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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GORDON NOBORU YAMAGATA and STAMATIS F. PELARDIS, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

RECKITT BENCKISER LLC,

Defendant.

Case No. 3:17-cv-03529-VC

Assigned to Judge Vince Chhabria, Courtroom No. 4, 17th Floor

DEFENDANT RECKITT BENCKISER LLC'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

[Filed concurrently with:
(1) Notice of Motion and Motion; and
(2) Appendix of Evidence]

Hearing:
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Courtroom: 4

Complaint filed: June 19, 2017
Trial Date: TBD

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PRELIMINARY STATEMENT

A. Introduction

This cookie-cutter false advertising case filed by Plaintiffs Gordon Yamagata ("Yamagata") and Stamatis Pelardis ("Pelardis") (collectively, "Plaintiffs") alleges that Defendant Reckitt Benckiser, LLC's ("Defendant" or "RB") falsely advertised its Move Free Advanced ("MFA" or the "Products") line of joint health dietary supplements because two of the ingredients in the Products, glucosamine and chondroitin (collectively, "GC"), allegedly do not provide any joint health benefits. Plaintiffs seek a full refund for themselves and all consumers who purchased the Products in California and New York from May 28, 2015 to the present, arguing that the Products are worthless, and provide zero benefit to consumers.

The undisputed facts establish that Plaintiffs' repurposed theory is legally faulty for several separate and alternative reasons.[1] First, Plaintiffs challenge proper structure/function claims that are expressly allowed by the federal Food, Drug, and Cosmetics Act. Therefore, their state law false advertising claims are expressly preempted by federal law.

Second, Plaintiffs' Complaint focuses exclusively on GC, and ignores all of the other ingredients in the Products, including a calcium fructoborate product called FruiteX-B®, which ***alone*** provides the advertised joint health benefits. Because FruiteX-B® provides the advertised benefits, regardless of whether or not GC also provides such benefits, Plaintiffs will be unable to prove that the advertising for the Products is false and misleading as a matter of law.

Finally, the ingredients in the Products provide a variety of health benefits ***independent*** of joint health benefits (some advertised benefits and some not). Therefore, Plaintiffs will be unable to prove that the Products are worthless as a matter of law and confer no benefits on consumers. Plaintiffs' full refund damages theory consequently fails.

For these reasons, it is respectfully submitted that summary judgment be granted with

[1] Plaintiffs' counsel is counsel of record in several other nearly identical lawsuits relating to GC supplements, and one of Plaintiffs' attorneys filed a nearly identical lawsuit relating to Move Free Advanced that settled in 2015, with the class period ending on May 27, 2015—one day before the current class period begins. (Declaration of Adrianne E. Marshack ("Marshack Decl."), ¶¶ 7-9.)

respect to all of Plaintiffs' claims. Alternatively, summary judgment should be granted on the issue that the Products are not worthless, and class members are not entitled to full refunds.

B. Relevant Summary of Undisputed Material Facts

1. RB's Move Free Product Line

"Move Free" is RB's joint health product line, which is separated into two segments: "Move Free Advanced" ("MFA") products and "Move Free Ultra" products.[2] (Sexton Decl., ¶ 2.) The three products in RB's MFA product line at issue have different formulations, although all three contain the same base formula:

Product	Ingredients
MFA (the "Base Formula")	• 1500 mg of glucosamine hydrochloride • 200 mg of chondroitin sulfate • 3.3 mg of hyaluronic acid • 216 mg of FruiteX-B® (calcium fructoborate) (the "Base Formula")[3]
MFA Plus MSM	• Base Formula • 750 mg of methylsulfonylmethane ("MSM")
MFA Plus MSM & Vitamin D	• Base Formula • 750 mg of MSM • 2000 IU of Vitamin D3

The MFA packaging offers different benefits depending on the ingredients. For example, the "Plus MSM" package says "**PLUS**: Extra Cartilage Support," and the "Plus MSM and Vitamin D3" package says "**PLUS:** Extra Bone Support." (*See* Dkt. No. 86-3 [Ex. 11 to Motion for Class Certification]; Sexton Decl., ¶¶ 6-7.)

2. Plaintiffs' Allegations Regarding the Products At Issue

Yamagata is a 73-year-old retiree living in California. (Ex. R to the Marshack Decl.) at

[2] RB's "Ultra" products do not contain glucosamine or chondroitin and are not at issue in this litigation. (Sexton Decl. at ¶ 3.)

[3] Fruitex-B is calcium fructoborate manufactured through a patented process and sold by Futureceuticals, Inc. (Sexton Decl., ¶ 4; Declaration of Zbigniew Pietrzkowski ["Pietrzkowski Decl."], ¶ 5; Ex. B at 112; Ex. C at 895; Ex. D at 224; Ex. E at 32.) RB includes FruiteX-B® in MFA as Uniflex®, and has done so since approximately 2011. (Sexton Decl. at ¶ 5.) The ingredients that constitute Uniflex have changed over time. Prior to 2011, Uniflex did not contain FruiteX-B® and was a different formulation than today. (*Id.*) Thus, any studies done on MFA prior to 2011 would have been based on a different formulation of MFA and would not be applicable to any of the current MFA products.

17:21-22.) Plaintiff Pelardis is 44 years old and lives in New York. (Ex. U to Marshack Decl. at 17:21-22.) Neither Plaintiff has been diagnosed with osteoarthritis. (Ex. T to Marshack Decl.; Ex. U at 26:25-27:1.) Rather, both Yamagata and Pelardis have a history of shoulder problems and at various times took Advil to relieve the pain and stiffness. (Ex. R to Marshack Decl. at 22:7-25:16; Ex. U at 20:25-24:18; 25:5-14.)

Both Plaintiffs purchased one MFA Product on a single occasion (specifically, MFA Plus MSM). (Ex. R to Marshack Decl. at 54:10-57:14; 61:10-68:19; Ex. S; Ex. U at 33:9-34:14; Ex. V at p. 3.) Yamagata testified that he saw a commercial for MFA on television, and that approximately one week later, he went to Target to purchase the product that he had seen on the commercial. Yamagata relied solely on the alleged commercial and admittedly did not read the label for the Product other than to verify that it contained GC. (Ex. R to Marshack Decl. at 54:10-57:14; 61:10-68:19.) By contrast, Pelardis testified that he was walking down an aisle in a drugstore and the Product "attract[ed]" him, but he could not remember what, specifically, about the package attracted him, other than the package had a number "5" and purportedly a picture of bones (which it does not have). (Ex. U to Marshack Decl. at 33:9-40:10.)

Yamagata admittedly only used the Product for approximately three weeks and failed to finish the entire bottle. (Ex. R to Marshack Decl. at 47:14-48:8; 76:19-81:22.) Pelardis offers conflicting stories regarding the length of time that he used the Product, admitting, however, that it was only either "approximately one week" or "a few weeks." (Marshack Decl., ¶ 6; Exs. V and W at p. 4; Ex. U at 42:14-43:1.)

Within a month after they stopped taking MFA, Plaintiffs hired the same attorneys[4] and filed their complaint alleging claims for: (1) violation of the Unfair Competition Law, California Business & Professions Code §§17200, et seq. ("UCL"); (2) violation of the California Consumers Legal Remedies Act, California Civil Code §1750, et seq. ("CLRA"), and (3) violation of the California False Advertising Law, California Business & Professions Code § 17500, et seq. ("FAL"); and (4) violation of the New York General Business Law, §§

[4] (Ex. R to Marshack Decl. at 40:24-48:25, 81:23-82:1; Ex. U at 27:14-30:5; 53:3-23.)

349 and 350 (the "Complaint") (see Dkt. Nos. 1 and 24).

Plaintiffs' Complaint challenges the advertising claim that the Products "Support[] Five Signs of Joint Health: Mobility, Comfort, Strength, Flexibility, Lubrication." (*Id.* at 7:7-14; Dkt. No. 24 at ¶ 33.)[5] Plaintiffs also take issue with the name of the Product ("Move Free"), the silhouette of a runner on the Products' packaging, as well as the presence of the Arthritis Foundation logo, which expressly includes the language: "Proud sponsor of the Arthritis Foundation" along with the explanation that "Move Free is proud to support the Arthritis Foundation's efforts to help people take control of arthritis. Funds from Move Free are used for cutting-edge scientific research, advocacy and education." (Dkt. No. 86 [Motion for Class Certification] at 6:17-7:6, 7:21-25; Dkt. No. 86-3; Dkt. No. 24 [Complaint] at ¶¶ 28-29.)

Plaintiffs allege that the Products' advertising is "intended to induce a common belief in consumers that the [Products] are capable of providing meaningful joint health benefits for all those who consume them," but that the Products cannot provide such benefits. (Dkt. No. 24 at ¶¶ 34-35.) Plaintiffs' entire Complaint, and their allegations that the Products cannot provide the advertised joint health benefits, are based on the theory that two of the ingredients in the products, GC, "is [sic] not effective at supporting or benefiting joint health." (Dkt. No. 24 at ¶¶ 35-75.) To purportedly support this allegation, Plaintiffs rely primarily on studies, meta-analyses, and medical guidelines focusing on GC as a ***treatment for disease (osteoarthritis)*** (Dkt. No. 24 at ¶¶ 36-56, 58-75), or as a ***prevention of disease (osteoarthritis)*** in overweight women (*id.* at ¶ 57).

None of the studies, meta-analyses, or medical guidelines relied on by Plaintiffs focus on the effect of GC, let alone the Products, on non-diseased joints or on the joints of members

[5] Plaintiffs' Complaint erroneously quotes older versions of the Products' packaging that have not been on the MFA Products' packaging during the class period, and were the subject of a release in a prior lawsuit. (Sexton Decl., ¶ 8.) RB's more recent advertising claims for the MFA Products were specifically mentioned in Plaintiffs' Motion for Class Certification (*see* Dkt. No. 86 [Motion]; Ex. 86-3 [MFA packaging exemplars].

of the general population in supporting overall joint health.[6] Moreover, RB does not advertise MFA as a treatment for osteoarthritis, and expressly states that the Products are "not intended to diagnose, treat, cure or prevent any disease." (Dkt. No. 24 at ¶ 28; Dkt. No. 86-3.)

Plaintiffs' Complaint, and their allegations that the advertising for MFA is false and misleading, focus solely on GC, and completely ignores the other ingredients in the Products. (*See generally,* Dkt. No. 24.)

Plaintiffs seek a full refund for all class members, claiming that the Products provide no joint health benefits and are therefore worthless.[7] (Dkt. No. 86 [Plaintiffs' Motion for Class Certification] at 23:20-24:11; Dkt. No. 94 [Plaintiffs' Reply] at 14:18-15:12.)

3. The Products' Ingredients and Their Multitude of Benefits

Although Plaintiffs' Complaint is focused solely on GC, the Products' ingredients, including GC, provide a multitude of benefits in addition to supporting joint health.[8]

a. Calcium Fructoborate (FruiteX-B®)

All of the Products in the MFA product line contain 216 mg of calcium fructoborate per serving, sold under the brand name FruiteX-B®. (Sexton Decl., ¶ 4.) Calcium fructoborate is complex of boron, fructose, and calcium. (Pietrzkowski Decl., Ex. A at 255; Ex. B at 112; Declaration of Daniel A. Grande ["Grande Decl."], ¶ 17.) In multiple clinical trials, the amount of FruiteX-B® in the MFA Products has been shown to provide both short-term (14-day) and longer term (90-day) joint health benefits, including reducing pain, stiffness, and joint discomfort, and increasing physical mobility. (Pietrzkowski Decl., ¶¶ 7-33; Exs. A-

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[6] Although RB disputes Plaintiffs' allegations that GC cannot provide the advertised benefits, for the purposes of this Motion, RB is not moving on the grounds that GC provides the joint health benefits that are advertised.

[7] The Court certified classes of California and New York purchasers for the Products from May 28, 2015 to the present, and denied certification of a California Senior Class. (*See* Dkt. No. 110 at 2, 3.)

[8] Because MFA is a dietary supplement, advertising for the Products cannot and do not make disease-related claims. The additional health benefits for MFA's ingredients described in this Motion and the supporting declarations, including any reference to their potential effect on specific diseases, are intended solely to demonstrate that the Products provide health benefits in addition to the advertised claims of supporting joint health, and therefore the Products are not worthless. RB does not make such claims in the advertising for MFA.

E.) Therefore, FruiteX-B® ***alone*** is effective in providing joint health benefits. (*Id*.)

In addition to the joint health benefits provided by FruiteX-B®**,** various clinical trials have found that FruiteX-B® has additional health benefits, even in amounts lower than the amount in MFA. (Grande Decl., ¶¶ 17-23; Ex. J.) These additional health benefits include reducing inflammation, and reducing the levels of various proteins, amino acids, and fats in the blood that can lead to heart disease, auto-inflammatory conditions, and blood clots. (Grande Decl. at ¶¶ 18-23; Exs. H-J.) Thus, consumption of the amount of FruiteX-B®/calcium fructoborate in the Products may help reduce the risk of these conditions, and help support a healthy cardiovascular system, ***in addition*** to providing joint health benefits. (Grande Decl. at ¶¶ 18-23; Exs. H-J.)

b. Methylsulfonylmethane (MSM)

Two of the three MFA Products at issue (MFA Plus MSM & MFA Plus MSM and Vitamin D3)—including the Products purchased by both Plaintiffs—contain 750 mg of MSM per serving (MFA Plus MSM and MFA Plus MSM & Vitamin D). (Sexton Decl., ¶ 6.) MSM is a naturally occurring compound that is used in dietary supplements for a variety of applications. (Grande Decl., ¶ 24.) In clinical studies, MSM has been shown to help maintain proper cellular function, and assist in preventing healthy cells from transitioning into unhealthy cells, such as cancer. (*Id.* at ¶ 25; Ex. K.)

MSM has also been shown to have an anti-inflammatory effect on the body, and an antioxidant effect on cells. These effects of MSM can potentially prevent, or at least slow the progression of, certain diseases linked to the oxidative stress caused by free radicals, such as Alzheimer's disease, and cardiovascular disease due to clogged arteries. They can also help prevent or slow the progression of autoimmune and inflammatory disorders, such as rheumatoid arthritis and cancer, as well as cataracts and age-related vision decline, and diabetes. Finally, the effects of MSM can also help slow the progression of genetic degenerative diseases such as Huntington's disease and Parkinson's. (Grande Decl., ¶¶ 26-27; Ex. K.)

Further, MSM has been shown to support immune response in the body, and induce

apoptosis (*i.e.* death) in certain kinds of cancer cells. (Grande Decl., ¶ 28; Ex. K.)

Additional benefits of MSM include normalizing collagen formation and improving skin health, and allowing cells to more easily eliminate toxins after exercise and decrease post-exercise recovery time. (Grande Decl., ¶ 29; Ex. L.)

c. Vitamin D3

One of the MFA Products at issue (MFA Plus MSM and Vitamin D3) contains 2000 IU of Vitamin D per serving, which is 5 times the level of Vitamin D considered merely "adequate" for individuals aged 51-70 years old, and is within safe limits. (Sexton Decl., ¶ 7; Grande Decl., ¶ 41; Ex. M.) Vitamin D's major function in humans is to maintain calcium and phosphorus concentrations within a normal range. Vitamin D does this by enhancing the efficiency of the small intestine to absorb calcium and phosphorus from the diet, including from dietary supplements. (Grande Decl., ¶ 32; Ex. M.) In other words, Vitamin D, and particularly Vitamin D3, is a critical nutrient for the transport and absorption of calcium and the development and maintenance of bone in the human body, including increasing bone density, reducing the risk of fracture, and stimulating remodeling (i.e. rebuilding) of the bones (*Id.* at ¶¶ 32-34; Ex. M-O.)

Vitamin D deficiency can lead to a number of negative health issues, including destruction and degradation of bone, muscle weakness, and all-cause mortality. (Grande Decl., ¶¶ 36-38; Exs. M-P.)

Vitamin D also has effects on the body other than the bones/skeletal system. For example, it has been associated with the control of more than 200 genes, including genes that are responsible for regulating rapid cell growth, and cell differentiation (changes in a cell's gene expression to become a different type of cell), and formation of new blood vessels from older ones. These effects can impact diseases that are caused by cell mutation, like cancer. (Grande Decl., ¶ 39; Ex. N.) As a result, some studies have suggested that Vitamin D deficiency is associated with an increased risk of certain cancers. (*Id.* at ¶ 40; Exs. M-N.) Conversely, Vitamin D3 also has been shown to decrease cell multiplication and act as an anti-inflammatory, and studies have presented a link between high vitamin D3 levels and a lower

risk of cancer. (*Id.* at ¶ 40; Ex. N.)

d. Glucosamine

Although the central dispute in this matter is whether glucosamine and chondroitin provide joint health benefits, which is not at issue in this Motion, glucosamine has recently been demonstrated to provide health benefits ***other than*** for joints. Specifically, a May 2019 peer-reviewed and published study with over 500,000 participants found that regular use of glucosamine was associated with a reduced risk of cardiovascular disease and individual cardiovascular health events, such as death resulting from such disease, stroke, and coronary heart disease. (Grande Decl., ¶¶ 13-16; Ex. G.)

C. Relevant Statutory Framework Governing Dietary Supplement Advertising

Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*., to govern the labeling and marketing of foods and drugs. In 1990, Congress enacted the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343 *et seq*., which amended the FDCA, in an effort to "clarify and strengthen [FDA's] authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods." *Nat'l Counsel for Improved Health v. Shalala,* 122 F.3d 878, 880 (10th Cir. 1997) *quoting* H.R. Rep. No. 101-538, at 7 (1990).

Four years later, in 1994, Congress enacted a series of amendments to the FDCA known as the Dietary Supplement Health and Education Act ("DSHEA") (Pub. L. No. 103-417, 108 Stat. 4325-35) (codified as amended in various sections of 21 U.S.C. and 42 U.S.C.) to uniformly regulate the manufacture, labeling, advertising, and distribution of dietary supplements, which typically qualify as "foods" under the FDCA. *See generally*, 21 U.S.C. § 321(ff); *see also* 21 U.S.C. §§ 343 & 343-1. As a result, the FDCA, through the NLEA, governs permissible advertising for dietary supplements such as the Product.

The FDCA allows dietary supplement manufacturers like RB to make "structure/function claims" about their products if (1) there is substantiation for the statement, and (2) the statement includes a prominent disclaimer that the FDA has not evaluated the statement and that the product "is not intended to diagnose, treat, cure, or prevent any disease"

("DSHEA Statement"). 21 U.S.C. § 343(r)(6). The FDCA does not permit manufacturers to make "disease claims" in relation to dietary supplements. *Id.*; 21 C.F.R. § 101.93(g)(2)(ii).

A "structure/function claim" under the FDCA is a statement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." 21 U.S.C. § 343(r)(6). A structure/function claim "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases" (21 U.S.C. § 343(r)(6)), otherwise it qualifies as a "disease claim." *See* 21 C.F.R. § 101.93(g)(2)(ii) (defining a "disease claim" as one that "claims to diagnose, mitigate, treat, cure, or prevent disease"). A disease claim can be made either explicitly or implicitly (such as by claiming that a product treats a disease's "characteristic signs or symptoms"). *Id*.

In addition to the requirements above, the FDCA also includes an express preemption provision that precludes states from directly or indirectly imposing any requirements for advertising of dietary supplements that are "not identical to" the requirements of the FDCA. 21 U.S.C. § 343-1(a)(5). The phrase "not identical to" in this context means:

> that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of [dietary supplements 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].

21 C.F.R. § 100.1(c)(4).

ARGUMENT

I. SUMMARY JUDGMENT STANDARD

Summary judgment is properly granted where "a movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). An issue is "genuine" only if there is sufficient evidence for a reasonable fact-finder to find for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). A fact is

"material" if the fact may affect the outcome of the case. *Id*. at 248.

A defendant moving for summary judgment bears the initial burden of either producing evidence that negates an essential element of a plaintiff's claim or by showing that the plaintiff does not have enough evidence of an essential element to satisfy her ultimate burden of persuasion at trial. *Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Companies, Inc.*, 210 F.3d 1099, 1102 (9th Cir. 2000) (citation omitted). Once a defendant makes this showing, the burden then switches to the plaintiff to produce some "significant probative evidence" supporting his claims in order to defeat summary judgment. *Summers v. Teichert & Son, Inc*., 127 F.3d 1150, 1152 (9th Cir. 1997). If the plaintiff fails to make this showing, and "the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial'" and summary judgment must be granted. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986) (citation omitted); *see also, Celotex*, 477 U.S. at 322.

II.
SUMMARY JUDGMENT SHOULD BE GRANTED ON ALL OF PLAINTIFFS' CLAIMS BECAUSE THEY ARE ALL PREEMPTED BY FEDERAL LAW.

The Ninth Circuit has recently held that the FDCA "preempts state-law requirements for claims about dietary supplements that differ from the FDCA's requirements." *Dauchaer v. NBTY, Inc*., 913 F.3d. 844, 848-49 (9th Cir. 2019) (citing 21 U.S.C. § 343-1(a)(5)). When the FDCA expressly permits certain labeling, and a state law false advertising claim is premised on the alleged false or misleading nature of a claim that satisfies the requirements of the FDCA, the state law claim is subject to the FDCA's express preemption provision. *See Durnford v. MusclePharm Corp*., 907 F.3d 595, 603 (9th Cir. 2018); *see also, Trujillo v. Walgreen Co.*, No. 13 CV 1852, 2013 WL 4047717, at *1 (N.D. Ill. Aug. 9, 2013) ("If a statement for a food product satisfies federal labeling requirements, the NLEA's express preemption clause precludes state law consumer fraud claims.") (citation omitted); *Gillum v. Safeway Inc.*, No. 2:13-cv-02047, 2015 WL 1538453, at *9, n. 7 (W.D. Wash. Apr. 7, 2015) (noting "it is proper to raise a federal preemption defense at summary judgment") (citation omitted).

The Ninth Circuit also held that, to the extent a plaintiff is challenging the defendant's permissible structure/function claims as false and misleading because the product at issue did not prevent or reduce the risk of disease, the plaintiff's claims are similarly preempted by the FDCA. *See Dachauer,* 913 F.3d at 848-49 (citing 21 U.S.C. § 343-1(a)(5)). The Ninth Circuit reasoned that, if true, plaintiff's claims under state law would impose different labeling requirements than the FDCA (*i.e.*, that the product had been shown to prevent or reduce the risk of disease rather than affect the structure or function of the body). *Id*.

At least three recent district courts in California have followed *Dachauer* and concluded that plaintiffs' false advertising claims were preempted by the FDCA because the challenged claims were proper structure/function claims that were expressly permitted under the FDCA. *See Greenberg v. Target Corp.,* No. 17-cv-01862-RS, 2019 WL 4182729, at *3-4 (N.D. Cal. Aug. 29, 2019) (granting summary judgment, finding plaintiff's state law false advertising claims [UCL and CLRA] were preempted by the FDCA because they challenged permissible structure/function claims); *Korolshteyn v. Costco Wholesale Corp.*, No. 3:15-cv-709-CAB-RBB, 2019 WL 2617043, at *3-4 (S.D. Cal. June 25, 2019) (same); *Kroessler v. CVS Health Corp.*, 387 F. Supp. 3d 1064, 1066-71 (S.D. Cal. 2019) (granting motion to dismiss for failure to state a claim in a similar glucosamine case filed by the same attorneys representing Plaintiff here, holding that the plaintiff's California CLRA, UCL, and breach of express warranty claims, which were based on allegedly false and misleading structure/function claims, were preempted by the FDCA).[9]

The FDA has published guidelines discussing, among other things, the parameters of what constitutes permissible structure/function claims under the FDCA, as compared to an impermissible disease claim. *See* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000-01 (Jan. 6, 2000) (the "Regulations"). The Ninth Circuit relied on the Regulations in deciding the preemption issue in *Dachauer*. *See Dachauer,* 913 F.3d at 847 (discussing the

[9] RB acknowledges that appeals have been filed in *Korolshteyn* and *Kroessler*. However, both rely on *Dachauer*, and RB respectfully proffers that the courts' reasoning and analysis in both those cases is sound and applies with equal force in the present case.

Regulations). In pertinent part, the Regulations provide that:

> statements that mention a body system, organ, or function affected by the supplement using terms such as "stimulate," "***maintain***," "***support***," "regulate," or "***promote***" can be appropriate when the statements do not suggest disease prevention or treatment for a serious health condition that is beyond the ability of the consumer to evaluate.

Regulations, 65 Fed. Reg. at 1015 (emphasis added); *see also Dachauer,* 913 F.3d at 847 (noting that FDA "guidance recognizes that structure/function claims may use general terms such as 'strengthen,' 'improve,' and 'protect,' as long as the claims 'do not suggest disease prevention or treatment.'") (citing Regulations, 65 Fed. Reg. at 1028) (emphasis added). The FDA has also given examples of what constitutes a permissible structure/function claim, such as claims that a dietary supplement "***supports*** the immune system." *Id.* at 1028-29 (emphasis added).

Further, the FDA has also recognized that the FDCA "expressly permits statements that 'characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.'" Regulations, 65 Fed. Reg. at 1018. Similarly, the FDA has recognized that "claims concerning the ***maintenance*** of 'normal' or '***healthy***' structure or function ***do not imply disease prevention*** in the context of dietary supplement labeling." *Id.* (emphasis added). The FDA has given examples of health maintenance claims that would rise to the level of a disease claim, *e.g.,* "maintaining a tumor free state," which would imply preventing cancer, and "maintain normal bone density in post-menopausal women," which would imply prevention of osteoporosis. *Id.*

Moreover, with respect to dietary supplements for joints in particular, like the Products at issue in this case, the FDA has directly addressed acceptable claims, saying:

> FDA also believes that "joint pain" is a characteristic of arthritis. [J]oint tenderness is the most sensitive physical sign of rheumatoid arthritis[]. *The claim* ***"helps support cartilage and joint function,"*** *on the other hand,* ***would be a permissible structure/function claim****, because it relates to maintaining normal function rather than treating joint pain.*

Regulations, 65 Fed. Reg. at 1016-17 (emphasis added, internal citations omitted). *See also*

Greenberg, 2019 WL 4182729 at * 3 (quoting the Regulations); *Kroessler,* 387 F. Supp. 3d at 1069-71 (same). And perhaps most importantly for present purposes, the FDA has expressly reiterated that "***claims related to maintenance or support of joints*** . . . ***are appropriate structure/function statements***." Regulations, 65 Fed. Reg. at 1030 (emphasis added).

Here, the claims for the Products that Plaintiffs allege are false and misleading fall squarely into the category of proper structure/function claims under the FDA's guidance. Specifically, the advertising claim challenged by Plaintiff, that the Products "***Support***[] ***Five Signs of Joint Health***: Mobility, Comfort, Strength, Flexibility, Lubrication," are ***indistinguishable*** from the statements that the FDA has expressly stated are permissible structure/function claims under the FDCA, as discussed above.[10] *See, e.g., Kroessler,* 387 F. Supp. 3d at 1067-71 (finding substantially similar statements made about a different GC product sold by another manufacturer, such as "joint health," "strengthen joints," "improves joint comfort," "supports flexibility & range of motion," "Nourishes cartilage and promotes comfortable joint movement," "helps maintain healthy joint flexibility and lubrication," and "Supports healthy cartilage & joint comfort," to all be FDA-sanctioned structure/function claims). *See also, Dachauer*, 913 F.3d. at 846-49 (finding the statements "support cardiovascular health" and "heart health" on vitamin E supplement labels constituted permissible structure/function claims); *Greenberg,* 2019 WL 4182729 at *1-4 (finding claims that supplement "helps support healthy hair and skin" was a structure/function claim); *Korolshteyn,* 2019 WL 2617043 at *1-4 (finding claims that supplement "supports alertness & memory," "can help with mental clarity and memory," and "helps maintain healthy blood flow to the brain to assist mental clarity and memory, especially occasional mild memory problems associated with aging" were structure/function claims).

[10] Indeed, the foregoing statement indisputably makes *no* reference, either expressly or impliedly, to any of the "signs and symptoms" of osteoarthritis (OA), which Plaintiff describes as "joint pain, joint tenderness, joint stiffness, and the inability to move joints through full range of motion." (Dkt. No. 24 at ¶ 26.) Rather, the statement refers only to how the Product "acts to maintain [the] structure or function [of joints]" and "describe[] general well-being [of the joints] from consumption" of the ingredients in the Products, which are expressly permitted under the FDCA as structure/function claims. 21 U.S.C. § 343(r)(6)(A).

Moreover, Plaintiffs do not (and indeed cannot) dispute that the required DSHEA Statement appears on the packaging, labeling, and website for the Products, as required by 21 U.S.C. § 343(r)(6)(C). (*See* Dkt. No. 86-3.) Thus, RB has complied with federal labeling requirements for dietary supplements.

Because Plaintiffs' state law UCL, CLRA, FAL and NY GBL claims would impose requirements above and beyond that of federal law, they are expressly preempted by the FDCA and NLEA. *See Dachauer*, 913 F.3d at 846-49; *Durnford*, 907 F.3d at 600; *Greenberg,* 20019 WL 4182729 at *3-4; *Korolshteyn*, 2019 WL 2617043 at *4; *Kroessler,* 387 F. Supp. 3d at 1067-71.

III.
ALTERNATIVELY, PLAINTIFFS' CLAIMS FAIL AS A MATTER OF LAW BECAUSE PLAINTIFFS CANNOT ESTABLISH THAT RB'S ADVERTISING FOR THE PRODUCTS WAS FALSE AND MISLEADING.

Alternatively, summary judgment should be granted on all of Plaintiffs' claims because Plaintiffs cannot demonstrate that RB's advertisements are false or misleading as a matter of law. Unrefuted evidence supports that one of the ingredients in the Products—FruiteX-B®—***alone*** provides the advertised joint health benefits. Therefore the advertising for the Products is not false or misleading as a matter of law.

In the false advertising context, to create a genuine issue of material fact regarding whether advertising for a dietary supplement is false or misleading, a Plaintiff must produce **affirmative evidence** that the product does not work as advertised—the Plaintiff cannot merely attack the quality of defendant's substantiation for its claims. *See, e.g., Sonner v. Schwabe North America, Inc.,* 911 F. 3d 989, 992-93 (9th Cir. 2019); *Kwan v. SanMedica Int'l, LLC,* 854 F.3d 1088, 1095-98 (9th Cir. 2017). If a plaintiff does not present affirmative evidence that a defendant's advertising claims are false and misleading, but rather, only attempts to undermine the defendant's support for the claims, a plaintiff is attempting to make an impermissible "lack of substantiation" claim. *Kwan,* 854 F.3d at 1095-98; *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.,* 107 Cal. App. 4th 1336, 1345-48 (2003).

Here, multiple clinical studies have demonstrated that FruiteX-B®, or calcium fructoborate, ***on its own***, or in combination with GC, provides both short- and long-term joint health benefits, including reducing pain, stiffness, and joint discomfort, and increasing physical mobility. (Pietrzkowski Decl., ¶¶ 7-33; Exs. A-E.) Consequently, and regardless of whether GC does or does not provide joint health benefits or "support[] 5 signs of joint health," FruiteX-B® ***does*** provide such advertised benefits. (*Id.*) "In the absence of affirmative evidence that scientific research does not support [RB's] claims, the strength of [RB's] evidence is irrelevant and Plaintiffs' claims are based on 'lack of substantiation' rather than proof of falsity." *Johns v. Bayer Corp.*, No. 09CV1935 AJB (DHB), 2013 WL 1498965, at *43 (S.D. Cal. Apr. 10, 2013) (granting summary judgment in favor of defendant).

Because Plaintiffs will be unable to present any evidence to the contrary that FruiteX-B® does not provide such joint health benefits, Plaintiffs will be unable to raise a triable issue of fact regarding whether the advertising for the Products was false or misleading. Summary judgment in favor of RB is therefore proper. *Id.*

IV.
ALTERNATIVELY, PLAINTIFFS' "FULL REFUND" DAMAGES THEORY ALSO FAILS AS A MATTER OF LAW BECAUSE PLAINTIFFS CANNOT ESTABLISH THE PRODUCTS ARE WORTHLESS.

Finally, if the Court is not inclined to dismiss Plaintiffs' claims outright, the Court can, and should, decide as a matter of law that Plaintiffs' "full refund" damages theory cannot be supported because the various ingredients in the Products provide a variety of other health benefits to consumers. Therefore, the Products have value independent of whether they provide the advertised joint health benefits, and are not "worthless" as a matter of law. *See, e.g., Ewert v. eBay, Inc.*, 602 F. App'x 357, 359 (9th Cir. 2015) ("When damages are an essential element of the plaintiffs' claim, failure to 'offer competent evidence of damages' supports a grant of summary judgment.") (citations omitted); *Corvello v. Wells Fargo Bank N.A.*, Nos. 10-cv-05072-VC & 11-cv-03884-VC, 2017 WL 3449072, at *2–3 (N.D. Cal. May 4, 2017) ("Summary judgment must nonetheless be granted … on the UCL claim because the plaintiffs have not presented a viable, evidence-based theory of restitution").

The proper measure of restitution for all of Plaintiffs' claims is the difference between what the plaintiff paid and the value of what was received. *See*, *e.g.*, *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 131 (2009); *Dash v. Seagate Tech. (U.S.) Holdings, Inc.*, 27 F. Supp. 3d 357, 361–62 (E.D.N.Y. 2014) (citing *Small v. Lorillard Tobacco Co.*, 94 N.Y.2d 43, 56 (1999) and *Servedio v. State Farm Ins. Co.*, 889 F. Supp. 2d 450, 452 (E.D.N.Y. 2012)).

To receive a full refund under California's UCL, FAL, and CLRA and New York General Business Law §§ 349-350—the damages Plaintiffs seek—Plaintiffs must prove that the Products have ***no*** value for ***any*** class members. *See*, *e.g.*, *In re POM Wonderful LLC*, No. ML 10–02199 DDP (RZx), 2014 WL 1225184, at *3 & n. 2 (C.D. Cal. Mar. 25, 2014) ("[T]he Full Refund model depends upon the assumption that not a single consumer received a single benefit . . . ."); *Red v. Kraft Foods, Inc.*, No. CV 10–1028–GW(AGRx), 2012 WL 8019257, at *11 (C.D. Cal. Apr. 12, 2012) (holding that the court could not approve disgorgement of full profits from the defendant because "Plaintiffs received some benefit from the Products and thus awarding class members full refunds on their purchases would constitute [improper] nonrestitutionary disgorgement" under California law); *Sperling v. Stein Mart, Inc.*, No. EDCV 15-01411 BRO (KKx), 2016 WL 8925347, at *10 (C.D. Cal. Jan. 26, 2016) ("A California Court of Appeal recently explained, in a UCL and FAL case, that 'a full refund may be proper when a product confers no benefit on consumers,' but found that 'the court lacked discretion to award restitution' because 'plaintiffs did not establish any price/value differential.'") (quoting *In re Tobacco Cases II*, 240 Cal. App. 4th 779, 802 (2015));[11] *In re Scotts EZ Seed Litigation,* 304 F.R.D. 397, 412 (S.D.N.Y. 2015) (acknowledging that on all of Plaintiffs' claims, including NY GBL 349-350, a full refund model "rests on the assumption that plaintiffs received no benefit whatsoever" from the product); *Dash,* 27 F. Supp. 3d at 361-62 ("[I]t is well-settled that a consumer is not entitled to a refund of the price of a good or

[11] *See also, Colgan v. Leatherman Tool Grp., Inc.*, 135 Cal. App. 4th 663, 700 (2006) (measure of restitution under UCL. FAL and CLRA must be supported by "substantial evidence"); *id*. at 694 & n. 22 (noting that the standards for awarding restitution are the same in UCL, FAL, and CLRA actions); *Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal.4th 1134, 1148 (2003) (disgorgement under the UCL and FAL must be "restitutionary in nature").

service whose purchase was allegedly procured through deception under Sections 349 and 350 of the New York General Business Law.") (citing *Small,* 94 N.Y.2d at 56); *Servedio*, 889 F. Supp. 2d at 452 (collecting cases). Plaintiffs cannot make this showing.

Ingredients contained in ***all*** of the Products at issue, including glucosamine and calcium fructoborate (FruiteX-B®), have been shown to provide cardiovascular benefits, reduce inflammation, and reduce the levels of various proteins, amino acids, and fats in the blood that can lead to heart disease, auto-inflammatory conditions and blood clots, thereby reducing the risks of these conditions. (Grande Decl., ¶ 18-23; Exs. H-J.)

Additional health benefits are provided by MSM for consumers, including Plaintiffs, who purchased two of the three Products at issue (MFA Plus MSM or MFA Plus MSM and Vitamin D3).[12] Specifically, MSM has been shown to help maintain proper cellular function, has an anti-inflammatory effect on the body, and an antioxidant effect on cells. (Grande Decl. at ¶¶ 25-27; Ex. K.) These effects of MSM can potentially prevent, or at least slow, the progression of certain diseases such as Alzheimer's disease, cardiovascular disease due to clogged arteries, autoimmune and inflammatory disorders, such as rheumatoid arthritis and cancer, cataracts and age-related vision decline, diabetes, and genetic degenerative diseases such as Huntington's disease and Parkinson's. (Grande Decl. at ¶¶ 26-27; Ex. K.) MSM has been shown to support immune response in the body, and induce apoptosis (*i.e.* death) in certain kinds of cancer cells, normalize collagen formation and improve skin health, and allow cells to more easily eliminate toxins after exercise and decrease post-exercise recovery time. (Grande Decl. at ¶¶ 28-29; Exs. K-L.)

Consumers who purchased MFA Plus MSM and Vitamin D3 received additional benefits from the Vitamin D in the Product.[13] Specifically, Vitamin D3 enhances the transport and absorption of calcium and the development and maintenance of bone in the human body, including increasing bone density, reducing the risk of fracture, and stimulating remodeling

[12] MFA Plus MSM contains the additional advertising claim: "PLUS: Extra Cartilage Support." (Sexton Decl., ¶ 6.)

[13] MFA Plus MSM contains the additional advertising claim: "PLUS: Extra Bone Support." (Sexton Decl., ¶ 7.)

(i.e. rebuilding) of the bones. (Grande Decl., ¶ 34; Ex. M-O.) Vitamin D3 also has been shown to decrease cell multiplication and act as an anti-inflammatory, and studies have presented a link between high vitamin D3 levels and a lower risk of cancer. (Grande Decl., ¶ 40; Ex. N.) Vitamin D deficiency can cause a number of negative health issues, including destruction and degradation of bone, muscle weakness, an increased risk of certain cancers, and all-cause mortality. (Grande Decl., ¶¶ 36-38; Ex. M-P.) Thus, supplementation with the 2000 IU of Vitamin D contained in MFA Plus MSM and Vitamin D3 can provide health benefits independent of joint health benefits.

Where, as here, products are shown to have some value to a consumer, even if the advertising is false and misleading, courts reject a "full refund" theory of damages. *See, e.g., In re Tobacco Cases II*, 240 Cal. App. 4th at 794-802 (consumers received some value from cigarettes, and restitution "may not be based solely on deterrence"); *Stathakos v. Columbia Sportswear Co.,* No. 15-cv-04543-YGR, 2017 WL 1957063, at *10 (N.D. Cal. May 11, 2017) (rejecting full refund theory where "plaintiffs undeniably obtained some value from the garments they purchased, separate and apart from the allegedly deceptive advertising practices"); *Chowning v. Kohl's Dep't Stores, Inc*., No. CV 15-08673 RGK (SPx), 2016 WL 1072129, at *6 (C.D. Cal. Mar. 15, 2016) ("[E]ven though plaintiffs may pursue alternative forms of restitution, any proposed method must account for the benefits or value that a plaintiff received at the time of purchase."); *In re POM Wonderful LLC*, 2014 WL 1225184, at *3 (rejecting the "full refund" theory because plaintiffs could not plausibly contend they received no benefit from the products); *Allen v. Conagra Foods, Inc*., No. 3:13-cv-01279-WHO, 2019 WL 3302821, at *21–24 (N.D. Cal. July 22, 2019) (same); *Lanovaz v. Twinings N. Am., Inc.*, No. C–12–02646–RMW, 2014 WL 1652338, at *6 (N.D. Cal. April 24, 2014) (same); *see also Servedio*, 889 F. Supp. 2d at 452 (refusing to award full refund where plaintiff could not show the product he bought lacked value or that he paid a premium of over what he normally would have paid).

Because the Products conferred certain health benefits on consumers, independent of joint health benefits, Plaintiffs cannot present competent evidence that they and class members

are entitled to a full refund of their purchase price, because the Products have some value, and are not "worthless" as a matter of law. Therefore, it is respectfully submitted that the Court should grant summary judgment finding that the Products are not worthless as a matter of law and, therefore, Plaintiffs' "full refund" theory of damages also fails.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the Court should grant summary judgment in Defendant's favor on all of Plaintiffs' claims. Alternatively, the Court should grant summary judgment on the issue that the Products are not worthless as a matter of law and, therefore, Plaintiffs and the class are not entitled to a full refund of their purchase price as a measure of damages or restitution.

Dated: September 26, 2019

Respectfully submitted,

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By: */s/ Adrianne E. Marshack*
ADRIANNE E. MARSHACK

CERTIFICATE OF SERVICE

I hereby certify that on September 26, 2019, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the Electronic Mail Notice List, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the Electronic Mail Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on September 26, 2019.

/s/ Adrianne E. Marshack
ADRIANNE E. MARSHACK

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