UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

TONI WELK, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. NUTRACEUTICAL CORPORATION, doing business as Nutrabiogenesis doing business as Biogenesis, Defendant.	Case No.: 3:17-cv-02266-BEN-KSC **ORDER GRANTING MOTION TO DISMISS**

Before the Court is the motion to dismiss Plaintiff's First Amended Complaint filed by Defendant Nutraceutical Corporation ("Nutraceutical"). (Docket No. 15.) The motion is fully briefed. For the reasons that follow, the motion is **GRANTED**.

BACKGROUND[1]

Nutraceutical manufactures, distributes, and sells liquid Vitamin B12 as a dietary supplement under different brands and containing different amounts of Vitamin B12 per

[1] The following overview of the facts is drawn from the relevant allegations of Plaintiff's First Amended Complaint ("FAC"). (Docket No. 13.) The Court is not making findings of fact.

serving. On July 15, 2015, Plaintiff Toni Welk purchased a bottle of Nutraceutical's "Biogenesis – Methyl Factors 2 oz." ("Methyl Factors")[2] Liquid Vitamin B12 supplement. The "Supplement Facts" section of the Methyl Factors bottle declares, *inter alia*, that the serving size of is 1 milliliter (mL), that a single serving contains 1,000 micrograms (mcg) of "Vitamin B12 (as Methylcobalamin)," and that each bottle contains 59 servings. (FAC ¶ 27.)

Plaintiff alleges that Vitamin B12 as Methylcobalamin[3] in liquid form "undergoes degradation at an unknown rate." (*Id.* ¶ 31.) In 2015, "a reputable supplement analysis center located in California" conducted "scientific testing" on the contents of the Methyl Factors bottle and showed the amount of Methylcobalamin on day 1 of testing as 255.87 ug/ml, and on day 11 of testing as 213.16 ug/ml.[4] (*Id.* ¶ 32.) The testing facility received the "sealed" Methyl Factors bottle "in a liquid state in an amber glass bottle at room temperature." (*Id.* ¶ 33.) Based on the test results, Plaintiff alleges the Methyl Factors bottle's label was untrue, false, misleading, and misbranded because a reasonable consumer would expect that each serving from the Methyl Factors bottle would contain 1,000 micrograms of Vitamin B12 for each of the 59 servings. However, because the Methyl Factors product "become[s] unstable immediately after opening" and "starts degrading over time," this does not occur because the amount of Vitamin B12 "becomes negligible and ineffective." (*Id.* ¶ 14.)

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[2] The Court uses "Methyl Factors" to refer to both Nutraceutical's "Biogenesis – Methyl Factors 2 oz." product, and the actual bottle of "Biogenesis – Methyl Factors 2 oz." that Plaintiff allegedly purchased.

[3] The FAC uses "Vitamin B12" and "Methylcobalamin" interchangeably.

[4] The FAC does not discuss the equivalence or measurement conversion, if any, of the Methylcobalamin's weight stated as mcg/mL or ug/ml. However, the parties' briefings do not appear to dispute that Plaintiff's test results indicated the amount of Methylcobalamin in the bottle of Methyl Factors Plaintiff purchased was less than 1,000 micrograms. Therefore, because this issue is not germane to the Court's analysis at this time, the Court assumes this fact to be true in resolving the instant motion.

On November 11, 2017, Plaintiff filed her initial complaint, to which Nutraceutical responded by filing its first motion to dismiss. (Docket Nos. 1, 8.) Instead of responding to Nutraceutical's motion, Plaintiff exercised her right to amend her complaint. The FAC asserts four claims for violations of: (1) Cal. Civ. Code §§ 1750 *et seq.*; (2) Cal. Bus. & Prof. Code §§ 17500 *et seq.*; (3) Cal. Health & Safety Code §§ 110660 *et seq.*; and (4) Cal. Bus. & Prof. Code §§ 17200 *et seq.*, and two additional California state-law claims for negligent misrepresentation and intentional misrepresentation.

In addition to her individual claims, Plaintiff also seeks to obtain "class wide relief on behalf of all purchasers of any of Defendant's Products that are substantially similar to the product purchased by Plaintiff (i.e., all of Defendant's liquid vitamin B12 products, regardless of the brand they are advertised under and the exact amount of liquid B12 vitamin advertised per serving)." (FAC ¶ 1 n.1.)

Nutraceutical now moves for dismissal pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure of all of Plaintiff's claims on three grounds: 1) Plaintiff's claims are preempted; 2) Plaintiff's individual claims are insufficiently pleaded; and 3) Plaintiff lacks standing to assert claims for products she did not purchase.

LEGAL STANDARD

1. Rule 12(b)(1)

"It is a fundamental principle that federal courts are courts of limited jurisdiction." *Stock W., Inc. v. Confederated Tribes of the Colville Reservation*, 873 F.2d 1221, 1225 (9th Cir. 1989) (quoting *Owen Equip. & Erection Co. v. Kroger*, 437 U.S. 365, 374, (1978)). Under Rule 12(b)(1), a party can move a court to dismiss an action for lack of subject matter jurisdiction. Fed. R. Civ. Proc. 12(b)(1). In such a motion, the party asserting jurisdiction bears the burden to establish jurisdiction. *See Kokkonen v. Guardian Life Ins. Co. of America,* 511 U.S. 375 (1994) ("It is to be presumed that a cause lies outside [federal court] jurisdiction . . . and the burden of establishing the contrary rests upon the party asserting jurisdiction.") (internal citations omitted).

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A Rule 12(b)(1) jurisdictional attack may be facial or factual. *White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000). A facial attack asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction. *See Safe Air v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). A Rule 12(b)(1) motion will be granted if, on the face of the complaint, and when considered in its entirety, the complaint fails to allege facts sufficient to establish subject matter jurisdiction. *Id.*

2. Rule 12(b)(6)

Under Federal Rule of Civil Procedure 12(b)(6), a court may dismiss a complaint if, taking all factual allegations as true, the complaint fails to state a plausible claim for relief on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556-57 (2007). Dismissal is appropriate if the complaint fails to state enough facts to raise a reasonable expectation that discovery will reveal evidence of the matter complained of, or if the complaint lacks a cognizable legal theory under which relief may be granted. *Twombly*, 550 U.S. at 556.

DISCUSSION

Defendant contends Plaintiff's claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA") and Nutrition Labeling and Education Act ("NLEA") because Plaintiff does not allege the Methyl Factors product was tested using the methods established by the Food and Drug Administration ("FDA").[5] The Court agrees.

A. Preemption Under the FDCA & NLEA Generally

The FDCA "governs the labeling of food, drugs, cosmetic products and medical devices." *Lilly v. ConAgra Foods, Inc.*, 743 F.3d 662, 664-65 (9th Cir. 2014). In 1990, Congress amended the FDCA by enacting the NLEA, "which established uniform food labeling requirements[.]" *Id.* The NLEA contains an express preemption provision that preempts state-law food-labeling requirements that are "not identical to the requirements

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[5] After Congress enacted the FDCA, the FDA was established. 21 U.S.C. § 393(a).

of section 343(r)." 21 U.S.C. § 343-1(a)(5). The phrase "not identical to" means "that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food [that] . . . [a]re not imposed by or contained in the applicable [federal regulation] . . . or [d]iffer from those specifically imposed by or contained in the applicable [federal regulation]." *Lilly*, at 665 (quoting 21 C.F.R. § 100.1(c)(4)) (alterations in original). These provisions apply to dietary supplements because dietary supplements are deemed to be "food" for purposes of the FDCA. 21 U.S.C. § 321(ff).

Under this framework, state-law claims are generally preempted only "where application of state laws would impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA." *Gallagher v. Bayer AG*, No. 14-CV-04601-WHO, 2015 WL 1056480, at *4 (N.D. Cal. Mar. 10, 2015)). Conversely, "[i]f a lawsuit asserts that a manufacturer has violated the FDCA (as amended by NLEA) and does not seek to impose additional or contrary burdens to those imposed under the FDCA, the claims raised under state law are not preempted." *Id.*, at *4 (citing *Salazar v. Honest Tea, Inc.*, No. 2:13-CV-02318-KJM, 2014 WL 2593601, at *4 (E.D. Cal. June 10, 2014)). In short, to avoid preemption under 21 U.S.C. § 343-1(a), "the plaintiff must be suing for conduct that violates the FDCA" but not "solely because the conduct violates the FDCA, else his claim would be impliedly preempted under [21 U.S.C. §] 337(a)." *Trazo v. Nestle USA, Inc.*, No. 5:12-CV-2272-PSG, 2013 WL 4083218, at *5 (N.D. Cal. Aug. 9, 2013) (emphasis in original omitted).

B. Federal Labeling Requirements for Vitamin B12

Under 21 U.S.C. § 343(a), a dietary supplement is misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 343(a). Federal regulations established by the FDA require that the "nutrition information on the label" include a "declaration of vitamins and minerals . . . listed in paragraph (c)(8)(iv) . . . as a statement of the amount per serving . . . as described in this paragraph, calculated as a percent of the RDI and expressed as a percent of the Daily Value, when they are added as a nutrient

supplement, unless otherwise stated as quantitative amount by weight and percent of the Daily Value."[6] *See* 21 C.F.R. § 101.9(c)(8). Vitamin B12 is one of the listed vitamins. *See* 21 C.F.R. § 101.9(c)(8)(iv). The "quantitative amount" of Vitamin B12 "shall be the amount . . . included in one serving" using micrograms as the unit of measurement. *See* 21 C.F.R. § 101.9 subds. (c)(8)(iii)-(c)(8)(iv).

Compliance with the labeling requirements under 21 C.F.R. § 101.9(c)(8) is determined based on a specific testing methodology described in 21 C.F.R. § 101.9(g)(2), which provides:

> The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.

21 C.F.R. § 101.9(g)(2). Thus, in order to comply with federal labeling requirements, the Methyl Factors products' label's statement that it contains 1,000 micrograms of Vitamin B12 as Methylcobalamin must be based on results of testing conducted in accordance with 21 C.F.R. § 101.9(g)(2).

C. Whether Plaintiff's Claims are Preempted

Each of Plaintiff's claims are predicated on Plaintiff's ability to prove that, *once opened*, Defendant's Biogenesis – Methyl Factors 2 oz. product does not contain 1,000 micrograms of Methylcobalamin per 1 milliliter serving for each of the 59 servings throughout the duration of its shelf life. Indeed, the FAC is careful to avoid allegations

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[6] For "dietary supplements," such as the Methyl Factors products, the "nutrition information" must be "enclosed in a box" titled "Supplement Facts." *See* 21 C.F.R. § 101.36(e).

that the Methyl Factors bottle did not contain the stated amount of Vitamin B12 at the time of manufacturing lest her claim be impliedly preempted under 21 U.S.C. § 337(a). *See Trazo*, 2013 WL 4083218, at *5.

Plaintiff's theory is that the Methyl Factors label is misleading because it fails to disclose that the product "become[s] unstable upon opening and degrade[s] over time, such that the amount of B vitamins becomes negligible and ineffective." (FAC ¶ 40.)[7] To establish this theory, Plaintiff alleges:

> In 2015, scientific testing by a reputable supplement analysis center located in California of [Methyl Factors] (labeled as "Serving Per Container: 59" with a "Serving Size 1ml") revealed that on day 1 of testing, the level of Methylcobalamin in the product was 255.87 ug/ml, and on day 11 of testing it was213.16 ug/ml.
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> The product was received by the testing facility in a liquid state in an amber glass bottle at room temperature, in a sealed bottle.

(FAC ¶¶ 32-33.) These are the only factual allegations supporting Plaintiff's conclusion that the Methyl Factors products "become unstable immediately upon opening," and "starts degrading over time such that the amount of vitamin B12 becomes negligible and ineffective." (*Id.* ¶ 14.)

Defendant contends Plaintiff's claims are preempted because the testing methodology referenced above does not comply with 21 C.F.R. § 101.9(g)(2), and therefore Plaintiff ultimately seeks to seek to impose obligations under California state law that conflict with those set forth in the FDCA and NLEA. Specifically, Defendant points out that Plaintiff's own allegations indicate only one bottle of the Methyl Factors

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[7] Plaintiff's opposition improperly attempts to argue a new theory of liability, *i.e.*, that Defendant failed its "obligation to design its packaging in such a way that the product would not be subjected to degradation." (Opp'n at p. 9.) This theory was not previously alleged in the FAC, and therefore the Court does not consider Plaintiff's arguments regarding this theory.

product was tested, from which the Court may draw an inference that the testing method mandated by 21 C.F.R. § 101.9(g)(2) was not followed. Defendant further cited a number of district court cases with similar facts who all dismissed a plaintiff's claims as preempted in failing to allege compliance with 21 C.F.R. § 101.9(g)(2). (*See* Mot. at pp. 9-12.)

In opposition, Plaintiff agrees that her claim under California Health & Safety Code § 10660 ("the Sherman Act") for label misbranding is identical to 21 U.S.C. § 343(a) and that "they are identical in language and standards." (Opp'n at p. 8.) However, she nevertheless argues it would be "illogical" and "unfair" to require her to use testing that complies with 21 C.F.R. § 101.9(g)(2) because her claim is based on the Methyl Factors products' "rapid degradation," which is "measured by one sample's change over a period of time." (Opp'n at p. 12.) Plaintiff cites no authority for this conclusion, and the Court is not persuaded by its premise.

In the words of one district court: "where, as here, an FDA regulation provides that the question of compliance must be determined using the method specified therein, a state law claim that seeks to establish a violation of such regulation by a different methodology is preempted." *Mee v. I A Nutrition, Inc.*, No. C-14-5006 MMC, 2015 WL 2251303, at *4 (N.D. Cal. May 13, 2015) (citing *Salazar*, 2014 WL 2593601, at *1, 6 (granting motion to dismiss claim that defendant's teas "did not contain the amount of antioxidants represented on their labels," where plaintiff failed to allege the "independent testing" on which she relied had been conducted in accordance with § 101.9(g)(2)); *Vital v. One World Co.*, 2012 U.S. Dist. LEXIS 186203, at *2, 13-18 (C.D. Cal. November 30, 2012) (finding defendant entitled to summary judgment on claim defendant made "overstatement of the magnesium and sodium content" of its coconut water product, where plaintiffs failed to offer evidence to show report on which they relied had been conducted in accordance with § 101.9(g)(2)); *Burke v. Weight Watchers Int'l, Inc.*, 983 F. Supp. 2d 478, 480, 483 (D.N.J. 2013) (granting motion to dismiss claim alleging defendant's ice cream bars' "calorie content [was] 20%-36% greater than the calorie

content listed on the box," where plaintiff, inter alia, failed to allege the "independent laboratory tests" on which she relied were conducted in accordance with the methodology set forth in § 101.9(c)(1)(I))).

In sum, in order for Plaintiff to ultimately prove her claims that the Methyl Factors products "become unstable immediately after opening" and "start[] degrading over time" such that the Methyl Factors label is misleading and/or misbranded, the Methyl Factors products must be tested. As discussed above, federal law preempts how the testing must be conducted. Plaintiff's opposition effectively concedes that the "scientific testing" upon which her claims rely does not comply with the requirements for testing under 21 C.F.R. § 101.9(g)(2). And, even construing the factual allegations in a light most favorable to Plaintiff, the Court is unable to draw this inference. As a result, the Court **GRANTS** Defendant's motion to dismiss on this ground.[8]

CONCLUSION

For the forgoing reasons, the Court finds Plaintiff's claims are preempted by the FDCA and NLEA, and Defendant's motion to dismiss Plaintiff's First Amended Complaint is **GRANTED**. However, the Court shall provide Plaintiff with an opportunity to amend her pleading to correct the deficiencies identified in this Order. Therefore, Plaintiff's FAC is **DISMISSED without prejudice**. If Plaintiff elects to amend her pleading, it must be filed by no later **August 17, 2018**.

IT IS SO ORDERED.

Dated: August 10, 2018

Hon. Roger T. Benitez
United States District Judge

[8] Because the Court finds Plaintiff's claims preempted by the FDCA and NLEA, it declines to rule on Defendant's remaining arguments.