UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DEREK GUBALA, individually and on behalf of all others similarly situated,	)	
Plaintiff,	)	
	)	No. 14 C 9039
vs.	)	
CVS PHARMACY, INC.,	)	Judge Thomas M. Durkin
Defendant.	)	

MEMORANDUM OPINION AND ORDER

TABLE OF CONTENTS

I. INTRODUCTION

II. BACKGROUND

- **A. THE AMENDED COMPLAINT**
- **B. CVS'S MOTION TO DISMISS**

III. DISCUSSION

- **A. FEDERAL PREEMPTION PRINCIPLES**
- **B. NUTRITION FACTS DISCLOSURES ("BACK PANEL")**
  - **1. SECTION 101.9(c)(7)(i) AND (ii)—PROTEIN CONTENT VERSUS PROTEIN QUALITY**
  - **2. SECTION 101.9(g)(2)—COMPOSITE OF 12 SUBSAMPLES**
  - **3. SECTION 101.9(g)(4)(ii)—80% SAFE HARBOR RULE**
- **C. FRONT LABEL DISCLOSURES**
  - **1. PRODUCT NAME—"WHEY PROTEIN POWDER"**
  - **2. NUTRIENT CONTENT CLAIM—"26 GRAMS OF HIGH-QUALITY PROTEIN"**
- **D. INGREDIENTS DISCLOSURES**

1. ASPARAGINE AND HYDROXYPROLINE

2. GLUTAMINE AND BCAAS L-LEUCINE, L-ISOLEUCINE, AND L-VALINE

E. PRIMARY JURISDICTION

F. FAILURE TO STATE VALID STATE LAW CLAIMS

1. DECEPTIVE TRADE PRACTICES

2. UNJUST ENRICHMENT

3. BREACH OF EXPRESS WARRANTY

III. CONCLUSION

I.
INTRODUCTION

Plaintiff Derek Gubala filed this putative consumer class action lawsuit on November 11, 2014, alleging that Defendant CVS Pharmacy, Inc. ("CVS") makes false and misleading claims on the label of its protein powder supplement "WHEY PROTEIN POWDER NATURALLY AND ARTIFICIALLY FLAVORED DRINK MIX" (hereinafter the "Product"). CVS filed its first motion to dismiss on January 15, 2015, R. 16, which the Court granted without prejudice on June 16, 2015, R. 32 (*Gubala v. CVS, Inc.*, 2015 WL 3777627 (N.D. Ill. June 16, 2015)). Thereafter, Plaintiff filed an amended complaint. R. 33. Currently before the Court is CVS's second motion to dismiss ("Motion"), which addresses Plaintiff's new allegations in the amended complaint. R. 40. For the reasons that follow, the Court now denies CVS's Motion.

II.

BACKGROUND

A. THE AMENDED COMPLAINT[1]

Plaintiff alleges that CVS makes false statements regarding the Product's (1) total protein content in grams, (2) protein daily value percentage ("DV%"), and (3) amino acids under "Ingredients" on the back label. Plaintiff also alleges that the product name "Whey Protein Powder" and representation "26 grams of high-quality protein," appearing on the Product's front label, are misleading.[2] According to Plaintiff, the only protein source that is an "actual protein" is whey protein.[3] Plaintiff alleges the Product contains only 21.8 grams of whey protein, and he attaches a copy of a laboratory report to support that allegation. The remaining 4.2 grams of protein CVS advertises on the label is not made up of whey protein but free form amino acids and other non-protein ingredients, which are cheaper and less nutritionally beneficial than whey protein. Plaintiff alleges that this difference is significant because "[s]everal studies show that free-form amino acids are not

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[1] In deciding CVS's Motion, the Court accepts all well-pleaded facts of the amended complaint as true and draws all reasonable inferences in favor of Plaintiff. *See Mann v. Vogel*, 707 F.3d 872, 877 (7th Cir. 2013).

[2] The front and back package labels are reproduced in the Appendix to this opinion.

[3] The amended complaint alleges that "[w]hey is a complete protein source, meaning it contains all the essential amino acids needed to build protein-based compounds, such as muscle tissue, skin, fingernails, hair and enzymes. It is especially rich in branded chain amino acids—leucine, isoleucine, and valine—which are metabolized directly within the muscles (as opposed to being processed in the liver first)." R. 33, ¶ 10.

absorbed as effectively as whole protein" and therefore "do not provide the same beneficial effects as whole protein." R. 33, ¶ 25 (footnote omitted).

How these free form amino acids and other non-protein ingredients come to be included in the total protein count disclosed on the Product's label is explained in somewhat greater detail in the amended complaint. *See* R. 33, ¶¶13-14. Essentially, however, the parties appear to agree that, pursuant to 21 C.F.R. § 101.9(c)(7), the United States Food and Drug Administration ("FDA") generally allows the protein content in food products to be calculated based on a methodology that measures the nitrogen content of the food:

> Protein 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" . . . , except when the official procedure for a specific food requires another factor.

The Court will refer to the FDA-approved methodology for determining protein content as the nitrogen content method. The nitrogen content method allows a manufacturer to boost the declared protein content in a food product by adding nitrogen-containing ingredients that are not actually proteins, such as free form amino acids. Plaintiff refers to this practice as "protein-spiking," and it has sparked the filing of numerous putative consumer class action lawsuits like the present one,[4]

[4] *See, e.g., Durnford v. Musclepharm Corp.*, 2015 WL 9258079 (N.D. Cal. Dec. 18, 2015); *Gubala v. Allmax Nutrition, Inc.*, 2015 WL 6460086 (N.D. Ill. Oct. 26, 2015); *Clay v. Cytosport, Inc.*, 2015 WL 5007884 (S.D. Cal. Aug. 19, 2015); *Brauner v. MusclePharm Corp.*, 2015 WL 4747941 (C.D. Cal. Aug. 11, 2015); *Mee v. IA*

as well as commentary from within the food industry.[5]

Plaintiff's claims in the amended complaint are based on state law: Count I alleges a claim for unfair and deceptive trade practices under the Illinois Consumer Fraud Act, 815 ILCS 505/1 *et seq*.; Count II alleges a claim for unjust enrichment; and Count III alleges a claim for breach of express warranty. The amended complaint seeks certification of a national class of all persons in the United States who purchased the Product, as well as a subclass of Illinois purchasers. Jurisdiction in this Court is premised on the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d)(2)(A).[6]

Nutrition, Inc., 2015 WL 2251303 (N.D. Cal. May 13, 2015); *Rodriquez v. Giant Sports Prods*., 2014-cv-08378 (C.D. Cal. Oct. 29, 2014); *Mencer v. NBTY, Inc.*, 2014-cv-05030 (E.D.N.Y. Aug. 25, 2014); *see also Smith v. Allmax Nutrition, Inc.*, 2015 WL 9434768 (E.D. Cal. Dec. 24, 2015).

[5] The amended complaint cites to comments purportedly made in the press as well as on the website of a company that sells nutritional supplements. Also, both parties cite to published comments submitted to the FDA by the American Herbal Products Association (AHPA), which do not discuss "protein spiking," but do advocate that the nitrogen content method be eliminated from the regulations and that the FDA require food manufacturers to exclude non-protein nitrogen sources such as free form amino acids from the declared grams of protein on the labels of all products. *See* Comments of AHPA on Proposed Rule on Food Labeling: Revision of the Nutrition And Supplement Facts Labels (hereinafter "AHPA Comments"), Dkt. No. FDA-2012-N-1210 at 4-5 (Aug. 2014), available at *http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0399*. The Court can take judicial notice of the *AHPA Comments* and their contents. *See Indep. Trust Corp. v. Stewart Info. Servs. Corp*., 665 F.3d 930, 943 (7th Cir. 2012) (in ruling on motion to dismiss, district court may take judicial notice of the indisputable facts that documents in the public domain exist and that they say what they say).

[6] The CAFA grants federal jurisdiction over class actions in which at least $5,000,000 is in controversy, minimal diversity exists between the parties, and the total number of members of the class is greater than 100. *See* 28 U.S.C. § 1322(d). Plaintiff alleges that he is a citizen of Illinois and that CVS is a citizen of Delaware and Rhode Island, thus establishing the minimal diversity requirement. The

B. CVS's Motion To Dismiss

The original complaint was premised on the same underlying alleged misconduct as the amended complaint—that the Product's label suggests that the entire protein content in the Product is made up of whey protein when, in fact, that is not the case. The Court dismissed the original complaint because Plaintiff conceded that CVS was permitted by federal law to calculate the protein content of the Product using the nitrogen content method. Therefore, the Court held, Plaintiff's state law claims seeking to recover for deception that allegedly flows from the permitted calculation were preempted by federal law. In the current Motion, CVS argues that Plaintiff's re-pled state law claims also are preempted. In addition, CVS raises various other arguments it previously made in moving to dismiss the original complaint. The Court will address each of CVS's arguments in turn.

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amended complaint alleges upon information and belief that "[c]lass members number in the thousands to millions." R. 33, ¶ 78. While this number is sufficient to establish the minimum class number of more than 100, the question remains whether there is a sufficient number of class members to satisfy the $5,000,000 threshold amount in controversy. If the only damages each member of the class suffered is the $20 purchase price alleged in the amended complaint, then the class would have to consist of at least 250,000 members. Thus, the thousands to millions range given in the amended complaint is too broad for the Court to say whether Plaintiff can meet the jurisdictional minimum. Nevertheless, Plaintiff alleges that his claims and the claims of the other members of the Class exceed $5,000,000, R. 33, ¶ 5, and CVS has not challenged that allegation. Therefore, the Court concludes for purposes of CVS's Motion that jurisdiction has been properly alleged. *See Meridian Sec. Ins. Co. v. Sadowski*, 441 F.3d 536, 542-43 (7th Cir. 2006) (court must accept the plaintiff's factual allegations on which jurisdiction is based at pleading stage unless they are contested by the defendant).

III.

DISCUSSION

A. FEDERAL PREEMPTION PRINCIPLES

CVS's arguments for dismissal based on federal preemption are properly addressed under Fed. R. Civ. P. 12(b)(6). *See Healy v. Metro. Pier & Exposition Auth.*, 804 F.3d 836, 840-41 (7th Cir. 2015) (*citing Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 425 (7th Cir. 2011) (holding that if plaintiff's state law claim is preempted then dismissal under Rule 12(b)(6) is the proper outcome rather than dismissal for want of federal jurisdiction)). The Seventh Circuit has "treated federal preemption as an affirmative defense upon which the defendant bears the burden of proof, and presumably the burden of persuasion, even if no additional facts must be proven and the issue is only a question of law." *Russian Media Grp., LLC v. Cable Am., Inc.*, 598 F.3d 302, 309 (7th Cir. 2010). Moreover, the Supreme Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action," particularly in cases involving the historic police powers of the States to regulate health and safety. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

CVS argues that Plaintiff's state law claims are preempted by the express labeling requirements of the Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Nutrition Labeling and Education Act ("NLEA"). The FDCA requires most foods to bear nutrition labeling and regulates nutrient content claims and certain health messages on food labels. Section 343(q)(1)(D) requires food labels to bear nutrition information that provides, among other things, the amount of total protein contained in each serving size or other unit of measure. 21 U.S.C. § 343(q)(1)(D).

Section 343(r) states that if a food label makes an express or implied characterization about the level of a nutrient in a product it must comply with certain specified requirements. 21 U.S.C. § 343(r). Section 343(a) declares generally that a food is misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 343(a)(1).

CVS's Motion is premised on § 343-1, which is an express preemption provision that prohibits the establishment of any labeling requirement falling within the scope of the FDCA provisions enumerated therein unless the labeling requirement is identical to the requirements of the enumerated provisions. 21 U.S.C. § 343-1. As Plaintiff points out, 21 U.S.C. § 343(a)(1), which contains the general "false or misleading in any particular" language, is not one of the provisions identified in 21 U.S.C. § 343-1 as having preemptive effect. Section 343(q) and § 343(r), however, are included among the enumerated provisions to which § 343-1 expressly gives preemptive effect. The labeling requirements of those sections are further delineated in 21 C.F.R. § 101.9 and other parts of the implementing regulations of the FDA, which also have preemptive effect. *See Fidelity Fed. Savs. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) ("Federal regulations have no less pre-emptive effect than federal statutes.").

The preemptive effect of § 343-1 "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005). A cause of action under Illinois law for false or misleading product labeling is preempted, therefore, whether based on an

Illinois statute, regulation, or common law duty, if it seeks to impose labeling or other requirements that are not identical to the requirements imposed by § 343(q), § 343(r), and the implementing regulations for those provisions. The FDA has said that "'[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) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or (ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act." 21 C.F.R. § 100.1(c)(4). Claims under state law that parallel the FDCA's requirements, however, are *not* preempted. *Turek*, 662 F.3d at 426; *see Beverages: Bottled Water*, 60 Fed. Reg. 57076-01, 57120, 1995 WL 668939 (FDA Nov. 13, 1995) ("[I]f the State requirement does the same thing that the Federal law does, . . . then it is effectively the same requirement as the Federal requirement. . . . [T]he only State requirements that are subject to preemption are those that are affirmatively different from the Federal requirements on matters that are covered by section [343-1] of the act.").[7] "The state thus can impose the identical requirement or requirements, and by doing so be enabled, because of the narrow scope of the

[7] The Court may consider FDA documents in the Federal Register in ruling on CVS's Motion. *See Denius v. Dunlap*, 330 F.3d 919, 926-27 (7th Cir. 2003) (citing 44 U.S.C. § 1507 ("The contents of the Federal Register shall be judicially noticed . . . ."); *City of Charleston v. A Fisherman's Best, Inc.*, 310 F.3d 155, 172 (4th Cir. 2002) (appeals court can take judicial notice of proposed rule published in Federal Register even if the proposed rule was not called to the attention of the trial court); *Poindexter v. United States*, 777 F.2d 231, 236 (5th Cir. 1985) (appeals court is required to take judicial notice of information contained in agency regulations)).

preemption provision in the [NLEA], to enforce a violation of the Act as a violation of state law. This is important because the [FDCA] does not create a private right of action." *Turek,* 662 F.3d at 426 (citations omitted).

CVS argues that the Court must "ignore" any allegation by Plaintiff "that CVS is violating or has violated the FDCA." R. 41 at 4 n.7. That statement, however, is incorrect. Instead, "the conduct on which [Plaintiff's] claim[s] [are] premised *must* violate the FDCA if [his] claim[s] [are] to escape express preemption." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (emphasis in original). At the same time, Plaintiff's claims also must be premised on "the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted." *Id.* Whether Plaintiff has adequately alleged a violation of Illinois law is addressed later in this opinion. For purposes of federal preemption, however, the issue to be decided is whether Plaintiff alleges a violation of the FDCA.

B. NUTRITION FACTS DISCLOSURES ("BACK PANEL")

The original complaint did not allege that the protein content disclosed on the Product label was inaccurate using the nitrogen content method in 21 C.F.R. § 101.9(c)(7). Further, Plaintiff conceded that § 101.9(c)(7) permitted CVS to use that method to calculate the protein content of the Product. *See* R. 26 at 14-15. Nevertheless, Plaintiff contended that the Product label was misleading because it failed to disclose that the protein content in the Product included non-protein amino acids. In its ruling on CVS's first motion to dismiss, the Court concluded that Plaintiff's claims would require CVS to differentiate in some manner on the Product

label between whey protein and non-protein ingredients, which would have the effect of imposing a labeling requirement different from what federal law imposed on CVS. As a result, the Court held that Plaintiff's deceptive labeling claims were preempted by the federal regulations, which allow CVS to do exactly what it does (include non-protein ingredients in the total protein calculation). *See* R. 32 at 10.

The amended complaint differs from the original complaint in that it contains additional allegations regarding the requirements of the federal regulations. The primary new allegation is that federal regulations require CVS to calculate and disclose the *quality* of the protein in the Product, not just the total amount of protein in the Product. Plaintiff alleges that the quality of the protein must be calculated according to a methodology set out in 21 C.F.R. § 101.9(c)(7)(ii) called the Protein Digestibility Amino Acid Correct Score or "PDCAAS."

CVS does not say in its Motion whether it agrees with or contests Plaintiff's allegation that it is required to calculate and disclose the quality of the protein in the Product using the PDCAAS. Instead, CVS proceeds as if it is unnecessary to address that issue, arguing that even if that allegation is true, Plaintiff's new claims based on the PDCAAS are preempted by two provisions of the implementing regulations found in 21 C.F.R. § 101.9(g). Those provisions address the method (21 C.F.R. § 101.9(g)(2)) and standard (21 C.F.R. § 101.9(g)(4)) by which the FDA measures a food manufacturer's compliance with federal labeling requirements. As an initial matter, it seems inaccurate to say that CVS's arguments are preemption arguments. Both Plaintiff's new allegations and CVS's reasons for dismissal of those

new allegations are based on FDA regulations, and it would be incorrect to say that one federal regulation can preempt another. In reality, CVS's argument is that the regulatory provisions on which it relies substantively preclude a claim from being asserted under the regulatory provisions on which Plaintiff' relies. To properly evaluate that argument, the Court must consider the regulations as a whole, and how each of the provisions at issue fit into the overall scheme. To that end, the Court first will outline the regulatory provisions on which Plaintiff's new allegations regarding the PDCAAS are based, and then address the two provisions on which CVS relies for dismissal of Plaintiff's claims.

1. SECTION 101.9(c)(7)(i) AND (ii)—PROTEIN CONTENT VERSUS PROTEIN QUALITY

The primary regulation that governs nutritional labeling of food is 21 C.F.R. § 101.9. As provided in § 101.9(c), the declaration of nutritional information on the label of a food must contain information about the level of certain specified nutrients, one of which is protein. *See* 21 C.F.R. § 101.9(c)(7). The label's declaration regarding protein must include "[a] statement of the number of grams of protein in a serving[.]"[8] *Id.* The number of grams of protein per serving is referred to as the protein content. *Id.* As the Court noted earlier, protein content may be calculated using the nitrogen content method, as set forth § 101.9(c)(7).

In addition to the concept of protein content, § 101.9(c)(7) introduces the concept of "protein quality value." The regulatory language is somewhat confusing,

[8] A serving or serving size is defined as "an amount of food customarily consumed per eating occasion by a person 4 years of age or older which is expressed in a common household measure that is appropriate to the food." 21 C.F.R. § 101.9(b)(1).

but based upon the Court's reading, the language appears to relate "protein quality value" to the term "protein digestibility-corrected amino acid score," which in turn appears to be a measurement used to calculate something called the "corrected amount of protein per serving." The "corrected amount of protein" is determined by a procedure set out in § 101.9(c)(7)(ii), which states:

> The "corrected amount of protein (gram) per serving" . . . is equal to the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility. . . . The protein digestibility-corrected amino acid score shall be determined by methods given in . . . "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, except that when official AOAC procedures described in section (c)(7) of this paragraph require a specific food factor other than 6.25, that specific factor shall be used. . . .

Pursuant to § 101.9(c)(7)(ii) in conjunction with § 101.9(c)(7), it appears that the quality of the protein in a product is measured by multiplying the protein content (determined using the nitrogen content method) by the PDCAAS, to arrive at a "corrected amount of protein (gram) per serving." Once the corrected amount of protein (gram) per serving is determined using § 101.9(c)(7)(ii), that number is "calculated as a percentage of the Daily Reference Value (DRV) . . . and expressed as Percent of Daily Value." 21 C.F.R. § 101.9(c)(7). In other words, the corrected amount of protein is expressed not as a content score or measurement in weight (grams), but as a percentage of the daily reference value (%DV).[9]

[9] The daily reference value for protein for adults and children over 4 is defined in the regulations as 50. *See* 21 C.F.R. § 101.9(c)(7)(iii).

Although it is not immediately obvious from reading the regulations, it appears that in most cases a %DV for protein is not required to be placed on the food label. For instance, under § 101.9(c)(7), if the "protein quality value" is "less than 20 expressed as a percent," then the label must contain "adjacent to the declaration of protein content by weight" (*i.e.,* the uncorrected protein content score) either (1) the statement "not a significant source of protein"; or (2) a "listing . . . of the corrected amount of protein . . . expressed as Percent of Daily Value." 21 C.F.R. § 101.9(c)(7); *see* Food Labeling: Revision of the Nutrition and Supplement Facts Labels (hereinafter "FDA 2014 Proposed Revisions"), 79 Fed. Reg. 11880-01, 11912, 2014 WL 794562 (Mar. 2014) ("FDA regulations require the declaration of the amount of protein by weight, and provide for voluntary declaration of the percent DV for protein on the Nutrition Facts label (§ 101.9(c)(7)(i))."). FDA guidelines confirm that the regulations do not require that a %DV for protein be placed on the label of a food product except in limited circumstances. *See* FDA Food Labeling Guide, 2008 WL 2155725 at *26 (April 2008) (Section VII, Question No. N22), *available at http://www.fda.gov/Food/GuidanceRegulationGuidanceDocuments RegulatoryInformation/LabelingNutrition/ucm064894.htm*.[10] FDA guidelines state that the reasons for not requiring a protein %DV are: (1) current scientific evidence that protein intake is not a public health concern for adults and children over 4

[10] The Court can take judicial notice of the FDA Food Labeling Guide because it is available on a government agency website. *See, e.g., Gustavson v. Wrigley Sales Co.*, 2014 WL 60197, at *3 (N.D. Cal. Jan. 7, 2014); *Shepard v. DineEquity, Inc.*, 2009 WL 8518288, at *3 n.4 (D. Kan. Sept. 25, 2009); *Hansen Beverage Co. v. Innovation Ventures, LLC*, 2009 WL 6597891, at *2 (S.D. Cal. Dec. 23, 2009).

years of age; and (2) the costs associated with a determination of the PDCAAS. *Id.* The salient point, however, is that when a %DV is disclosed, the regulations require that it be calculated using the *corrected protein content*, which means the protein content (calculated using the nitrogen content method) *corrected* by the PDCAAS for protein digestibility (protein quality). *Id.* at *26-27 (Section VII, Question No. N23). ("When . . . the % DV is calculated . . . the actual amount of protein in grams per serving [is corrected] by multiplying the amount by its amino acid score corrected for protein digestibility . . . .").

Plaintiff's claims in the amended complaint are based on the new allegation that CVS was required to use the corrected protein content to calculate a protein %DV for the Product. The reason this was required and not optional, Plaintiff alleges, is that the label makes a protein claim for the Product. The regulatory basis for this allegation is § 101.9(c)(7)(i):

> A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as Percent of Daily Value, may be placed on the label, except that such a statement *shall* be given *if* a protein claim is made for the product. . . .

21 C.R.F. § 101.9(c)(7)(i) (emphasis added). Plaintiff's new allegation thus raises the question of what is a "protein claim." For the answer, the Court looks to 21 C.F.R. § 101.13.

Section 101.13 sets forth the general rules applicable to "nutrient content claims." It defines a nutrient content claim as "[a] claim that expressly or implicitly

characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36."[11] 21 C.F.R. § 101.13(b). The label declares in the Nutrient Fact panel on the *back* label that the Product contains 26 grams of protein. This type of statement falls in the category of express nutrient content claims. *See id.* (defining an expressed nutrient content claim as "any direct statement about the level (or range) of a nutrient in the food, e.g., 'low sodium' or 'contains 100 calories'").[12] It is *not* a nutrient content claim, however, because of its location on the nutrition panel on the back label. *See* 21 C.F.R. § 101.13(c) (excluding from the definition of a nutrient content claim "information that is required or permitted by § 101.9 or § 101.36, as applicable, to be declared in nutrition labeling, *and that appears as part of the nutrition label*") (emphasis added). On the other hand, the statement "26 grams of high-quality protein" appearing on the *front* label of the Product *is* a nutrient content claim. *See id.* ("If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to

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[11] Section 101.36 relates to dietary supplements, whereas § 101.9 relates to nutrients in foods. The requirements are parallel, but the parties appear to be in agreement that the Product is a food governed by § 101.9, rather than a dietary supplement governed by § 101.36.

[12] *See also* Food Labeling; General Provisions; Nutrition Labeling; Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food (hereinafter "FDA Comments on Final Rule"), 58 Fed. Reg. 2302-01, 2303-2304, 1993 WL 1540 (F.R.) (Jan. 1993) (rejecting suggestion that the definition of a nutrient content claim should be limited to nutrient claims that "characterize" the level of a nutrient such as "high in protein" (*i.e.,* implied nutrient content claims) and exclude claims about a specific level of a nutrient such as "26 grams" (*i.e.,* express nutrient content claims), stating that Congress intended the term "nutrient content claims" to include both types of claims).

the requirements for nutrient content claims."). Thus, "[w]hile a required statement inside a nutrition label escapes regulations reserved for nutrient content claims, the identical statement outside of the nutrition label is still considered a nutrient content claim and is therefore subject to section 101.13." *Reid v. Johnson & Johnson,* 780 F.3d 952, 960 (9th Cir. 2015).

Because the Product contains a nutrient content (protein) claim on the front label, both the requirements of § 101.13 and § 101.9(c)(7)(i) apply. Insofar as the Product's back label Nutrition Facts disclosures are concerned, Plaintiff alleges a violation of § 101.9(c)(7)(i).[13] As previously noted, § 101.9(c)(7)(i) requires that if a protein claim is made, the manufacturer is required to calculate a %DV using a "corrected amount of protein per serving" according to the PDCAAS. This means that the manufacturer must "correct the actual amount of protein in grams per serving by multiplying the amount by its amino acid score corrected for protein digestibility, divid[e] by 50 grams, and convert[ ] to percent." FDA Food Labeling Questions and Answers, 1994 WL 16188668 at *2-3 (Question No. N17) (Aug. 1994).[14] In short, Plaintiff's new allegation is that, because of the protein claim on

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[13] While the nutrient content claim appears on the front label of the Product, the making of that claim has implications for both the back and front label. This section deals with § 101.9(c)(7)(i) and the back label. But Plaintiff also alleges a violation of § 101.13 regarding the front label, which is addressed in the next section.

[14] *See also* FDA Food Labeling Guide, 2008 WL 2155725 at *27 (Section VII, Question No. N.23) ("When protein is listed as a percent of the 50 gram DRV and expressed as % DV, the % DV is calculated by correcting the actual amount of protein in grams per serving by multiplying the amount by its amino acid score corrected for protein digestibility, dividing by 50 grams and converting to percent. 21 CFR 101.9(c)(7)(ii).").

the front label of the Product ("26 grams of high-quality protein"), CVS was required pursuant to § 101.9(c)(7)(i) to take the 26 gram protein content (calculated with the nitrogen content method), correct that number for protein digestibility by using the PDCAAS, divide by 50, convert that number to a percent, and then list the result on the back label under the heading %DV.

2. SECTION 101.9(g)(2)—COMPOSITE OF 12 SUBSAMPLES

CVS's first argument for dismissal of Plaintiff's newly alleged claims is that Plaintiff fails to state a claim under the regulations discussed above because he has not alleged compliance with 21 C.F.R. § 101.9(g)(2). That provision states that nutrient analysis for compliance purposes shall be determined as follows:

> 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 ad appropriate analytical procedures . . . .

21 C.F.R. § 101.9(g)(2).

CVS argues that dismissal of Plaintiff's mislabeling claims is appropriate because Plaintiff does not allege that the results of his testing of the protein content of the Product was based on a composite of 12 subsamples taken 1 from each of 12 different randomly chosen shipping cases. Instead, Plaintiff attaches to the amended complaint the result of what appears to be a single test on a single sample of the Product. CVS cites to several district court opinions that have dismissed a

mislabeling claim based on this argument. The first decision so holding was *Vital v. One World Company*, No. 12-314, unpublished order (C.D. Cal. Nov. 30, 2012). *Vital* involved the alleged overstatement of the magnesium and sodium content in a coconut water product. The court held that the plaintiffs' state law claims were preempted by § 101.9(g)(2) because the plaintiffs did not calculate the magnesium and sodium content from a composite of 12 subsamples in attempting to show that the actual content of those minerals in the defendant's product was less than represented on the label. Significantly, *Vital* was decided only after the district court converted the defendant's motion to dismiss to a motion for summary judgment and gave the plaintiffs a 45-day extension of time to conduct discovery. The court said that the plaintiffs "could have conducted testing using the § 101-9(g)(2) methodology, but decided against it." *Id.,* slip op at 11. *Vital* therefore does not stand for the proposition that a plaintiff must *allege* the results of testing from a composite of 12 subsamples to avoid dismissal of his or her complaint.

Nevertheless, that was the ruling of the next district court to consider the issue. In *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304 (E.D. Cal. 2014), the court extended *Vital* to a ruling on a motion to dismiss, holding that because the plaintiff failed to *allege* that she had conducted testing on a composite of 12 subsamples, her state law claim that the defendant's teas "did not contain the amount of antioxidants represented on their labels" was preempted. *Id.* at 1313-14. Several other district courts have followed suit. *See, e.g., In re Whole Foods Mkt., Inc.*, 2016 WL 631532, at *5-6 (W.D. Tex. Feb. 16, 2016); *Dougherty v. Source Naturals, Inc.*,

2015 WL 8481864, at *3-4 (E.D. Mo. Dec. 8, 2015); *Durnford*, 2015 WL 9258079, at *4; *Mee,* 2015 WL 2251303, at *4.[15]

In response, Plaintiff cites to two district court cases that reached the opposite result. *See Clay,* 2015 WL 5007884; *Smith v. Allmax Nutrition, Inc.*, 2015 WL 9434768, at *7 (E.D. Cal. Dec. 24, 2015). The *Smith* court explained its reasoning as follows:

> To the extent that other courts have found that supporting a complaint with test results that do not show compliance with the 12 sample methodology implicates preemption, this Court disagrees. . . . Rule 8 requires a plaintiff to state sufficient factual detail to allow the Court to reasonably infer that each named defendant is liable for the misconduct alleged. Based upon the allegations in the complaint, the Court can plausibly infer that tests conducted in compliance with the 12 sample methodology would support Plaintiff's allegations that the Product is mislabeled.

Id.

The Court agrees with the *Clay* and *Smith* courts. On a motion to dismiss for failure to state a claim, the complaint must overcome "two easy-to-clear hurdles": (1) "the complaint must describe the claim in sufficient detail to give the defendant fair notice of what the claim is and the grounds on which it rests"; and (2) "its allegations must plausibly suggest that the plaintiff has a right to relief, raising that possibility above a 'speculative level [.]'" *Tamayo v. Blagojevich*, 526 F.3d 1074, 1084 (7th Cir. 2008). "Plausibility" in this context does not imply that a court "should decide whose version to believe, or which version is more likely than not."

[15] CVS also cites to *Burke v. Weight Watchers Int'l, Inc.,* 983 F. Supp. 2d 478, 483 (D.N.J. 2013), but that case involves another regulatory provision, not § 101.9(g)(2).

Swanson v. Citibank, N.A., 614 F.3d 400, 404 (7th Cir. 2010). Rather, to survive a motion to dismiss under Rule 12(b)(6), the "plaintiff must give enough details about the subject-matter of the case to present a story that holds together." *Id.* In other words, "the court will ask itself could these things have happened, not did they happen." *Id.* Like the district courts in *Clay* and *Smith,* this Court holds that Plaintiff may rely on the testing results attached to the amended complaint to nudge his claims based on an overstated declaration of protein content "across the line from conceivable to plausible." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Whether independent testing along the lines of § 101.9(g)(2) confirms Plaintiff's claim of overstated protein content is an issue of proof, and Plaintiff does not need to prove his case at the pleading stage of the case.[16]

In addition to the above, Plaintiff makes two other arguments that also may have merit. To begin with, Plaintiff argues that the sampling method in § 101.9(g)(2) is used by the FDA in compliance and enforcement actions, and that not even CVS is required to use that method in determining the contents of its label. This does appear to be the case, as shown by the following statement of the FDA regarding § 101.9(g)(2):

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[16] Plaintiff argues that it is not possible for him to perform the 12 sample testing because he does not have access to facilities to ensure proper collection of the "12 subsamples . . . taken 1 from each of 12 different randomly chosen shipping cases." 12 C.F.R. § 101.9(g)(2). CVS responds that argument is ludicrous because all Plaintiff has to do is purchase the Product from 12 different CVS stores. The parties appear to have a different understanding regarding what is required to compile the composite described in § 101.9(g)(2). If it later becomes necessary to address this issue, the Court will require further clarification from both sides regarding their divergent views of how to implement the methodology of § 101.9(g)(2).

> Section 101.9(g) sets out the methods that the agency will use for compliance determinations. Manufacturers may use nonofficial methods of analysis to establish nutrient content label values, but in doing so, they should ensure the validity of their methods with respect to applicability, specificity, sensitivity, accuracy, precision, and detectability. If they fail to do so, and their methods produce significantly different results than the official method, their label may subject them to regulatory action. . . . Thus, . . . [a *manufacturer] [is] not preclude[d] . . . from using alternative analytical methods for determining nutrient content label values.*

FDA Comments on Final Rule, *supra* n.12, 58 Fed. Reg. 2302-1, 2311.[17]

If CVS can show regulatory compliance using other reliable methods, then it would make sense that Plaintiff should similarly be able to show non-compliance using other reliable methods. Whether this is the proper approach to § 101.9(g)(2) in the context of a private enforcement action or whether § 101.9(g)(2) is in fact a substantive requirement that Plaintiff would have to meet to establish liability on the part of CVS is simply not clear to the Court at this point in time. Because CVS bears the burden of persuasion on preemption issues, however, *see Russian Media Grp., LLC*, 598 F.3d at 309, the Court is not prepared to dismiss the amended

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[17] *See also* Guidance For Industry FDA Nutrition Labeling Manual—A Guide For Developing and Using Data Bases (hereinafter "FDA Guide for Developing Data Bases"), 1998 WL 34327548 (F.D.A.), at *2 (Mar. 1998) ("The source of the data used to calculate nutrition label values is the prerogative of the manufacturer."); Food Labeling; General Requirements for Nutrition Labeling for Dietary Supplements of Vitamins, Minerals, Herbs, or Other Similar Nutritional Substances, Supplemental Information Final Rule (hereinafter "F.R. Supplemental Info."), FR Doc No: 93-31813, Section E, paragraph 40 (Jan. 4, 1994), available at https://www.gpo.gov/fdsys/pkg/FR-1994-01-04/html/93-31813.htm ("Manufacturers . . . are free to use whatever methodology they believe will give results consistent with methods used by FDA.").

complaint on this basis. *See Gustavson*, 2014 WL 60197, at *6 (rejecting defendant's interpretation of FDA regulation where defendant did not cite to any "interpretive authority that would support" it).

In addition, Plaintiff makes a possibly more compelling argument that § 101.9(g)(2) is irrelevant to his claims in this case. Plaintiff alleges that CVS did not correct the protein content using the PDCAAS before disclosing the protein %DV. That allegation is supported by the Product label, which Plaintiff attaches to the amended complaint. The Product label discloses 26 grams of protein and a 52% DV. CVS concedes that the 26 grams of protein is calculated using the nitrogen content method. Thus, Plaintiff makes a credible argument that the Product is misbranded on its face, because the 52% DV stated on the back label is obviously calculated using the *un*-corrected protein content of 26 grams (26÷50=0.52). If the protein content were to be corrected, Plaintiff alleges it would be 21.8 grams, which means the %DV should be 44% (21.8÷50=0.436).

If Plaintiff's claim was simply that the 26 grams protein content disclosure is inaccurate, then it would make more sense to apply the testing method of § 101.9(g)(2). But Plaintiff's claim is that CVS did not test for and disclose protein quality as required by § 101.9(c)(i), a claim that can be proven without proving the inaccuracy of the 26 grams protein content disclosure. The focus under Plaintiff's claim is CVS's alleged failure to use the correct testing method to make the required %DV disclosure. Therefore, Plaintiff argues, he is entitled to discover what testing methods CVS followed in determining the %DV, and thereby establish a violation of

the FDCA without having to prove an inaccurate protein content claim by the composite of 12 samples methodology. The FDA's explanation of the required PDCAAS testing confirms that the goal of the PDCAAS is to disclose to the consumer information about the quality of protein in the product. *See* FDA 2014 Proposed Revisions, *supra*, 79 Fed. Reg. 11880-01, 11935 ("Calculating the percent DV for protein incorporates a measure of protein quality," making it "a useful tool to indicate protein quality to the consumer"). Accordingly, it makes sense that the violation at issue here might be the failure to use the PDCAAS, not the disclosure of amount of protein in grams. Again, CVS has not met its burden of persuading the Court that the correct interpretation of the regulations is otherwise. Therefore, this is an additional reason why CVS's argument for Rule 12(b)(6) dismissal of the amended complaint based on § 101.9(g)(2) must be rejected.

3. SECTION 101.9(g)(4)(ii)—80% SAFE HARBOR RULE

CVS's second reason for dismissal of Plaintiff's new allegations even if PDCAAS testing is required is that, assuming the truth of Plaintiff's allegation that the Product contains only 21.8 grams of actual protein, that number is 83.8% of the 26 grams of protein declared on the Product's label and therefore within the 80% safe harbor provision of § 101.9(g)(4)(ii). As an initial matter, if Plaintiff is correct and the violation is CVS's failure to use the PDCAAS to provide a corrected protein content value expressed as a %DV, then it may not be relevant that the disclosure of the *un*corrected protein content is within the safe-harbor range.

Aside from that issue, the Court also disagrees with CVS's interpretation of the regulations regarding when the 80% safe harbor rule applies. When interpreting a regulation promulgated by a federal agency under its statutory authority, "analysis begins with the text." *Chase Rank USA, N.A. v. McCoy*, 562 U.S. 195, 204 (2011). Section 101.9(g) defines two nutrient classes—Class I and Class II. 21 C.F.R. 101.9(g)(3). Class I nutrients are defined as "[a]dded nutrients in fortified or fabricated foods." 21 C.F.R. § 101.9(g)(3)(i). Class II nutrients are "[n]aturally occurring (indigenous) nutrients" that are added to foods. 21 C.F.R. § 101.9(g)(3)(ii). If a product contains a Class I nutrient, the rule is that the amount of that nutrient in the Product must be equal to the value for that nutrient declared on the product's label. 21 C.F.R. § 101.9(g)(4)(i). If the nutrient is a Class II nutrient, however, the regulations state that the product can contain less than the amount declared on the product label, so long as it contains at least 80% of the declared value. 21 C.F.R. § 101.9(g)(4)(ii).

FDA guidelines state that Class I applies to nutrients "added in fortified or fabricated foods," whereas Class II applies to nutrients "that occur naturally in a food product." FDA Guide for Developing Data Bases, *supra* n.17, 1998 WL 34327548, at *3. For Class II to be applicable, protein would have to "occur naturally" in the Product. It seems self-evident that it does not. Instead, whey protein (along with other ingredients) is added to the Product to create a fabricated drink called Whey Protein Powder. CVS concedes that the Product is a manufactured food. *See* R. 45 at 6 (the Product is a "flavored whey protein powder

drink mix"). Thus, CVS concedes the Product is a "fabricated" food within the meaning of § 101.9(g)(3)(i). *See* Oxford English Dictionary ("fabricate: . . . 1a. to construct, manufacture"). Further, the Product, is "fortified" with protein. *See id.* ("fortify: . . . 4b. To add nutrients, usually vitamins, to (food)"). Thus, the protein in the Product fits within the definition of a Class I nutrient because it is an "added nutrient in a fortified or fabricated food." *Cf. CreAgri, Inc. v. USANA Health Sciences., Inc.,* 474 F.3d 626, 628 (9th Cir. 2007) ("There is no evidence, nor could there be, that hydroxytyrosol is 'naturally' found in Olivenol, a manufactured dietary supplement. Rather, hydroxytyrosol is added to Olivenol, which is manufactured pursuant to a patented method."); F.R. Supplemental Info., *supra* n.17, Section E, paragraph 41 ("dietary supplements of vitamins and minerals are fabricated products"). "Consequently, federal regulations require that [protein] be, in fact, found in [the Product] in a quantity 'at least equal' to that stated on the label." *CreAgri, Inc.*, 474 F.3d at 628.

In reaching this conclusion, the Court does not disagree with CVS's contention that not all nutrients in manufactured foods are Class I nutrients; some may in fact be Class II nutrients. The definition of a Class II nutrient is:

> "Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to class II requirements unless the same nutrient is also added.

21 C.F.R. § 101.9(g)(3)(ii). CVS argues that the whey protein added to the Product constitutes a "naturally occurring (indigenous) nutrient[ ] [that] is added to" the

Product, within the meaning of this provision. But is whey protein an "ingredient" which "contains" protein, or is whey protein just simply protein, meaning it is itself the nutrient in question? Without knowing more about whey protein, the Court cannot say. If whey protein is itself the nutrient, then Class I still applies.

But even if whey protein is an *ingredient* which contains protein, CVS still fails to take into account the last clause of the Class II definition stating that "the final food product is subject to class II requirements *unless the same nutrient is also added*." 21 C.F.R. § 101.9(g)(c)(ii) (emphasis added). The "same nutrient" language could be read to encompass the non-protein amino acids and other nitrogen-containing ingredients that CVS includes in the 26-gram protein content. In other words, the Product would not fall under Class II even assuming the whey protein constitutes an ingredient that contains "a naturally occurring (indigenous) nutrient" (protein) which "is added" to the Product, because "the same nutrient" (other forms of protein) is "also added" to the Product.[18]

[18] At the very least, CVS has not met its burden of persuasion on this point. *See Mee v. I A Nutrition, Inc.*, 2015 WL 4776301, at *9 (N.D. Cal. Aug. 13, 2015) (finding that the defendant's reliance on § 101.9(g)(4) was "at best, premature," because it failed to cite to anything that would suggest "the 'protein' referenced on the front of the label of Super Quad Protein is a Class II protein"); *Clay,* 2015 WL 5007884, at *5 and n.2 (stating that it was unclear from both the parties' briefs and a reading of § 101.9(g) how a nutrient's Class I or Class II membership is to be determined, and therefore the Court would not resolve the issue on a motion to dismiss).

C. FRONT LABEL DISCLOSURES

1. PRODUCT NAME—"WHEY PROTEIN POWDER"

The Court previously held that Plaintiff's state law claims based on the product name, "Whey Protein Powder," were not preempted because Plaintiff sought to enforce a violation of the FDCA, namely, 21 C.F.R. § 101.18(b). Section 101.18(b) provides that "[t]he labeling of a good which contains two or more ingredients may be misleading by reason (among other things) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling." *See Ackerman v. Coca-Cola Co.*, 2010 WL 2925955, at *12 (E.D.N.Y. July 21, 2010) (state law claim "that vitaminwater's labeling is misleading in that it uses a product name that includes [ ] two of the product's ingredients (vitamins and water) but fails to mention one other notable ingredient (sugar)" is not preempted because it seeks to enforce § 101.18(b)). While the Court held that this claim was not preempted, the Court also held that the name "Whey Protein Powder" was not misleading as a matter of law because the Product label also stated that the Product was a Vanilla "Naturally and Artificially Flavored Drink Mix," thereby making clear that the Product did in fact include ingredients other than whey protein.

Upon reconsideration of this issue, the Court concludes that a reasonable person might be misled by the Product name, but for a different reason. Rather than focusing on whether a reasonable person might be misled as to whether the Product contains only one ingredient to the exclusion of others, the Court now

focuses on whether a reasonable person might be misled by the Product name into believing that the Product contains only one kind of *protein* (whey protein) to the exclusion of other proteins (or more accurately, protein-like substances that are used in place of actual proteins). This characterization of Plaintiff's claim based on the Product name was rejected under the allegations of the original complaint because it was preempted based on Plaintiff's concession that CVS was authorized by federal regulation to calculate protein content using the nitrogen content method. *See, e.g. Henderson v. Gruma Corp.*, 2011 WL 1362188, at *13 (C.D. Cal. Apr. 11, 2011) (state law claim that "0 g transfat" and "0 g cholesterol" are misleading because they falsely suggest the products are healthy is preempted because plaintiff was challenging "the use of terms that the FDA, through its regulations, has defined and permitted").

But under the new allegations of the amended complaint, this characterization of Plaintiff's claim is not preempted, because Plaintiff plausibly alleges that the use of the term "protein" to include both actual protein and non-protein substances is not sanctioned by the FDA in this case. Therefore, Plaintiff has adequately alleged a disputed issue of fact as to whether the Product name is misleading in that it suggests that the protein in the Product is comprised exclusively of pure whey protein, as opposed to whey protein mixed with other non-protein substances. *See Ackerman*, 2010 WL 2925955, at *15 ("The plaintiffs have sufficiently alleged that the collective effect of the challenged statements was to

mislead a reasonable consumer into believing that vitaminwater is either composed solely of vitamins and water, or that it is a beneficial source of nutrients[.]").

2. NUTRIENT CONTENT CLAIM—"26 GRAMS OF HIGH-QUALITY PROTEIN"

In ruling on CVS's first motion to dismiss, the Court held that Plaintiff's state law claims based on the front label statement "26 grams of high-quality protein" were preempted because the FDCA does not require CVS to distinguish between whey protein and non-protein amino acids. The amended complaint now alleges, however, that CVS was required to distinguish between the two kinds of protein by virtue of § 101.9(c)(7)(i). In addition the amended complaint's new allegations also raise the applicability of § 101.13, which states that, while CVS is permitted to make a nutrient content claim such as "26 grams of high-quality protein" on the front label, that claim cannot be "false or misleading in any respect." 21 C.F.R. § 101.13(i)(3). Under the allegations of the original complaint, Plaintiff had no factual basis for alleging that the front label representation was false or misleading because such a finding would have required CVS to distinguish between actual protein and non-protein content. But because the Court now finds that Plaintiff has alleged a plausible claim for why the FDCA does require CVS to distinguish between whey protein and non-protein amino acids, the Court also finds that Plaintiff has stated a valid claim that the front label representation "26 grams of high-quality protein" is misleading in violation of § 101.13(i)(3).[19]

[19] In its previous discussion of this issue, the Court relied on a citation provided by CVS to comments of the FDA. *See* R. 32 at 10-11 (quoting FDA Comments on Final

CVS argues for dismissal of Plaintiff's front label claim for two additional reasons. The first is that Plaintiff's claim based on the front label representation "26

Rule, *supra* n.12, 58 Fed. Reg. 2302, 2344; R. 17 at 8 (quoting same). Those comments, as it turns out, were misinterpreted. The FDA's comments were responding to a suggestion advocating that "high" and "source" claims for protein "be based on protein quality as well as level because such claims may be misleading if a food contains a lower quality protein." FDA Comments on Final Rule, 58 Fed. Reg. 2302, 2344. That suggestion was rejected by the FDA. *Id.* In the first place, the "high" protein claim addressed in this comment was not the same as the one currently before the Court. The comment dealt with a claim that a product is "high *in* protein," not a claim that the product contains "high-quality protein." Claims that a product is "high in" or a "good source of" a certain nutrient are implied nutrient claims governed by the additional criteria imposed under 21 C.F.R. § 101.54. Section 101.54 requires, among other things, that the product contain "20 percent or more of the RDI or the DRV per reference amount customarily consumed" before a "high in" or "good source of" claim can be made about the product. 21 C.F.R. § 101.54(b)(1). The phrase "26 grams of high-quality protein" on the Product's front label is an express nutrient content claim, which is not governed by § 101.54(b), so the FDA's response to the suggestion in question has no direct application to this case.

But more to the point, the FDA's response to the suggestion in question, when properly understood, actual supports Plaintiff's claims in this case. The comment "suggested a second criterion" under § 101.54 (*i.e.,* in addition to the 20% or more of the RDI or DRV criterion) that would require a certain PDCAAS score for either a "high in" or a "good source" claim to be made about a food. *See* FDA Comments on Final Rule, 58 Fed. Reg. 2302, 2344. The FDA rejected this suggestion, stating that it believed "adding a second criterion based on the PDCAAS for 'high' and 'good source' in protein claims is not necessary." *Id.* CVS quoted the "not necessary" language to suggest that the FDA rejected a requirement that food manufacturers distinguish between actual protein and non-protein content. But the real reason the FDA thought a second criterion for a § 101.54(b)(1) claim based on the PDCAAS was "not necessary" was *not* that it did not think manufacturers should have to distinguish between actual protein and non-protein content. Instead, it was because "§ 101.9(c)(7)(i) . . . provides that percent DRV for protein must represent the correct amount of protein based on its PDCAAS. Thus, the agency *has already factored in the PDCAAS*." *Id.* (emphasis added). In other words, the FDA did not add a requirement to use the PDCASS for implied nutrient content claims under § 101.54(b)(1) *because it already imposed that requirement* through § 101.9(c)(7)(i).

grams of high-quality protein" is preempted by the requirements of 21 C.F.R. § 101.9(g). The Court already has rejected that argument.

The second reason CVS gives is that the phrase "high-quality protein" is non-actionable puffery. In its previous memorandum opinion and order, the Court agreed with that argument. *See* R. 32 at 17-19. "Statements that boast unverifiably of the quality of a product constitute puffing and will not create express warranties." *Accurate Transmissions, Inc. v. Sonnax Indus., Inc.*, 2007 WL 1773195, at *5 (N.D. Ill. June 14, 2007) (citing *Avery v. State Farm Mut. Auto, Ins. Co.*, 835 N.E.2d 801, 846 (Ill. 2005) ("'Puffing' denotes the exaggerations reasonably to be expected of a seller as to the degree of quality of his or her product, the truth or falsity of which cannot be precisely determined.")); *see also Speakers of Sport, Inc. v. ProServ, Inc.,* 178 F.3d 862, 866 (7th Cir. 1999) ("Puffing in the usual sense signifies meaningless superlatives that no reasonable person would take seriously, and so it is not actionable as fraud.").

It is true that the term "high-quality" in most cases will fall into the category of puffing. *See Avery*, 35 N.E.2d at 846 (citing *Evanston Hosp. v. Crane*, 627 N.E.2d 29, 33, 36 (Ill. App. 1993) ("high-quality" patient care)). But in this case, Plaintiff's allegation is that the term "high-quality" is used not generically in reference to the quality of the Product but specifically to identify the supposed type or category of an *ingredient* in the Product. "Whether a statement is one of fact or of opinion can depend on the circumstances of the case. A statement that would otherwise be an opinion can constitute a statement of fact if it is made in such a way that the

consumer could reasonably treat it as a statement of fact." *Borcherding v. Anderson Remodeling Co.*, 624 N.E.2d 887, 892 (Ill. App. 1993) (citations omitted); *see Reid v. Unilever U.S., Inc.*, 964 F. Supp. 2d 893, 908 (N.D. Ill. 2013) ("statements that ascribe specific virtues to a product that it does not possess are not considered puffing."); *Sussman-Automatic Corp. v. Spa World Corp.*, 15 F. Supp. 3d 258, 270 (E.D.N.Y. 2014) ("Puffery is distinguishable from misdescriptions or false representations of specific characteristics of a product.") (internal quotation marks and citation omitted); *Mitchell v. Gen. Motors LLC*, 2014 WL 1319519, at *8 (W.D. Ky. Mar. 31, 2014) (An express warranty may arise regarding a product where a representation is made that refers to "specific factual attributes . . . of which a buyer might be ignorant.").

The Court must accept as true so long as it is plausible Plaintiff's allegation that the term "high-quality protein" has a specific factual meaning to a consumer of the Product.[20] Because the term "high-quality protein" could be understood as a factual representation regarding the source of the protein in question, Plaintiff has

[20] In its first motion to dismiss briefing, CVS urged the Court to "take judicial notice that there is no specific protein called 'high-quality protein,'" but rather that there are "proteins that fall into the subjectively-described category 'high-quality,'" which, according to CVS, "is a classic example of puffery." R. 29 at 8-9. For the Court to take judicial notice of a fact, the fact must not be "subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Resolution of this issue is not a proper subject for judicial notice because a statement to the effect that "high-quality protein" refers to a subjective quality rather than an objectively identifiable type of protein is subject to reasonable dispute. Indeed, the FDA appears to ascribe factual meaning to the similarly subjective-sounding term "good quality protein" by using that term interchangeably with the term "complete protein." *See* FDA 2014 Proposed Revisions, *supra,* 79 Fed. Reg. 11880-01, 11914.

stated a valid misrepresentation claim. *See, e.g., NetQuote, Inc. v. Byrd*, 504 F. Supp. 2d 1126, 1133 (D. Colo. 2007) (motion to dismiss denied where statements that defendant's "leads are 'better' or 'higher quality' than NetQuote's leads" could be understood as "'false factual statements with specific comparisons' between MostChoice's and NetQuote's services"); *F.T.C. v. US Sales Corp.,* 785 F. Supp. 737, 746 (N.D. Ill. 1992) ("Defendants' representations about the quality and cost of the cars available by auction are representations of fact and not of opinion.").

D. INGREDIENTS DISCLOSURES

1. ASPARAGINE AND HYDROXYPROLINE

Plaintiff alleges that the test results it attaches to the amended complaint show the presence of Asparagine and Hydroxyproline, which are not disclosed in the Ingredients list on the Product back label. These substances are, according to Plaintiff, non-essential amino acids that CVS uses to "spike" the protein content of the Product.

Plaintiff first alleges a violation of the FDCA based on CVS having added Asparagine and Hydroxyproline to the Product. According to Plaintiff, this is a separate violation from CVS's failure to disclose the presence of those substances on the Product's label because food additive amino acids may be used as nutrients added to foods only when they are "used or intended for use to significantly improve the biological quality of the total protein in a food containing naturally occurring primarily intact protein that is considered a significant dietary protein source." 21 C.F.R. § 172.320(c).

CVS asserts that it does not add Asparagine and Hydroxyproline to the Product but that those substances instead are present in partially hydrolyzed whey protein. CVS concedes that it does add partially hydrolyzed whey protein to the Product (and that ingredient is disclosed on the back label). According to CVS, "partially hydrolyzed" means partially broken down, and Asparagine and Hydroxyproline are two of the amino acids that make up whey protein and therefore appear in "partially broken down" whey protein. But the source of the Asparagine and Hydroxyproline in the Product is a factual issue, which the Court cannot decide on a motion to dismiss. In addition, even if the Court were to credit CVS's explanation in its brief regarding the source of these ingredients, that explanation still means that CVS adds the two substances; CVS is just saying that it does so under another name ("partially hydrolyzed whey protein"). CVS has not provided any argument to the Court to support the view that adding partially hydrolyzed whey protein (which pursuant to CVS's explanation is just another name for the amino acids that result from breaking whey protein down) is not a violation of 21 C.F.R. § 172.320(c). Therefore, CVS has not met its burden of persuasion on this issue.

Plaintiff also asserts a claim based on CVS's failure to disclose the presence and amounts of Asparagine and Hydroxyproline. Plaintiff alleges that CVS's failure to disclose violates 21 C.F.R. § 101.4(b)(2) and 21 C.F.R. § 172.320(e)(2):

> An ingredient which itself contains two or more ingredients and which has an established common or usual name, . . . shall be designated in the statement of ingredients on the label of such food by either . . . (i) . . .

> declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in . . . [or] (ii) . . . incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

21 C.F.R. § 101.4(b)(2).

> The food additive amino acids [listed herein] may be safely used as nutrients added to foods . . . [but] (e) [t]o assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear . . . (1) The name of the amino acid(s) contained therein . . . [and] (2) The amounts of each amino acid contained in any mixture.

21 C.F.R. § 172.320.

In response, CVS contends that § 101.4(b)(2) only requires itemization of sub-ingredients for ingredients that are known by a common name but actually contain two or more ingredients. Partially hydrolyzed whey protein, according to CVS, is not an ingredient made up of two or more ingredients; it is a single ingredient that is made up of certain substances, including the amino acids Asparagine and Hydroxyproline. CVS has not cited to any authority for its legal argument that disclosure of these amino acids is not required under the regulations. In this regard, the Court notes that the regulations state that "[w]hey, concentrated whey, reconstituted whey, and dried whey may be declared as 'whey,'" 21 C.F.R. § 101.4(b)(7), but they say nothing about "partially hydrolyzed whey." Moreover, even apart from whether CVS's legal interpretation of the regulations is correct, the Court cannot resolve in CVS's favor on a motion to dismiss the factual issue of

whether Asparagine and Hydroxyproline were added to the Product separately from or through the partially hydrolyzed whey protein.

2. GLUTAMINE AND BCAAS L-LEUCINE, L-ISOLEUCINE, AND L-VALINE

Plaintiff also alleges that the Product's Ingredient list falsely claims that the Product contains Glutamine and three Branched Chain Amino Acids ("BCAAs")—L-Leucine, L-Isoleucine, and L-Valine, two valuable and sought-after sub-nutrients. According to Plaintiff, the testing results attached to the amended complaint show that these substances are not found in the Product. This false disclosure, according the Plaintiff, constitutes a violation of 21 C.F.R. §§ 101.4(a)(1) and (b)(2). The only argument CVS has made regarding this allegation is that it is preempted by Plaintiff's failure to conduct testing on a composite of 12 subsamples pursuant to § 101.9(g)(2). Because the Court has rejected that argument as a basis for dismissal of the amended complaint, Plaintiff's claim regarding CVS's allegedly improper representations that the Product contains Glutamine and BCAAs survives CVS's Motion along with his other claims.

E. PRIMARY JURISDICTION

CVS next argues that the Court should stay or dismiss this case under the primary jurisdiction doctrine. "The doctrine of primary jurisdiction allows a federal court to refer a matter extending beyond the conventional experiences of judges or falling within the realm of administrative discretion to an administrative agency with more specialized experience, expertise, and insight." *In re StarNet, Inc.*, 355

F.3d 634, 639 (7th Cir. 2004) (internal quotation marks and citation omitted).[21] "Where, as here, the doctrine is invoked at the motion to dismiss stage, the question is whether the complaint plausibly asserts a claim that would not implicate the doctrine." *Chavez v. Nestle USA, Inc.,* 511 Fed. Appx. 606, 607 (9th Cir. 2013) (unpublished) (internal quotation marks and citation omitted). CVS advances two arguments for why the Court should apply the doctrine of primary jurisdiction here.

First, CVS argues that the issues raised by the amended complaint "are clearly technical questions," which the FDA is uniquely qualified to answer. R. 41 at 12-13. But this statement by itself is conclusory, and CVS fails to identify the issues it believes require the FDA's technical expertise. The Court is well qualified to interpret the regulations and to resolve matters regarding allegations of false and misleading representations. *See Sciortino v. Pepsico, Inc.,* 108 F. Supp. 3d 780, 813-14 (N.D. Cal. 2015) ("the issues raised by Plaintiffs' claims, particularly its state law misrepresentation claims, do not clearly require FDA's expertise or benefit from uniformity in administration") (citing cases); *In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig.*, 955 F. Supp. 2d 1311, 1349 (S.D. Fla. 2013)

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[21] The term "primary *jurisdiction*" as applied in this case is somewhat of a misnomer. As the Seventh Circuit has explained, "[c]ases in which a court refers an issue to an agency because of the agency's superior expertise, . . . rather than because of the agency's jurisdiction, are not felicitously described as cases of primary *jurisdiction*. They are akin to those *Burford* abstention cases that . . . concern arcane regulatory issues; or cases in which the court solicits an amicus curiae brief from an interested agency; or cases in which the court has in effect appointed the agency to be a special master . . . . In such cases, either court and agency have concurrent jurisdiction to decide an issue, or only the court has the power to decide it, and seeks merely the agency's advice." *Arsberry v. Illinois*, 244 F.3d 558, 563-64 (7th Cir. 2001) (emphasis in original).

(plaintiff's claims regarding whether defendant's representations were false or misleading and whether consumers relied on them did not raise any issues on which the FDA has greater technical expertise than the courts) (internal quotation marks and citation omitted) (citing cases). At least at this point in the proceedings, it is not apparent that agency expertise would be required to resolve the matters before the Court.

Second, CVS argues that the Court should stay this action while the FDA considers proposed amendments to the current food labeling requirements. But CVS does not point to any proposed amendments that would change the protein labeling requirements. From the Court's review of the proposed revisions, there do not appear to be any relevant changes. *See* FDA 2014 Proposed Revisions, *supra,* 79 Fed. Reg. 11880-01, 11912-11914. As CVS points out, R. 45 at 11, the FDA has already received public comments on this proposed rule, and issued a supplemental proposed rule. The supplemental proposed rule also does not appear to make any changes to the protein disclosure rules that would be applicable to this case. *See* Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule To Solicit Comment on Limited Additional Provisions, 80 Fed. Reg. 44303-01, 2015 WL 4504335 (FDA Dkt. No. 2015-17928 (July 2015). In short, the FDA appears to have "shown virtually no interest in" changing the regulations applicable to this case. *Chavez,* 511 Fed. Appx. at 607 (reversing district court's dismissal based on primary jurisdiction doctrine of claims alleging false and

misleading labeling and advertisements because "the product actually contains very small amounts of the touted ingredient, DHA").

The sole basis for CVS suggesting that the Court should defer to the agency rule-making process is the AHPA commentary referenced earlier in this opinion. *See supra* n.5. There is no indication that the FDA is interested in making changes in response the AHPA's suggestions, however, and, even if it did, those changes would not affect the issues in this case. AHPA is suggesting that the rules by modified to provide that protein quality always be taken into account in determining protein content. *See* AHPA Comments, *supra* n.5, at 4. The AHPA would do this by eliminating the nitrogen content method of accounting for protein content and replacing it with an analytical method called the Digestible Indispensible Amino Acid Score (DIAAS), which, like the PDCAAS, takes into account the digestibility of individual essential amino acids. The AHPA would use the DIAAS in place of the PDCAAS because the DIAAS "is believed to be a more accurate method of evaluating protein quality." *Id.* at 3.

CVS's argument to stay or dismiss under the primary jurisdiction doctrine based upon the AHPA's comments ignores the theory of liability now advanced in the amended complaint. The amended complaint alleges that the current regulations already require that protein quality be taken into account through the PDCAAS in the specific circumstances under consideration here—when a protein content claim is made about a product. The possibility that the FDA might agree with the comments of the AHPA and extend the use of the PDCAAS, or an

alternative analytical method for measuring protein quality such as the DIAAS to all products, not just those making a protein claim, would not have any bearing on CVS's liability in this case. In this respect, this case is similar to *McMahon v Bumble Bee Foods LLC*, 2015 WL 7755428, at *3-4 (N.D. Ill. Dec. 12, 2015), wherein Judge Tharp rejected the defendant's argument that the plaintiff's state law deceptive labeling claim was preempted by the FDCA because it alleged a violation of a new rule that had been announced by the FDA but had not yet taken effect. The new rule broadened the scope of the old rule, but the plaintiff stated a valid claim, the court held, under the old rule. Similarly, here, CVS urges the Court to wait to decide this case based on the possibility that the standard Plaintiff seeks to enforce here will ultimately be adopted for all situations, when the Plaintiff's claim is that it already has been adopted for the only purpose relevant to this Court in resolving this case. As the *McMahon* court stated, "there is no basis to infer that in deferring the implementation of more stringent regulation, the FDA intended to invalidate the existing regulatory requirements[.]" *Id.* at 4. In short, there is no reason for the Court to wait to see whether the FDA ultimately decides to impose a more stringent regulatory rule regarding the manner in which protein content is to be calculated. The Court therefore rejects CVS's primary jurisdiction argument.

F. Failure To State Valid State Law Claims

1. Deceptive Trade Practices

CVS argues that the Court should dismiss Plaintiff's Consumer Fraud Act claim for two reasons.

First, CVS contends that the Illinois Consumer Fraud Act does not apply to "[a]ctions or transactions specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States." 815 ILCS 505/10b(1). This argument requires a finding that Plaintiff's claims are based on labeling requirements not identical to those specified in the FDCA and implementing regulations. As discussed above, the Court has found that the amended complaint alleges claims that seek to impose requirements identical to those imposed by the FDCA. Therefore, 815 ILCS 505/10b(1) does not apply, and this argument must be rejected.

Second, CVS contends that the amended complaint alleges no more than a contract dispute. *See Sklodowski v. Countrywide Home Loans, Inc.*, 832 N.E.2d 189, 196-97 (Ill. App. 2005) ("It is well settled that the Consumer Fraud Act was not intended to apply to every contract dispute or to supplement every breach of contract claim with a redundant remedy.") (internal quotation marks and citation omitted). The principle stated in *Sklodowski,* however, does not mean that every case involving a contract fails to state a Consumer Fraud Act claim. "When allegations of consumer fraud arise in a contractual setting, the plaintiff must prove that the defendant engaged in deceptive acts or practices distinct from any underlying breach of contract." *Greenberger v. GEICO Gen. Ins. Co.*, 631 F.3d 392, 399 (7th Cir. 2011) (citation omitted). The amended complaint alleges more than just a breach of contract. Plaintiff alleges that, even if CVS did not enter into a contract with him promising 26 grams of whey protein, he was misled by the

Product label into believing that was what he was getting when he purchased the Product. *See Pressalite Corp. v. Matsushita Elec. Corp. of Am.*, 2003 WL 1811530, at *7 (N.D. Ill. Apr. 4, 2003) ("Pressalite does not allege fraud based on [ ] Matsushita's 'alleged *contractual* obligation' . . . . Rather, it alleges an entirely separate fraud arising from Matsushita's alleged intentional concealment of defects. As a result, Pressalite's [fraud] claim is not duplicative [of its breach of warranty claim].") (citations omitted) (emphasis in original).

Moreover, Illinois courts have explained the proper approach to distinguishing between garden variety breach of contract cases and cases involving a violation of the Consumer Fraud Act as follows: "where a plaintiff attempts to allege a violation of the Act in a case which appears on its face to involve only a breach of contract, the relevant inquiry is whether the alleged conduct * * * implicates consumer protection concerns." *Lake Cnty. Grading Co. of Libertyville, Inc. v. Advance Mech. Contractors, Inc.*, 654 N.E.2d 1109, 1116 (Ill. App. 1995) (internal quotation marks and citation omitted). False labeling of food products raises a quintessential consumer protection concern. *See Simon v. Oltmann*, 2001 WL 1035719, at *8 (N.D. Ill. Aug. 31, 2001) ("Courts have struggled to define the scope of [consumer protection concerns], but it generally involves sharp practices designed to mislead consumers about a competitor, or public health, safety or welfare issues.") (internal citations omitted). Thus, the Court concludes that Plaintiff has stated a claim under the Illinois Consumer Fraud Act, notwithstanding Plaintiff's pleading of the existence of a contractual relationship.

2. UNJUST ENRICHMENT

CVS argues that Plaintiff's unjust enrichment claim fails because "'unjust enrichment is based on an implied contract, and it does not apply where there is a specific contract that governs the relationships of the parties.'" R. 41 (quoting *SwedishAmerican Hosp. Ass'n of Rockford v. Ill. State Med. Inter-Insurance Exch.*, 916 N.E.2d 80, 108 (Ill. App. 2009)). CVS argues that because the amended complaint alleges the existence of a contract between Plaintiff and CVS, Plaintiff's claim for unjust enrichment must be dismissed. But the Federal Rules of Civil Procedure allow Plaintiff to plead alternative theories, one based on an implied contract (unjust enrichment), and one based on an express contract (breach of express warranty). *See* Fed. R. Civ. P. 8(d). Therefore, dismissal of Plaintiff's unjust enrichment claim on the basis of Plaintiff's breach of express warranty claim is not warranted.

CVS also contends that Plaintiff's unjust enrichment claim should be dismissed because the Court previously held that unjust enrichment was not a "stand-alone" cause of action. That statement is inaccurate. The Court held that unjust enrichment *is* a stand-alone claim, but that it was a theory of recovery which depended on the same underlying conduct held to be insufficient in that ruling to state a claim for false or deceptive labeling. *See Cleary v. Philip Morris Inc.*, 656 F.3d 511, 517-18 (7th Cir. 2011); *see also McMahon,* 2015 WL 7755428, at *5-6. On CVS's second motion to dismiss, the Court holds that Plaintiff's false and deceptive

labeling claims survive dismissal. Therefore, Plaintiff's unjust enrichment cause of action also survives.

3. BREACH OF EXPRESS WARRANTY

Plaintiff finally argues that the amended complaint does not sufficiently allege why Plaintiff purchased the Product and how he was deceived such that a reasonable inference can be drawn that CVS's allegedly false statement was the "basis for the bargain" between Plaintiff and CVS. The Court disagrees.

"To state a claim for breach of express warranty, the buyer must allege that the seller made: (1) an affirmation of fact or promise made to the plaintiff; (2) relating to the goods; (3) which becomes part of the basis for the bargain; and (4) guaranteeing that the goods will conform to the affirmation or promise." *Int'l Bhd. of Teamsters Local 734 Health & Welfare Trust Fund v. Phillip Morris, Inc.*, 34 F. Supp. 2d 656, 664 (N.D. Ill. 1998). "To satisfy these elements, it is sufficient for [a] plaintiff[ ] to attach the express warranty to the complaint." *Indus. Hard Chrome, Ltd. v. Hetran, Inc.*, 64 F. Supp. 2d 741, 747 (N.D. Ill. 1999) (citing *Bd. of Educ. of City of Chi. v. A, C & S, Inc.*, 546 N.E.2d 580, 595 (Ill. 1989)). The front and back label of the Product are reproduced in the amended complaint. Moreover, the amended complaint describes the alleged representations from the Product label on which Plaintiff allegedly relied, and further alleges that Plaintiff would not have purchased the Product had he known the true nature of the Product's ingredients and what the Product contained. R. 33, ¶ 100. The Court therefore rejects CVS's

argument that the amended complaint fails to allege facts sufficient to state a claim for breach of express warranty.

III.

CONCLUSION

In conclusion, Plaintiff has successfully pled around the preemption problems he encountered in the original complaint. In the original complaint, Plaintiff tried to impose an obligation that Plaintiff conceded at the time was explicitly disclaimed by FDA regulations, and so its imposition through state law was held to be preempted. In the amended complaint, Plaintiff's state law claims all rely on the theory that, by not complying with the relevant federal laws and regulations, the Product's label misleads and deceives consumers. The Court has found these new allegations to be plausible. Since the re-pled state law claims rely on federal law and regulations without modification, those claims are not preempted. Moreover, none of CVS's other arguments for dismissal of the amended complaint withstand scrutiny either. Accordingly, CVS's Motion to Dismiss the First Amended Class Action Complaint, R. 40, is denied.

ENTERED:

Thomas M Durkin

Honorable Thomas M. Durkin
United States District Judge

Dated: March 15, 2016

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Nutrition Facts

Serving Size 1 scoop (39g)
Servings Per Container: About 23

Amount Per Serving	Mix	with 8 fl oz fat free Milk
Calories	150	230
Calories from Fat	20	20
	% Daily Value*	
Total Fat 2g	**3**%	**3**%
Saturated Fat 1g	**5**%	**5**%
Trans Fat 0g		
Polyunsaturated Fat 0g		
Monounsaturated Fat 1g		
Cholesterol 45mg	**15**%	**17**%
Sodium 60mg	**3**%	**7**%
Potassium 180mg	**5**%	**14**%
Total Carbohydrate 8g	**3**%	**7**%
Dietary Fiber 0g	**0**%	**0**%
Sugars 2g		
Protein 26g	**52**%	**68**%
Vitamin A	1%	11%
Vitamin C	0%	0%
Calcium	12%	42%
Iron	5%	5%
Vitamin D	0%	25%

*Percent Daily Values are based on a 2,000 calorie diet.

CVS/pharmacy® Whey Protein contains essential amino acids that our bodies need every day. Because of whey protein's excellent and fast absorption, these amino acids get into the bloodstream quickly to support lean muscle and recovery following exercise.

DIRECTIONS FOR USE:
Mix one scoop with 6-8 oz. of water or vitamin A & D fortified fat free milk. CVS/pharmacy® Whey Protein Powder can also be added to smoothies, cereal or pancake mix.

NOTE: This product is not intended for use as a sole source of nutrition. This product is not formulated for children. This product is sold by weight, not volume. Contents may settle during shipping and handling. Consult with a physician before starting any diet and exercise program, including this one specifically, if you are under the age of 18, pregnant, nursing or have a health problem (such as diabetes, heart disease, high blood pressure, etc.).

INGREDIENTS: PROTEIN-AMINO ACID BLEND (WHEY PROTEIN CONCENTRATE, WHEY PROTEIN ISOLATE, L-LEUCINE, PARTIALLY HYDROLYZED WHEY PROTEIN, L-ISOLEUCINE, L-VALINE, L-GLUTAMINE), MALTODEXTRIN, CREATINE MONOHYDRATE, NONDAIRY CREAMER (SUNFLOWER OIL, CORN SYRUP SOLIDS, SODIUM CASEINATE, MONO- AND DIGLYCERIDES, DIPOTASSIUM PHOSPHATE, TRICALCIUM PHOSPHATE, LECITHIN, TOCOPHEROLS), NATURAL & ARTIFICIAL FLAVORS, GUAR GUM, CELLULOSE GUM, LECITHIN, ACESULFAME POTASSIUM, SUCRALOSE, PAPAIN, AMYLASE

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