STEPHEN D. GILLETT, an individual, Plaintiff, v. METAGENICS, INC., Defendant.	No. CGC-09-494987 Action Filed: December 4, 2009
STEPHEN D. GILLETT, an individual, Plaintiff, v. MILK SPECIALTIES, INC., et al., Defendants.	No. CGC-10-495959 (*consolidated with lead case* 08-479027) Action Filed: December 23, 2008

I. INTRODUCTION

Plaintiff Stephen Gillett brought these above-captioned related actions in a representative capacity against the following defendants: (1) Nature's Bounty, Inc., (2) NBTY, Inc., (3) Metagenics, Inc., (4) Garden of Life, Inc., (5) Garden of Life LLC, (6) Whole Foods Market California, Inc., (7) Milk Specialties, Inc, (8) Nature's Products, Inc., (9) Atrium Innovations, Inc., and (10) HVL, Inc. (collectively "defendants"). Plaintiff alleges that defendants manufacture, package, distribute, market, and/or sell products to California consumers without first warning them that those products expose them to lead in violation of California Health & Safety Code § 25249.5 *et seq*. (also known as "Proposition 65"). Defendants dispute that allegation. According to them, exposures to lead, if any, caused by their products fall within an exemption to Proposition 65's warning requirement.

These actions involve a multitude of similar products. To simplify matters, the parties stipulated to a list of ten products, five selected by plaintiff and five by defendants, deemed by the parties to be representative of all the products in these actions (the "Representative Products").[1]

On May 23, 2012, the parties presented the following stipulated question for resolution by the Court: "Whether and, if not, the extent to which the representative products at issue are 'food'" for purposes of title 27, § 25501 of the California Code of Regulations ("Section 25501"). Stip. Stmt., filed May 23, 2012. Pursuant to Section 25501, exposures to naturally occurring chemicals in food are exempt from Proposition 65's warning requirement. On the stipulated question, the parties seek only a determination as to whether the Representative Products are foods within the meaning of that exemption, not whether any alleged lead in those products is naturally occurring.

[1] The Representative Products consist of: (1) Exhilarin, (2) Nazanol, (3) Black Cohosh, (4) Valerian Root Plus Calming Blend, (5) Primal Defense ULTRA, (6) Primal Defense, (7) OmegaZyme ULTRA, (8) Living Multi, (9) Perfect Food Super Green Formula, and (10) FYI Joint and Tissue Food. Stip. Representative Products, filed February 9, 2012.

The Court held a bench trial on August 6-9, November 16, and December 14, 2012 to resolve that issue. On November 30, the parties submitted proposed statements of decision, and thereafter, on December 21, they submitted revised proposed statements. The parties also submitted post-trial briefs with the last being filed on January 4, at which time this matter was submitted for final resolution by the Court.

The parties have stipulated to waive a tentative statement of decision. Aug. 7, 2012 Hr'g Tr. at pp. 177-78. Accordingly, having fully considered all the admitted evidence and all the arguments of counsel presented orally and in briefing, the Court now issues this Final Statement of Decision.

II. REPRESENTATIVE PRODUCTS

The Court's findings of fact regarding the Representative Products include the following:

Each Representative Product is sold, marketed, and/or labeled as a dietary, herbal or vitamin supplement. None is represented for use as a conventional food or as the sole item of a meal. Each comes in a bottle containing tablets, capsules, or powder intended both for human consumption and to supplement the diet. Under neither.state nor federal law are any of the Representative Products regulated as a drug.

The ingredients in the Representative Products are accurately listed on the product labels. Those labels reflect the end result of long processes with checks and balances to ensure labeling accuracy. Those processes give assurance that the Representative Products are manufactured in accordance with the good manufacturing practices required by the FDA. To ensure labeling accuracy, identity testing is performed for each ingredient in the Representative Products. The product labels are used, and relied upon as accurate, in the normal course of business. The formulas and ingredients listed on the product labels have remained unchanged since 2007, and the labels are accurate.

Each of the Representative Products contains at least one of the following dietary ingredients: a vitamin, mineral, or herb. Even though only some of the Representative Products list nutritional information on their product labels, all of the Representative Products contain macronutrients (*e.g.*, fats, carbohydrates, or proteins) or micronutrients (*e.g.*, vitamins), or both. Each of the Representative Products is designed to, and does in fact, provide nutrition when consumed.

All the Representative Products' labels, except the label on Living Multi, include a "structure function claim," that being a statement about the beneficial effect of the product on the natural structure or normal functioning of the body. Further, except for the label on Living Multi, each label includes a statement that the product is not intended to diagnose, treat, cure or prevent any disease. None of the labels on any Representative Product includes a "disease claim," meaning a statement evidencing an intention to treat, mitigate or cure a disease. In fact, there is no intention that any of the Representative Products be used as a drug.

III. ANALYSIS

Proposition 65 is a "right to know" statute requiring businesses that expose consumers to certain chemicals to provide a written warning unless the exposure falls within a statutory exemption. Specifically, Proposition 65 provides as follows: "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual," except as provided by statute. Health & Safety Code § 25249.6.

As previously noted, there are exemptions to Proposition 65's warning requirement. The exemption here relevant is found in Section 25501. Under that exemption, "the duty to warn before exposing any person to a listed chemical . . . escapes activation to the extent a listed chemical is naturally occurring in the food. Human consumption of a food is not an 'exposure' under

Proposition 65 if a defendant can show that the targeted chemical is naturally occurring in food." *People v. Tri-Union Seafoods, LLC*, 171 Cal. App. 4th 1549, 1556 (2009)(internal citations omitted).

The dispute at hand concerns the applicability of the exemption for food found in Section 25501 to the Representative Products. Defendants contend that the Representative Products are foods for purposes of Section 25501 because they are dietary supplements. In contrast, plaintiff contends that the term food in Section 25501 has a narrow definition that does not include dietary supplements. For the reasons set forth below, the Court agrees with the defendants, and concludes that the Representative Products are foods for purposes of Section 25501.

Proposition 65 and its current implementing regulations do not expressly define the term food. Given that circumstance, the Court must construe the term food in accordance with pertinent rules of statutory construction. The fundamental goal of statutory construction is to ascertain and effectuate the drafter's intent. *Nolan v. City of Anaheim*, 33 Cal. 4th 335, 340 (2004); *Weaver v. Chavez*, 133 Cal. App. 4th 1350, 1355 (2005). To ascertain drafting intent, courts look to a variety of sources, including regulatory history where applicable. *Nolan*, 33 Cal. 4th at 340; *see, e.g.*, *Cal. Teachers Ass'n v. Comm. on Teacher Credentialing*, 7 Cal. App. 4th 1469, 1472 (1992). "[W]ords which have acquired a particular meaning in law are to be so construed." *Handlery v. Franchise Tax Bd.*, 26 Cal. App. 3d 970, 981 (1972). Furthermore, "statutes or statutory sections relating to the same subject must be harmonized, both internally and with each other, to the extent possible." *Cabrini Villas Homeowners Ass'n v. Haghverdian*, 111 Cal. App. 4th 683, 690 (2003). When the same word is used in similar laws, that word should be interpreted consistently. *People v. Casillas*, 92 Cal. App. 4th 171, 183 (2001); *Meanley v. McColgan*, 49 Cal. App. 2d 203, 209 (1942). Where a regulation incorporates a specific section of a statute by reference, and the text of the incorporated statutory section is thereafter amended, that change, in appropriate circumstances, is deemed to be incorporated as well. *See California Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233, 260

(2011)(where Proposition 65 incorporated by reference a section of the Labor Code which referred to a list of hazardous substances, subsequent changes to the list of hazardous substances in the Labor Code were deemed incorporated into Proposition 65).

This Court begins its analysis by examining the regulatory history of Section 25501. That section began with a petition filed with the California Health & Welfare Agency ("HWA") on April 30, 1987—just after Proposition 65 took effect—by 20 entities. Tr. Ex. 619 at 1539;[2] *see also Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 655 (1991). The HWA was designated by the Governor to be the lead agency for Proposition 65 and served in that role until 1991, when the Office of Environmental Health Hazard Assessment became the lead agency. *Nicolle-Wagner*, 230 Cal. App. 3d at 655; Cal. Code Regs., tit. 27, § 25102(o).

The petitioners explained to the HWA that many foods contain trace amounts of carcinogenic chemicals and that a requirement that warnings appear on all foods that may contain such chemicals would result in over warning that would confuse the public and not advance public health. Tr. Ex. 619 at 1545. The petitioners proposed that food complying with federal and California safety laws be exempted from the Proposition 65 warning requirement and that the term "food" in the requested regulation be the same "as it is defined in Federal and California law, broadly to include all 'articles used for food or drink for man or other animals, chewing gum, and components of any such article.'" Tr. Ex. 619 at 1551-1552.

In response to the petition, the HWA adopted an interim regulation known as "Section 12713." Cal. Code Regs., tit. 22, § 12713. Tr. Exs. 616, 617 at 15. That section exempted food that complied with applicable safety laws from the warning requirements of Proposition 65 and defined "food" as having the same meaning as under federal law, expressly referencing 21 U.S.C. § 321(f).

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[2] Page references for Exhibit 619 are to the 4-digit bates-number in the lower right corner of each page preceded by "000".

Tr. Ex. 616. The HWA's Final Statement of Reasons for Section 12713 stated that Section 12713's definition of food "is based upon existing federal and state law precedent," and stated that its intent in incorporating the federal definition into state law was to "make[ ] section 12713 consistent with the federal law to which it refers and confine[ ] the scope of the regulation to identifiable categories for which standards exist." Tr. Ex. 608 at 48. The HWA noted that Section 12713's definition of food "includes not only raw agricultural commodities (including meat, poultry and eggs) that are commonly regarded as food . . . but also all of the chemical constituents and ingredients, of natural or synthetic origin, that result from the production or processing of those commodities." *Id.* Section 12713 went into effect on February 27, 1988. Tr. Ex. 616.

Section 25501 was passed at the same time as Section 12713. During the public comment period for Section 25501, it was noted that the term "food" in Section 25501 would also incorporate the federal definition. Tr. Ex. 619 at 282. There are no comments in the administrative rule-making record for Section 25501 advocating for a definition of food different from the then-existing definition of food under Section 12713. Section 12713 was ultimately rescinded in 1993 for reasons unrelated to the definition of "food" therein. Tr. Exs. 608 at 47, 618 at 3-4 (Section 12713 was intended to be an interim regulation pending the development of chemical specific risk-based standards). In repealing Section 12713, HWA expressly stated that Section 25501 was to be "unaffected." Tr. Ex. 618 at 9.

This regulatory history demonstrates that it was the clear intent of the HWA that the federal definition of food would govern Section 25501. Nothing in the regulatory history or the text of Section 25501 persuasively suggests that the HWA intended to create a definition of "food" unique to Section 25501 or any different than federal law. In fact, that history shows the HWA intended to import the familiar federal definition of food already embodied in Section 12713.

Having determined that the federal definition of food governs Section 25501, the question becomes whether the Representative Products are foods under that definition. The pertinent federal law, the Food, Drug and Cosmetic Act of 1938 ("FDCA"), broadly defines food as all: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f). This was the federal definition of food at the time that Section 25501 went into effect. Subsequently, Congress amended that definition by deeming dietary supplements to be foods. 21 U.S.C. § 321(ff). Because the HWA intended to incorporate the federal definition of food with respect to Section 25501, this Court determines that the subsequent amendment to the federal definition is deemed to be incorporated in Section 25501 as well. In other words, this Court determines that the HWA intended to track the then-existing federal definition of food and any future changes to it, not a static definition frozen in time.

Under the FDCA, a product is a dietary supplement if it satisfies specific criteria, including: (1) it is intended to supplement the diet; (2) it contains dietary ingredients such as vitamins, minerals or herbs; (3) it is intended for ingestion; (4) it is not represented for use as a conventional food or as sole item of a meal or diet; (5) it is labeled as a dietary supplement; and (6) it is not regulated as a drug under the FDCA. 21 U.S.C. § 321(ff). The evidence presented by the defendants persuasively established that the Representative Products satisfy each of those requirements. Accordingly, the Court holds that the Representative Products are dietary supplements and as a result are foods under federal law. It therefore follows that the Representative Products are also foods for purposes of Section 25501.

This conclusion is consistent with, indeed supported by, other California laws concerning the same subject matter as Proposition 65. Like its federal counterpart, the FDCA, California's Sherman Food Drug and Cosmetic Law broadly defines food as: "(a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal. (b) Any article used or

intended for use as a component of any article designated in subdivision (a)." Health & Safety Code § 109935. Similarly, for purposes of warning labels on dietary supplements, California's Sherman Law adopts the federal definition of dietary supplements: "Whenever a warning label is included on any product defined as a dietary supplement pursuant to Section 321(ff) of Title 21 of the United States Code, that is manufactured or distributed in this state, the label shall be clear and conspicuous." *Id.* at § 110422(a).

California also separately tracks the federal definition of dietary supplement. *Compare* Cal. Code Regs. tit. 17, § 10200 ("Section 10200") *with* 21 U.S.C. § 321(ff). Under Section 10200, a product is a dietary supplement if it satisfies specific criteria, including: (1) it is intended to supplement the diet; (2) it contains dietary ingredients such as vitamins, minerals or herbs; (3) it is labeled as a dietary supplement; (4) it is intended for ingestion in a form such as a tablet, capsule or powder and (5) it is not regulated as a drug under California law. As noted above, the defendants presented evidence that persuasively established that the Representative Products satisfy those criteria. Accordingly, the Court holds that the Representative Products are dietary supplements within the meaning of Section 10200.

While the federal law deems a dietary supplement to be a food, Section 10200 provides that "a dietary supplement may be a food or a drug, or both a food and a drug, as those terms are defined in Health and Safety Code sections 109935 and 109925." That difference, if any, is of no consequence here because the defendants have persuasively established that the Representative Products are not drugs under either state law (Health and Safety Code § 109925) or federal law (21 U.S.C. § 321(g)). Since the Representative Products are dietary supplements and are not drugs, logic dictates that they must be foods under Section 10200.

All these California statutes and regulations, as well as their federal counterparts, relate to the same broad subject matter as Proposition 65—namely consumer health and safety. Under canons of

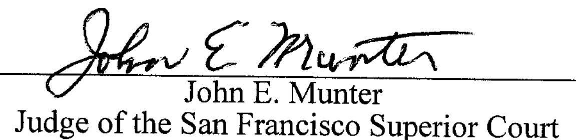
statutory construction, as cited above, similar words in such closely related statutes and regulations are to be interpreted consistently and harmonized with each other to the extent possible. As shown above, the word food has been broadly construed within those statutes and regulations. Moreover, for purposes of warning labels, it is clear that California is following the federal approach. Against that background, the Court determines that its holding that the Representative Products, as dietary supplements, are foods under Section 25501 is consistent with both the state and federal statutory schemes.[3]

Plaintiff's reliance on definitions of food found in other statutory schemes, such as California tax regulations and the international "Nice Classification" of goods and services, to support a narrow definition of food is misplaced. The overarching purpose of the California Health and Safety Code, of which Proposition 65 is a part, is to protect and promote the health and safety of the citizens of this state, and the fact that other areas of law unrelated to that purpose define food differently is irrelevant.

IV. CONCLUSION

The Court answers the stipulated issue by finding and concluding that each of the Representative Products here at issue is a "food" under Section 25501. The defendants have proven this by a preponderance of the evidence.

Dated: February 13, 2013



John E. Munter
Judge of the San Francisco Superior Court

[3] Defendants advanced the contention, vigorously disputed by plaintiff, that various consent judgments issued by California trial courts in Proposition 65 cases support, indeed compel, the conclusion that the Representative Products are foods under Section 25501. That dispute is moot because the Court, without relying in any respect on those consent judgments, has resolved the stipulated issue in defendants' favor.

Superior Court of California
County of San Francisco

STEPHEN D. GILLETT, Plaintiff vs. GARDEN OF LIFE, INC., et al., Defendants	Case Number: CGC-08-479027 Consolidated with CGC-09-488136, CGC-09-491662, CGC-09-494987 and CGC-10-495959 **CERTIFICATE OF ELECTRONIC SERVICE** (CCP 1010.6(6) & CRC 2.260(g))
And consolidated cases	

I, Craig Blackstone, a Deputy Clerk of the Superior Court of the County of San Francisco, certify that I am not a party to the within action.

On February 13, 2013, I electronically served the FINAL STATEMENT OF DECISION ON FOODS TRIAL via LexisNexis File & Serve on the recipients designated on the Transaction Receipt located on the LexisNexis File & Serve website.

Dated: February 13, 2013

T. Michael Yuen, Clerk

By:
Craig Blackstone, Deputy Clerk