IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

MARTIN MEE and JUNIOR HERMIDA,

Plaintiffs,

v.

I A NUTRITION, INC.,

Defendant.
/

No. C-14-5006 MMC

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS; DISMISSING FIRST AMENDED COMPLAINT; AFFORDING PLAINTIFFS LEAVE TO AMEND; CONTINUING CASE MANAGEMENT CONFERENCE

Before the Court is defendant I A Nutrition, Inc.'s Motion to Dismiss, filed March 6, 2015. Plaintiffs Martin Mee and Junior Hermida have filed opposition, to which defendant has replied. Having read and considered the papers filed in support of and in opposition to the motion, the Court rules as follows.[1]

I. BACKGROUND

A. Products at Issue

In the operative complaint, the First Amended Complaint ("FAC"), plaintiffs allege they each purchased defendant's Inner Armour "dietary supplements," specifically, "Mass Peak Whey Hydrolysate Enhanced," "Nitro Peak Whey Hydrolysate Enhanced," "Casein Peak," "Whey Protein," and "Super Quad Protein." (See FAC ¶¶ 1, 10, 11, 45.) According to plaintiffs, defendant labels and sells the above-referenced five products in a "misleading

[1]By order filed May 5, 2015, the Court took the matter under submission.

and deceptive manner." (See FAC ¶ 8.)

B. Plaintiffs' Claims

The FAC contains six causes of action, each arising under California or Florida law,[2] and each of which is based on the following claims:

1. False or Misleading Representations in "Supplement Facts" Section of Labels

Plaintiffs allege the representation as to the amount of protein contained in each of the five subject products, made in the "Supplement Facts" section on the back of the label for each product, is false or misleading because, according to "scientific tests" performed for plaintiffs, the actual amount of protein contained in the products is lower than the amount stated. (See FAC ¶¶ 27-28, 33-34, 38-39, 43-44, 50, Exs. A-E.)

2. False or Misleading Representations on Front of Labels

a. Plaintiffs allege the representation as to the amount of protein contained in each of the five subject products, made on the front label of each product, is false or misleading because, according to "scientific tests" performed for plaintiffs, the actual amount of protein contained in the products is lower than the amount stated. (See FAC ¶¶ 28, 34, 39, 44, 50-51, 63-65, Exs. A-E.)

b. Plaintiffs allege the representation as to the amount of "BCAAs,"[3] a reference to "the free form amino acids L-Leucine, L-Valine, and L-Isoleucine" (see FAC ¶ 62), contained in Mass Peak Whey Hydrolysate, Nitro Peak Whey Hydrolysate, and Casein Peak, made on the front label of said products, is false or misleading, because, according to "scientific testing" performed for plaintiffs, the actual amount of BCAAs contained in the products is lower than the amount stated. (See FAC ¶ 63-65; Exs. A-C.)

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[2]Mee is a California resident who allegedly purchased the subject products in California (see FAC ¶ 10), and Hermida is a Florida resident who allegedly purchased the subject products in Florida (see FAC ¶ 11).

[3]The term "BCAAs" is, according to plaintiffs, a reference to "free form amino acids L-Leucine, L-Valine, and L-Isoleucine." (See FAC ¶ 62.)

c. Plaintiffs allege the amount of amino acid "Glutamine" contained in Mass Peak Whey Hydrolysate and Nitro Peak Whey Hydrolysate, made on the front label of said products, is false or misleading, because, according to "scientific testing" performed for plaintiffs the actual amount of Glutamine contained in the products is lower than the amount stated. (See FAC ¶ 63-64; Exs. A-B.)

d. Plaintiffs allege a reasonable consumer would believe the statement as to the amount of protein contained in Super Quad Protein, made on the front of the label, refers to the amount of four "quad" proteins, when, according to "scientific testing" performed for plaintiffs, the referenced amount corresponds not only to the amount of four "quad" proteins, but also to the amount of "several free form amino acids" contained in Super Quad Protein. (See FAC ¶¶ 50, 52-57, Ex. E.)

3. False Statements or Omissions Regarding Presence of Ingredients

a. Plaintiffs allege the ingredient list on the labels of Mass Peak Whey Hydrolysate Enhanced, Nitro Peak Whey Hydrolysate and Casein Peak state the products contain "free form amino acids L-Leucine, L-Valine, and L-Isoleucine," but, according to "scientific testing" performed for plaintiffs, said products do not contain any of those amino acids. (See FAC ¶ 62, Exs. A-C.)[4]

b. Plaintiffs allege the front label of Casein Peak states the product contains "Glutamine," but, according to "scientific testing" performed for plaintiffs, said product does not contain "free form Glutamine." (See FAC 65, Ex. C.)

c. Plaintiffs allege that, according to "laboratory results" obtained by plaintiffs, Mass Peak Whey Hydrolysate Enhanced and Nitro Peak Whey Hydrolysate each contain two amino acids, specifically, "Alanine" and "Tryptophan," that are "not declared in the labeling." (See FAC ¶¶ 60-61, 67, Exs. A-B.)

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[4]The Court notes that, as stated above, plaintiffs have alleged that Mass Peak Whey Hydrolysate and Nitro Peak Whey Hydrolysate do contain "BCAAs," i.e., "free form amino acids L-Leucine, L-Valine, and L-Isoleucine," albeit not in the amount stated on the label. (See FAC ¶¶ 63, 64.) Consequently, it appears plaintiffs are alleging, in the alternative, that said two products either have no BCAAs or have less than the amount stated on the label.

II. DISCUSSION

Defendant argues that each of plaintiffs' causes of action is preempted by the Food, Drug and Cosmetic Act ("FDCA").

"The [FDCA] governs the labeling of food, drugs, cosmetic products and medical devices." Lilly v. ConAgra Foods, Inc., 743 F.3d 662, 664 (9th Cir. 2014). Under the FDCA, the Food and Drug Administration ("FDA") is required to "establish[ ] uniform food labeling requirements," see id. at 664-65, and states are prohibited from imposing "'any requirement for the labeling of food that is not identical to' the federal requirements." See id. at 664-65 (quoting 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].'" Id. at 665 (quoting 21 C.F.R. § 100.1(c)(4); ellipses and alterations in original). In sum, as one district court has observed, "[t]o avoid preemption under Section 343-1(a), the plaintiff must be suing for conduct that violates the FDCA." See Trazo v. Nestle USA, Inc., 2013 WL 4083218, at *5 (N.D. Cal. August 9, 2013) (emphasis omitted).

Defendant contends each of plaintiffs' claims seeks to impose obligations on defendant that conflict with those set forth in the FDCA.

First, with respect to plaintiffs' claim that defendant has misrepresented the amount of protein in the "Supplement Facts" section on the back of each label, defendant argues said claim is preempted in light of 21 C.F.R. § 101.9(c)(7). As discussed below, the Court agrees.

Federal regulations require that the "declaration of nutrition information on the label," see 21 C.F.R. § 101.9(c)(7),[5] include "the number of grams of protein in a serving, expressed to the nearest gram," see 21 C.F.R. § 101.9(c)(7), and further provide that

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

"[p]rotein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the 'Official Methods of Analysis of the AOAC International,'" see id. In the FAC, plaintiffs do not allege the protein content set forth in the Supplement Facts was not calculated in conformity with § 101.9(c)(7), Rather, plaintiffs allege, calculating protein content using nitrogen as a "tag," i.e., the method allowed under § 101.9(c)(7), does not result in "a direct measure of the actual protein content" (see FAC ¶ 3), and that, in order to state the "[t]rue [p]rotein content, the manufacturer must "exclude[ ] any non-protein nitrogen-containing substances" (see FAC ¶ 6). Plaintiffs' claim, specifically, that the protein content stated in the Supplement Facts is false for the reason that the calculation was made without excluding such non-protein nitrogen-containing substances (see FAC ¶¶ 19, 25, 31, 36, 41, 48), is preempted, as it seeks to base liability on defendant's failure to employ a testing procedure not imposed by or contained in any federal regulation, and, indeed, is a challenge to the very method allowed by the FDA.

Accordingly, to the extent plaintiffs' causes of action are based on the claim that defendant has misrepresented the amount of protein in the Supplement Facts, plaintiffs' causes of action are subject to dismissal. Plaintiffs may amend this claim if plaintiffs can in good faith allege defendant's representations as to the amount of protein in the Supplement Facts section are in violation of § 101.9(c)(7).

Second, defendant argues, the remaining claims are preempted for the reason that plaintiffs have failed to allege the testing they employed, in order to determine the amount of protein and amino acids in the products and to determine which ingredients are or are not contained therein, complies with the testing method set forth in 21 C.F.R. § 101.9(g)(2). The methodology set forth in § 101.9(g)(2) requires that 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." See 21 C.F.R. § 101.9(g)(2). Said methodology must be used to determine "compliance with the requirements for nutrient content claims," see 21 C.F.R. § 101.13(o), i.e., plaintiffs' claims

that the front of the labels contains false statements as to the amount of protein and amino acids contained in the products, see 21 C.F.R. §§ 101.13(b)(1), 101.13(c). That same methodology also must be used to determine "compliance with [21 C.F.R. § 101.36]," see 21 C.F.R. § 101.36(f)(1), which regulation addresses which "dietary ingredients" must be contained in the ingredient list in the Supplement Facts section of a dietary supplement, see 21 C.F.R. §§ 101.36(a), 101.36(b)(2)-(b)(3), 101.36(c), 101.36(e). In sum, the accuracy of the statements on the front of defendant's labels as to the protein content and the amino acid content and the accuracy of the list of ingredients in the Supplement Facts must be determined using the 12-sample method set forth in § 101.9(g).[6]

As each district court to have considered the matter has found, 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. See Salazar v. Honest Tea, Inc., 2014 WL 2593601, at *1, 6 (E.D. Cal. June 10, 2014) (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)); see also Burke v.

[6]The Court notes that, with respect to Nitro Peak Whey Hydrolysate Enhanced, plaintiffs allege the front label states the product has "48g Protein," while the Supplement Facts states the product has "24g" of protein. (See FAC ¶¶ 29-30.) It would appear, at least in the absence of some explanation not immediately evident from the copy of the labels shown in the FAC, that one of those statements, or both, is false or misleading. If plaintiffs had conceded the "24g" statement was true, plaintiffs might have been able to establish the "48g" statement was false, without having to show non-compliance using the 12-sample method set forth in § 101.9(g). Here, however, plaintiffs, relying on "scientific testing," allege that both statements regarding the protein content of Nitro Peak Whey Hydrolysate Enhanced are false, in that the "actual" content is alleged to be 12.761 grams of protein. (See FAC ¶ 33.)

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)).

Plaintiffs do not allege the testing on which they rely was conducted in accordance with the 12-sample method set forth in § 101.9(g)(2). Rather, plaintiffs argue the issue should not be considered in the context of a motion to dismiss, but, rather, as was the case in Vital, 2012 U.S. Dist. LEXIS 186203, in the context of a motion for summary judgment, or at a later stage of the proceedings.

The Court need not decide whether a plaintiff, to avoid dismissal on the basis of preemption, must in all cases allege compliance with § 101.9(g)(2) at the pleading stage, because, in the instant case, plaintiffs have attached, as exhibits to the FAC, copies of the laboratory reports showing the results of the testing on which they rely (see FAC Exs. A-E), and, consequently, appear to have pleaded facts demonstrating preemption. In particular, each report attached to the FAC pertains to one of the five products, each indicates that "the sample" was tested, and, for each of those five products, sets forth the amount of various ingredients found in a single sample. (See id.) Nothing in the reports suggests that the 12-sample method required by § 101.9(g)(2) was employed. Under such circumstances, the Court finds the remaining claims, as pleaded, are preempted. Given plaintiffs' assertion that the issue should be addressed at a later stage, however, which assertion could be understood to suggest plaintiffs are relying on other test results and/or that the results attached to the FAC are incomplete in some manner, the Court will afford plaintiffs leave to amend to allege compliance with § 101.9(g)(2).

Accordingly, to the extent plaintiffs' causes of action are based on a claim that defendant has misrepresented the amount of protein and amino acids on the front of the labels, that defendant has not included in the ingredient lists certain amino acids contained in some of the products, and that defendant has included in the ingredient lists certain

amino acids not contained in some of the products, plaintiffs' causes of action likewise will be dismissed, with leave to amend.[7]

III. CONCLUSION

For the reasons stated above, defendant's motion to dismiss is hereby GRANTED, and the First Amended Complaint is hereby DISMISSED with leave to amend.

Any Second Amended Complaint shall be filed no later than June 1, 2015.

In light of the above, the Case Management Conference is hereby CONTINUED from June 19, 2015, to August 21, 2015, at 10:30 a.m. A Joint Case Management Statement shall be filed no later than August 14, 2015.

IT IS SO ORDERED.

Dated: May 13, 2015

MAXINE M. CHESNEY
United States District Judge

[7]In light of the Court's ruling as to preemption, the Court need not address defendant's additional arguments in support of dismissal.