading could not possibly be cured by the allegation of other facts,'" quoting *Cook, Perkiss & Liehe v. N. Cal. Collection Serv.* , 911 F.2d 242, 247 (9th Cir. 1990)). Yumul is directed to file an amended complaint no later than **ten days** after the date of this order, which pleads non-preempted claims. Yumul is also directed to file a renewed motion for class

certification within **twenty-one** days of this order.

DATED: March 14, 2011

MARGARET M. MORROW
UNITED STATES DISTRICT JUDGE