UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IMAGENETIX, INC., Plaintiff, vs. FRUTAROM USA, INC., Defendant.	CASE NO. 12CV2823-GPC(WMC) **ORDER DENYING PLAINTIFF'S SUPPLEMENTAL MOTION FOR SUMMARY JUDGMENT AND DENYING DEFENDANT'S MOTION TO STRIKE** [Dkt. Nos. 80, 82.]

Plaintiff moves for partial summary judgment on the claim of breach of express warranty which is fully briefed. (Dkt. Nos. 80, 89, 98.) In its opposition to Plaintiff's motion, Defendant filed a motion to strike a portion of the declaration of Lowell Giffhorn, which is also fully briefed. (Dkt. Nos. 82, 95, 99.) Based on the reasons below, the Court DENIES Plaintiff's supplemental motion for summary judgment and DENIES Defendant's motion to strike.

Procedural Background

On November 21, 2012, Plaintiff Imagenetix, Inc. ("Imagenetix" or "Plaintiff") filed a complaint against Defendant Frutarom USA, Inc. ("Frutarom" or "Defendant") for breach of contract of the parties' Supply and Marketing Agreement ("Agreement") and related state law claim. An answer was filed on March 8, 2013 along with a Counterclaim against Plaintiff for breach of contract. (Dkt. No. 15.) Plaintiff alleges that Defendant, when it supplied Plaintiff with BLIS K12™ ("BLIS K12"), a probiotic

used in the mouth and throat, breached the express warranty concerning the legality of BLIS K12.

On December 9, 2013, the Court denied Plaintiff's motion for partial summary judgment on its claim that Defendant breached the express warranty, granted in part and denied in part Defendant's motion for summary judgment and stayed the case to allow Plaintiff to submit a Citizen's Petition with the Federal and Drug Administration ("FDA") to determine whether BLIS K12™ ("BLIS K12") was a drug, dietary supplement, old dietary ingredient ("ODI") or a new dietary ingredient ("NDI"). (Dkt. No. 56.)

Pursuant to the Court's order, on January 31, 2014, Plaintiff submitted a Citizen's Petition with the FDA. (Dkt. No. 66-1.) On May 1, 2014, Defendant submitted a response. (Dkt. No. 66-2.) In September 2016, FDA issued an opinion letter and found, at the time the marketing claims were made, BLIS K12 was a drug under section 201(g)(1)(B) of the Food, Drug, and Cosmetic Act ("FDCA") and not a dietary ingredient. (Dkt. No. 80-30, P's NOL, Ex. 26.) If a product is a "drug" as classified by the FDA, certain statutory and regulation requirements must be met. (Id. at 5.)

On September 19, 2016, after notification of the FDA's determination, the Court lifted the stay. (Dkt. No. 68.) After a telephonic status conference and discussing the prosecution of the case, the Court set a briefing schedule to allow Plaintiff to file a supplemental motion for summary judgment based on the recent FDA's determination. (Dkt. Nos. 70, 75.) On February 10, 2017, Plaintiff filed a supplemental motion for partial summary judgment solely on the breach of express warranty claim. (Dkt. No. 80.) On March 3, 2017, Defendant filed its motion to strike a portion of the declaration of Lowell Griffhorn. (Dkt. No. 82). Both motions have been fully briefed.

Factual Background

Imagenetix is a "nutritional supplement manufacturing company primarily engaged in developing, formulating and marketing over-the-counter, natural-based

nutritional supplements and skin care products." (Dkt. No. 80-22, P's NOL, Ex. 18, Spencer Decl. ¶ 1.) Frutarom is a "global company that manufactures, distributes, and markets flavors, fragrances, and ingredients to customers in the food, beverage, pharmaceutical, nutraceutical, and cosmetic industries." (Dkt. No. 1, Comp. ¶ 3.)

BLIS Technologies Ltd. ("BLIS"), a New Zealand company, created BLIS K12, a product from the naturally occurring bacterium *Streptococcus salivarius* ("*S. Salivarius*"). (Dkt. No. 89-2, D's Response to P's Separate Statement of Undisputed Material Fact ("SSUF"), No. 1.) BLIS K12 is an advanced oral probiotic developed for the mouth and throat. (Dkt. No. 80-6, P's NOL, Ex. 2 at 3[1].)

BLIS and Frutarom Ltd., the parent company of Defendant Frutarom USA, entered into a Distribution and Marketing Agreement effective October 20, 2008, where Frutarom Ltd. agreed to distribute BLIS K12 in the United States. (Dkt. No. 80-25, P's NOL, Ex. 21.) In 2008, BLIS sought to partner with an international company that was "able to assist with regulatory access" to the United States market. (Dkt. No. 89-2, D's Response to P's SSUF No. 11.) In the Distribution and Marketing Agreement, Frutarom Ltd. warranted that it "shall satisfy any legal and regulatory compliance requirements needed . . . in order to promote, market, distribute and sell [BLIS K12]." (Dkt. No. 80-25, P's NOL, Ex. 21 at ¶ 7.3.)

Plaintiff and Defendant subsequently entered into a Supply and Marketing Agreement ("Agreement"), effective September 1, 2009. (Dkt. No. 80-25, P's NOL, Ex. 1.) In the Agreement, Frutarom agreed to supply Imagenetix with BLIS K12, which Imagenetix incorporated into its product, BioGuard, a chewable tablet product. (Id.; Dkt. No. 80-22, P's NOL, Ex. 18, Spencer Decl. ¶¶ 4, 5.)

Specifically, Frutarom "agreed to grant Imagenetix the exclusive right, within the Territory, to use [BLIS K12] as an ingredient in the Products for distribution purposes as a dietary supplement in a form of a lozenges and/or chewable tablets . . . ." (Dkt. No. 80-25, P's NOL, Ex. 1 at Recital C.) The Agreement provided that

[1]Page numbers are based on the CM/ECF pagination.

Defendant expressly warranted that BLIS K12 "shall conform to all applicable Federal, State and local rules, regulations and rules and will be fit for human consumption in the Product." (Id. ¶ 8(b).) The Early Termination provision states that the "Agreement may be terminated upon ninety (90) days' written notice in the following events: . . . Either party fails to perform any obligation under this Agreement and fails to cure said default after ninety (90) days' written notice from the other specifically identifying the defaulted performance." (Id. ¶ 15(c).) In addition, the "Agreement may be amended only by a writing signed by the parties which states that it is intended to amend this Agreement." (Id. ¶ 17(b).)

On March 6, 2009, prior to entering into the Agreement, Defendant provided Plaintiff with sales and marketing brochures such as "Frutarom USA, Inc., BLIS K12 A New Generation of Advanced Probiotics, Protecting the Gateway to the Body's Health", (Dkt. No. 80-6, P's NOL, Ex. 2); "Frutarom USA, Inc., BLIS K12 Advanced Oral Cavity Probiotic that Protects the Gateway to the Body's Health", (Dkt. No. 80-7, P's NOL, Ex. 3); and "BLIS Technologies Ltd., BLIS K12 Technical Information." (Dkt. No. 80-8, P's NOL, Ex. 4.) The New Generation of Advanced Probiotics brochure and BLIS K12 Technical Information represented that BLIS K12 is compliant with U.S. regulations. For example, the New Generation of Advanced Probiotics brochure states that BLIS K12 "is deemed to be compliant with the USA's regulations DHSEA [Dietary Supplement Health and Education Act of 1994] as *S. Salivarius* is listed in the FDA listing of dietary ingredients in use before October 15th 1994 and has been the subject of safety studies without significant adverse reports." (Dkt. No. 80-6, P's NOL, Ex. 2 at 4.) The BLIS K12 Technical Information states, "*Streptococcus salivarius* is a [sic] listed as an ingredient in use in the US before 1994 by the National Nutritional Foods Association (now NPA) as documented on the FDA website." (Dkt. No. 80-8, P's NOL, Ex. 4 at 4.)

On September 18, 2008, prior to the effective date of the Distribution and Marking Agreement between BLIS and Defendant's parent company, the FDA placed

a shipment of product containing BLIS K12 called Travel Guard on hold pending FDA review. (Dkt. No. 80-15, P's NOL, Ex. 11.) On September 25, 2008, the FDA formally detained the shipment of Travel Guard because "the article appears to be a new drug without an approved drug application. Product has medical claims for [which] an NDA number is required." (Id. at 4-5.) On October 16, 2008, the FDA noted receipt of correspondence and commented that the product "will be refused next week. It makes medical claims." (Id. at 6.) Finally, on October 22, 2008, BLIS K12 Travel Guard was refused admission because it "appears to be a new drug without an approved new drug application. You have not solved the problem. Product is not in compliance." (Id. at 8-9.) Frutarom did not have knowledge of the 2008 regulatory issues with the FDA until after the filing of the instant complaint. (Dkt. No. 90-2, D's NOL, Ex. G, Katz Depo. at 42:2-10.)

After BioGuard was launched, in early February 2011, a consumer, Ed Seafeldt, who bought the product at Costco, complained that his wife became seriously ill after taking BioGuard. (Dkt. No. 80-22, P's NOL, Ex. 18, Spencer Decl. ¶ 6; Dkt. No. 101-3, D's NOL, Ex. I (UNDER SEAL).) Mr. Seafeldt notified Costco and Imagenetix. (Dkt. No. 98-3, P's Reply NOL, Ex. 31, Spencer Depo. at 29:7-10.) The consumer raised safety concerns about BLIS K12 and filed an adverse event report with the FDA. (Dkt. No. 80-22, P's NOL, Ex. 18, Spencer Decl. ¶ 6.) The consumer also notified Plaintiff that the FDA had barred import of a BLIS K12 product in 2008. (Id.) After the Plaintiff learned about the incident, it contacted its insurance company and filed an adverse report with the FDA. (Dkt. No. 98-3, P's Reply NOL, Ex. 31, Spencer Depo. at 29:1-16; Dkt. No. 103-5, P's Reply NOL, Ex. 43, Spencer Depo. at 25:20-23 (UNDER SEAL).) It also communicated with Frutarom, and let them know about the complaint. (Dkt. No. 98-3, P's Reply NOL, Ex. 31, Spencer Depo. at 29:18-20.)

During this investigation, Plaintiff learned that the FDA had not approved a New Drug Application ("NDA") for BLIS K12 and that a New Dietary Ingredient ("NDI") pre-market notification had not been filed for BLIS K12. (Dkt. No. 80-22, P's NOL,

Ex. 18, Spencer Decl. ¶ 8.) After investigating BLIS K12, Plaintiff stopped selling BioGuard. (Id. ¶ 7.) Around April 2011, Plaintiff stopped purchasing BLIS K12 from Defendant. (Dkt. No. 80-29, P's NOL, Ex. 25, Spencer Depo. at 39:21-14.)

Although the Agreement extended through 2011, "the parties agreed to part ways in April 2011. (Dkt. No. 49-1, P's Response to D's SSUF No. 4; see also Dkt. No. 90-3, D's NOL, Ex. J, Friedman Decl. ¶ 2 (the parties "mutually agreed to forego any claims under the original [Agreement] and part ways.") In April 2011, Frutarom agreed to accept the return of 44,000 kg of BLIS K12 from Imagenetix at 80% of the original invoice price less a 20% restocking fee. (Dkt. No. 90-8, D's NOL, Exs. AZ; BC.) In other words, Frutarom agreed to accept the return of over $500,000 of BLIS K12 and credit Plaintiff for the return. (Dkt. No. 90-3, D's NOL, Ex. J, Friedman Decl. ¶ 2; Dkt. No. 98-3, P's Reply NOL, Ex. 31, Spencer Depo. at 67:11-21; 7:7-18.) There remained a balance due for product not accepted for return and Plaintiff agreed to a payment plan and only made two payments. (Dkt. No. 90-3, D's NOL, Ex. J, Friedman Decl. ¶ 2.) After several requests for the amounts due, Defendant sent the account to collection in July 2012. (Id.) Imagenetix also destroyed $314,273 of BioGuard inventory. (Dkt. No. 98-9, P's Reply NOL, Ex. 41, Giffhorn Decl. ¶ 2.) While Imagenetix continued to sell BioGuard through at least December 2011. (Dkt. No. 101-1 at 30, D's NOL, Ex. D, Giffhorn Depo. at 80:7-12 (UNDER SEAL)), sales were *de minimus*. (Dkt. No. 103-4, P's Reply NOL, Ex. 42 at 2 (UNDER SEAL).)

On August 1, 2012, Plaintiff sent a letter to Defendant stating that it breached the Agreement because BLIS K12 did not comply with federal law and demanded $1,153,570.76 or it would seek litigation. (Dkt. No. 80-34, P's NOL, Ex. 30.) The letter also noted that Frutarom's attempt to seek unwarranted payments for product which was misrepresented to Imagenetix was unconscionable. (Id. at 2.) When Frutarom did not cure the breach, Plaintiff filed the instant complaint on November 21, 2012. (Dkt. No. 1, Compl.)

Although not specified as to when, BLIS Technologies disclosed to Imagenetix

a report it commissioned, in April 2004, entitled "Report on the significance of human infections with *Streptococcus salivarius*", in which the author concluded that *S Salivarius* "has the potential to cause human disease and even death, this occurs very rarely and almost exclusively in patients with underlying immunocompromise, or when the organism is inoculated directly into a sterile site." (Dkt. No. 80-28, P's NOL, Ex. 24 at 10.)

In September 2016, the FDA issued an opinion letter and found, at the time the marketing claims were made, BLIS K12 was a drug under section 201(g)(1)(B) of the FDCA and not a dietary ingredient. (Dkt. No. 80-30, P's NOL, Ex. 26.) In a footnote, the FDA specifically stated that it does not express an opinion whether BLIS K12 was a drug at any other point in time. (Id. at 5 n.7.) In coming to its conclusion, the FDA explained that at the time the claims were made BLIS K12 was a drug because "it was intended for use in the cure, mitigation, treatment, or prevention of disease" and not "a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any ingredient from the preceding categories." (Id. at 5, 7.)

Since BLIS K12 was a drug under section 201(g)(1)(B) of the FDCA, 21 U.S.C. § 321(g)(1)(B), at the time the claims were made, "it was subject to the statutory and regulatory requirements pertaining to human drug products." (Id. at 5.) "Failure to comply with such requirements would have rendered BLIS K12 adulterated or misbranded, and distribution of an adulterated or misbranded drug is a violation of section 301(a) of the FDCA." But the FDA noted it was not making a determination whether BLIS K12 was in compliance with these requirements. (Id. at 6 n.9.)

Discussion

In its motion, Plaintiff seeks partial summary judgment solely on the issue of whether Defendant breached its express warranty in the Agreement that BLIS K12 would conform to all applicable laws since it failed to comply with the regulatory

requirements for a drug. Defendant responds that there are triable issues of fact as to whether Defendant breached an express warranty, whether Plaintiff was harmed and whether Defendant's alleged breach caused Plaintiff's harm, and whether Plaintiff notified Defendant of the alleged breach. Defendant also contends there are material issue of fact as to the affirmative defense of notice and cure, and whether the parties modified or terminated the Agreement.

A. Legal Standard for Motion for Summary Judgment

Federal Rule ("Rule") of Civil Procedure 56 empowers the Court to enter summary judgment on factually unsupported claims or defenses, and thereby "secure the just, speedy and inexpensive determination of every action." Celotex Corp. v. Catrett, 477 U.S. 317, 325, 327 (1986). Summary judgment is appropriate if the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A fact is material when it affects the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

The moving party bears the initial burden of demonstrating the absence of any genuine issues of material fact. Celotex Corp., 477 U.S. at 323. The moving party can satisfy this burden by demonstrating that the nonmoving party failed to make a showing sufficient to establish an element of his or her claim on which that party will bear the burden of proof at trial. Id. at 322-23. If the moving party fails to bear the initial burden, summary judgment must be denied and the court need not consider the nonmoving party's evidence. Adickes v. S.H. Kress & Co., 398 U.S. 144, 159-60 (1970).

Once the moving party has satisfied this burden, the nonmoving party cannot rest on the mere allegations or denials of his pleading, but must "go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file' designate 'specific facts showing that there is a genuine issue for

trial.'" Celotex, 477 U.S. at 324. If the non-moving party fails to make a sufficient showing of an element of its case, the moving party is entitled to judgment as a matter of law. Id. at 325. "Where 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.'" Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). In making this determination, the court must "view[] the evidence in the light most favorable to the nonmoving party." Fontana v. Haskin, 262 F.3d 871, 876 (9th Cir. 2001). The Court does not engage in credibility determinations, weighing of evidence, or drawing of legitimate inferences from the facts; these functions are for the trier of fact. Anderson, 477 U.S. at 255.

When a plaintiff moves for summary judgment, a plaintiff must "demonstrate affirmatively (by admissible evidence) that there is no genuine dispute of material fact as to each element of its claim for relief, entitling it to judgment as a matter of law" and "demonstrate the lack of any genuine dispute of material fact as to affirmative defenses asserted by the defendant. But here, plaintiff need not provide any evidence. It may simply point out the absence of evidence from the defendant." O'Connell, et al., Federal Civil Procedure Before Trial, Calif & 9th Cir. eds., § 14:139 (2017).

B. Plaintiff's Request for Leave to File an Amended Complaint

In its opposition, Defendant, for the first time, argues that summary judgment should be denied because Plaintiff did not allege a claim for breach of express warranty in its complaint and no such claim can be alleged as the deadline for amendments have passed. Plaintiff does not dispute that the complaint does not allege a breach of express warranty claim but replies that Defendant has been on notice since at least July 2013 when it filed its motion for partial summary judgment raising the same claim and Defendant did not argue the breach of express warranty claim was not viable. Therefore, Defendant should be estopped from raising the argument, nearly four years later, or alternatively, Plaintiff should be granted leave to amend to add the cause of

action as it involves the same facts at issue since the filing of the complaint.[2]

Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). This liberal policy is subject to considerations of undue prejudice to the opposing party, bad faith, futility of amendment, and undue delay. See DCD Programs, Ltd. v. Leighton, 833 F.2d 183, 186 (9th Cir. 1987). Undue delay by itself is insufficient to justify denying a motion to amend. Id. "Prejudice to the opposing party is the most important factor" Jackson v. Bank of Hawaii, 902 F.2d 1385, 1387 (9th Cir. 1990) (citing Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 330-31 (1971) (trial court "required" to take potential prejudice into account in deciding Rule 15(a) motion)). "Absent prejudice or a strong showing of any of the remaining [ ] factors, there exists a presumption under Rule 15(a) in favor of granting leave to amend." Eminence Capital, LLC v. Aspeon, Inc., 316 F.3d 1048, 1051 (9th Cir. 2003).

Here, in July 2013, Plaintiff moved for partial summary judgment solely on whether Frutarom breached an express warranty in the Agreement. (Dkt. No. 35.) At the time, Defendant did not object that breach of warranty was not alleged in the complaint but engaged in an analysis opposing the summary judgment motion. (Dkt. No. 36.) Defendant has not been prejudiced as it has been defending the case as if the breach of warranty claim was alleged in the complaint. In addition, the elements of a breach of warranty claim is similar to a breach of contract claim. See Lehman Bros. Holdings, Inc. v. Mason McDuffie Mortg. Corp., No. C 12-5132, 2013 WL 76285, at *4 (N.D. Cal. Jan. 4, 2013) (citing Daugherty v. Am. Honda Motor Co., Inc., 144 Cal. App. 4th 824, 830 (2006) ("The law governing express warranties is clear. A warranty is a contractual promise.")). Therefore, the Court concludes no prejudice has been shown.

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[2]While the Court recognizes that Defendant has not had an opportunity to oppose the request for leave to file an amended complaint, it has not filed a request to file a sur-reply. It would appear that Plaintiff would have stipulated to such a filing. (See Dkt. No. 98 at 12.)

Accordingly, the Court GRANTS Plaintiff's motion for leave to amend the complaint to add the claim of breach of express warranty. Plaintiff will be directed to file an amended complaint; however, in the interests of efficiency, the Court will address the breach of express warranty claim since the parties have fully briefed the issue.[3]

C. Breach of Express Warranty

To make out a breach of express warranty claim, a plaintiff must show that the seller: "(1) made an affirmation of fact or promise or provided a description of its goods; (2) the promise or description formed part of the basis of the bargain; (3) the express warranty was breached; and (4) the breach caused injury to the plaintiff." Crystal Springs Upland Sch. v. Fieldturf USA, Inc., – F. Supp. 3d – , 2016 WL 6576634, at *3 (N.D. Cal. Nov. 7, 2016) (citing Cal. Comm. Code § 2313(1)). In California, a plaintiff alleging a breach of express warranty must also provide the defendant with pre-suit notice of the breach. See Cal. Com. Code § 2607(3)(A) ("buyer must, within a reasonable time after he or she discovers or should have discovered any breach [of warranty], notify the seller of breach or be barred from any remedy"); Sanders v. Apple, Inc., 672 F. Supp. 2d 978, 986 (N.D. Cal. 2009); Orichian v. BMW of N. Am., LLC, 226 Cal. App. 4th 1322, 1333-34 (2014), as modified (July 1, 2014).

Plaintiff claims Defendant made an express warranty that BLIS K12 "shall conform to all applicable Federal, State and local laws, regulations and rules." (Dkt. No. 80-25, P's NOL, Ex. 1.) Second, this express warranty formed the basis of the bargain because without regulatory approvals, BLIS K12 was worthless to Imagenetix and it would not have entered into the Agreement if it knew it was not lawful to sell in

[3]In its reply, for the first time and in response to Defendant's argument that the complaint does not allege a breach of express warranty claim, Plaintiff presents a legal analysis on the breach of contract cause of action. (Dkt. No. 98 at 8-12.) Plaintiff also invites Defendant to file a sur-reply to address the breach of contract elements. (Id. at 12.) Defendant did not seek leave to file a sur-reply. The Court declines to address the breach of contract analysis which is raised for the first time in the reply. See FT Travel-New York, LLC v. Your Travel Ctr, Inc., 112 F. Supp. 3d 1063, 1079 (C.D. Cal. 2015) (courts decline to consider arguments raised for the first time in a reply) (citing cases).

the United States. Third, Defendant breached the express warranty when it failed to comply with federal requirements for a drug such as filing a New Drug Application or complying with manufacturing and labeling requirements which Defendant admits it did not do. Fourth, Plaintiff was harmed by the breach as it invested significant amounts in BioGuard and suffered out-of-pocket losses, loss in expected profits and "a related diminution in Imagenetix's other key line of businesses because of the lost resources." (Dkt. No. 80-1 at 10.) Plaintiff does not address the issue of notice to the Defendant as one of the elements that it is required to establish the express warranty cause of action. Instead, Plaintiff addresses the notice and opportunity to cure language contained in the Agreement. As to the Agreement, Plaintiff claims it was not required to provide Defendant with notice and an opportunity to cure because the breach was material but even if there was a requirement, it provided notice to Plaintiff on August 1, 2012.

In response, Defendant argues there are triable issues of fact on the third factor, whether there was a breach, the fourth factor, whether Plaintiff was harmed, and the additional element that Plaintiff was required to provide pre-suit notice of the breach. Furthermore, Defendant contends that there are factual issues in dispute on the affirmative defenses of notice and cure and modification of the Agreement.

The Food and Drug Administration ("FDA") has regulatory authority over whether a product is a drug, food, dietary supplement, old dietary ingredient ("ODI") or a new dietary ingredient ("NDI") under the FDA's jurisdiction. 21 U.S.C. § 351 *et seq.* The Food, Drug, and Cosmetic Act ("FDCA") subjects the drug, dietary supplement, and food industries to a comprehensive regulatory authority. 21 U.S.C. § 301 *et seq.*

The classification of a product determines the rules and regulations that must be followed. A drug requires an approved New Drug Application, 21 U.S.C. § 355. On October 25, 1995, the Dietary Supplement Health and Education Act of 1994 ("DSHEA") was enacted and amended the FDCA by adding*, inter alia*, a premarket

notification requirement to the FDA for a new dietary ingredient ("NDI"). (Dkt. No. 80-20, P's NOL, Ex. 16, FDA Draft Guidance for Industry, dated July 2011 at 5; see 21 U.S.C. § 350b.) An "NDI" is "a dietary ingredient that was not marketed in the United States before October 15, 1994." 21 U.S.C. § 350b(d). Therefore, an old dietary ingredient ("ODI") is a dietary ingredient that was marketed in the United States before October 15, 1994 and is not subject to notice requirements under the FDCA. (Dkt. No. 80-20, P's NOL, Ex. 16, FDA Draft Guidance for Industry, dated July 2011 at 6.)

Subsequent to the passage of DSHEA, the dietary supplement industry and trade associations worked to compile lists of "old" dietary ingredients, those ingredients which were marketed before October 14, 1994, including the National Nutritional Foods Association ("NNFA"). (Dkt. No. 90-6, D's NOL, Ex. AB at 51-52.) *S. Salivaris* is listed on the old dietary ingredients list by the NNFA.[4] (Dkt. No. 90-6, D's NOL, Ex. AC; Dkt. No. 90-10, D's NOL, Ex. BW, Ullman Decl., Ex. C at 22 (NNFA List of Dietary Supplement Ingredients in Use Before October 15, 1994).) These lists were not verified by the FDA and were not supported by evidence. (Dkt. No. 80-20, P's NOL, Ex. 16, FDA Draft Guidance for Industry, dated July 2011 at 6.)

In August 2016, the FDA issued draft guidance on new dietary ingredients that replaced its draft guidance issued in July 2011. See https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM515733.pdf (last visited Mar. 20, 2017). "This guidance is intended to help manufacturers and distributors of dietary ingredients and dietary supplements [ ] decide whether to submit a premarket safety notification to FDA [ ] for a product that is or contains an NDI." See https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinforma

[4]In the complaint, Plaintiff alleges that an active ingredient in BLIS K12 is Salivaricin B, which is an anti-bacterial protein produced by S. Salivarius K12, which is a unique strain of S. Salivarius, a natural occurring microorganism. (Dkt. No. 1, Compl. ¶ 14.)

tion/dietarysupplements/ucm257563.htm (last visited Mar. 20, 2017).

1. Third Element - Whether Frutarom Breached an Express Warranty

Plaintiff claims Frutarom breached the express warranty because BLIS K12 was a drug and Defendant did not comply with the federal requirements for a drug by filing a New Drug Application and complying with labeling requirements.

Defendant does not dispute that it did not comply with FDA regulations for a drug but argues that it did not have to as it conducted due diligence and determined that BLIS K12 was legal to sell as an old dietary ingredient under the DSHEA (i.e., if it was marketed in the United States prior to October 15, 1994) based on the available resources in 2009-2011. As such, Defendant argues there is a triable issue of fact whether it breached the express warranty because at the time when Defendant allegedly improperly marketed and sold BLIS K12, in 2009 to 2011, the FDA's guidance was not clear as to whether Defendant improperly marketed and sold BLIS K12 as an old or grandfathered dietary ingredient. In reply, Plaintiff argues that Defendant improperly seeks to shift blame for the unapproved status of BLIS K12 to BLIS for its failure to disclose a 2008 FDA "Import Refusal" as to a product containing BLIS K12; to Plaintiff, for its failure to better market BLIS K12; and to the FDA, for its lack of clear guidance. However, Frutarom was the party contractually required to ensure the BLIS K12 complied with the law. In fact, when BLIS and Frutarom USA signed their Distribution and Marketing Agreement 2008, Frutarom's role was to assist with regulatory access to the United States market and would "satisfy any legal and regulatory compliance requirements needed . . . to promote, market, distribute and sell" BLIS K12 in the United States. (Dkt. No. 89-2, D's Response to P's SSUF Nos. 11 13.)

The Supply and Marketing Agreement provided that Defendant expressly warranted that BLIS K12 "shall conform to all applicable Federal, State and local rules, regulations and rules and will be fit for human consumption in the Product." (Dkt. No. 80-25, P's NOL, Ex. 1 at ¶ 8(b).) In September 2016, the FDA issued an opinion letter

and found, at the time the marketing claims were made, BLIS K12 was a drug under section 201(g)(1)(B) of the FDCA and not a dietary ingredient. (Dkt. No. 80-30, P's NOL, Ex. 26.) At the time the parties entered into the Agreement, the FDA had not determined whether BLIS K12 was a drug, dietary supplement, old dietary ingredient or a new dietary ingredient.

In its motion, Plaintiff simplistically argues that since BLIS K12 has been classified as a "drug", Defendant's failure to comply with the statutory and regulatory requirements for a "drug" is a breach of the express warranty in the Agreement. However, the question to be decided is whether BLIS K12 conformed to "applicable" regulations at the time that the BLIS K12 was sold and not years later when the 2016 opinion letter was issued. The parties do not dispute that, as of 2016, BLIS K12 has been classified a drug and that Defendant did not comply with FDA regulations concerning marketing a drug. However, Plaintiff has not provided any authority to support the notion that the 2016 opinion letter could be given retroactive effect to 2009-11. The parties also do not dispute that if BLIS K12 had been classified as an old dietary ingredient, Defendant would have been exempt from complying with the regulations. The issue of whether Defendant breached the express warranty is not clear cut as Plaintiff proposes.

In response, Defendant contends it took all reasonable and necessary steps to determine that BLIS K12 was legal to sell as marketed in the United States as a grandfathered dietary ingredient under the existing FDA guidance. In support, Defendant provides as evidence the "scientific and legal materials it received from BLIS Technologies showing that BLIS K12 complied with all regulatory requirements for legal sale in the United States as a grandfathered dietary ingredient. (UMF 78)." (Dkt. No. 89 at 18.) These documents include an email from Jocelyn Mathern, Frutarom's Technical Health Manager, to the sales team, on November 5, 2008 showing that she was comparing the scientific claims of BLIS K12 with the marketing materials and making sure both matched. (Dkt. No. 90-5, D's NOL, Ex. X.) Laurent

Leduc, the Vice President of Frutarom, testified that Mathern reviewed the clinical and regulatory documents about the product that were sold in other countries. (Dkt. No. 90-1, D's NOL, Ex. C, Leduc Depo. at 24:9-25:1.) Another document is an email with attachments about safety and regulatory documents in various markets such as Australia and New Zealand. (Dkt. No. 90-4, D's NOL, Ex. V.) The final document presented is an email about updated scientific research on BLIS K12 dated April 2009. (Dkt. No. 101-4, D's NOL, Ex. W (UNDER SEAL).) Upon the Court's review of these documents, they do not support Defendant's assertion that these materials demonstrated that BLIS K12 complied with regulatory requirements for legal sale in the United States as a grandfathered dietary ingredient. However, other documents contain some information regarding regulatory compliance in general, (Dkt. No. 90-6, Ds' NOL, Ex. AA), and as to packaging in the United States, (Dkt. No. 90-5, D's NOL, Ex. Z).

BLIS also provided Frutarom with a legal opinion letter from an attorney in the United States, dated June 19, 2007, that BLIS hired to provide an opinion on whether BLIS K12 is a "old" or "grandfathered" ingredient under the DSHEA. (Dkt. No. 90-6, D's NOL, Ex. AB.) The legal opinion letter recognizes that as of 2007, there was no regulatory guidance from the FDA, no guidance by Congress, no federal or state court decisions regarding how the grandfather provision should be legally construed by the FDA to establish whether a dietary ingredient is "old." (Id. at 53.) There are only "published lists from industry with ingredients that were presumably used in dietary supplement products before October 15, 1994" but "there does not appear to be any evidence showing which companies submitted the information for the lists, including when and what products apparently were marketed with the listed ingredients." (Id.) *S. Salivarius* is included on the published list by the NNFA that was presumably used in dietary supplement products marketed in the U.S. before October 15, 1994. (Id. at 51.) Since there are only published lists of ODIs from the industry, the attorney concluded there is "a reasonable, but not conclusive, basis for BLIS to assert that their Streptococcus salivarius ingredient, BLIS K12 is legally an 'old' or 'grandfathered'

ingredient under DSHEA and not subject to the requirements of Section 413 of the FDC Act." (Id. at 54.) Defendant claims it relied on this opinion to believe that BLIS K12 was legally a grandfathered dietary ingredient.

Defendant further claims that it enlisted the help of BLIS to review BioGuard's marketing claims. (Dkt. No. 98-1, P's Response to D's SSUF, Nos. 87-88.) In addition, Bill Spencer, Plaintiff's CEO, its legal counsel and a science expert reviewed the BioGuard structure/function claims. (Id., Nos. 94-95.) Spencer also hired outside counsel to review the structure/function claims to assure compliance with the FDCA. (Id., No. 96.) Lastly, Defendant provided Plaintiff a document notifying it of its duty to notify the FDA of its structure and function claims. (Id., No. 97.) Subsequently, on March 5, 2010, Spencer provided the FDA with notice of the structure/function claims of BioGuard but the FDA did not respond to the letter. (Id., Nos. 98-99.)

In support, Plaintiff cites to Chamberlain Group, Inc. v. Nassimi, No. C09-5438BHS, 2010 WL 4286178, at *7 (W.D. Wash. Oct. 25, 2010) where the district court granted partial summary judgment for the plaintiff on a claim of breach of warranty that it would be in material compliance with the applicable law, which were the FCC regulations. Id. The court rejected the defendant's argument that the noncompliant products could have easily been brought into compliance. Id. "Whether or not the noncompliant products could be remedied is irrelevant to the question of whether Nassimi delivered a company whose products were, in fact and as warranted, in material compliance with the applicable 'Law.'" Id. The court also noted that the defendant did not dispute the company's pre-sale knowledge regarding noncompliance with FCC regulations was fatal. Id. at *6. Since the company knew of the noncompliance of the product and the noncompliance violated applicable FCC regulations, the defendant breached the contract's warranty provision. Id. However, in this case, there is an issue of fact whether Defendant had pre-Agreement knowledge regarding the alleged non compliance. Defendant asserts it did not have knowledge about the 2008 regulatory issues with Travel Guard until after the complaint was filed.

(Dkt. No. 90-2, D's NOL, Ex. G, Katz Depo. at 42:2-10.) It is also not clear whether Defendant had knowledge about the Seafeldt complaint at the time of the incident. While Spencer testified that he communicated with Frutarom about the Seafeldt complaint, (Dkt. No. 98-3, P's Reply NOL, Ex. 31, Spencer Depo. at 29:19-20), Frutarom was not a recipient of the emails that were circulated during the Seafeldt complaint. (Dkt. No. 80-27, P's NOL, Ex. 23.)

The Court notes that some of documents reviewed by Frutarom from BLIS do not specially address regulatory requirements for legal sale in the U.S. as a grandfathered dietary ingredient but address safety issues, marketing issues, and regulatory issue in other countries. Others documents provide some guidance on regulatory issues although it is not clear whether they provide guidance on the issue of whether BLIS K12 is an ODI. In addition, the attorney opinion letter noted that the FDA provided informal guidance that in order to show that a dietary ingredient is "old", one needs to show that the listing of an "old ingredient" in a given publication or industry list is founded on accurate and reliable evidence, sufficient to support a finding that the ingredient was marketed prior to October 14, 1994. (Id. at 52.) A party could also submit documentation that the ingredient is not a new dietary ingredient by presenting an invoice, a bill of lading, or a product label. (Id.) It appears that, at least as of 2007, the date of the attorney opinion letter, the FDA provided some guidance on demonstrating whether a dietary ingredient is old, which involves more than just reliance on an industry list.

Despite being skeptical of Frutarom's exhibits, in viewing the evidence in the light most favorable to Defendant, the Court concludes that Plaintiff has demonstrated that there are genuine issues of material fact whether Defendant breached the express warranty. For example, there is an issue of fact as to whether Defendant's reliance on BLIS' documents and the attorney opinion letter was sufficient to satisfy its duty to make sure it complied with the express warranty, whether the FDA's lack of specific guidance and failing to respond to Plaintiff's notice of the structure/function claim of

BioGuard was sufficient for Defendant to believe that BLIS K12 was compliant with federal regulations, and whether Defendant should have done more to confirm the FDA classification of BLIS K12, such as directly seeking guidance from the FDA.

2. Fourth Element - Whether Frutarom's Alleged Breach Caused Imagenetix's Harm

Plaintiff asserts it suffered damages because it would never have invested in a BLIS K12 product had it known it was not lawful to sell and incurred out-of-pocket losses as well as loss in expected profits and related diminution in its other key line of business because of lost resources. Defendant opposes arguing that there are triable issues whether Imagenetix was harmed and whether Frutarom's alleged breach caused Imagentix's harm. Defendant suggests that BioGuard's failure in the market was due to poor marketing decisions and from being overpriced and not because BioGuard was not legal to sell as marketed.

Plaintiff alleges it has been damaged because if it had known that BLIS K12 was not lawful to sell in the United States, it would not have entered into the Agreement. (Dkt. No. 80-26, P's NOL, Ex. 22, Giffhorn Decl. ¶ 2.) Plaintiff expended money in investing in, marketing and selling BioGuard. (Id.) Plaintiff committed a significant amount of resources, such as advertising, to make sure BioGuard would be successful. (Dkt. No. 80-33, P's NOL, Ex. 29, Giffhorn Depo. at 56:19-57:18.) For example, Plaintiff spent about $1,050,000 in advertising. (Dkt. No. 80-29, Spencer Depo. at 38:12-39:23.) Plaintiff incurred lost profits in Celadrin another product being distributed through Costco while it was promoting BioGuard. (See Dkt. No. 103-3, P's Reply NOL, Ex. 40, Mangum Expert Report at 16 (UNDER SEAL).) Plaintiff also lost good will with Costco. (Dkt. No. 103-3, P's Reply NOL, Ex. 39, Giffhorn Depo. at 30:19-31:7 (UNDER SEAL).) It was forced to return BLIS K12 at a reduced price to Defendant, (Dkt. No. 90-8, D's NOL, Exs. AZ, BC), and was forced to destroy $314,273 inventory of BioGuard. (Dkt. No. 98-9, P's Reply NOL, Ex. 41, Giffhorn Decl. ¶ 2.) According to Plaintiff, Costco's decision to discontinue BioGuard was due,

in part, to the Seafeldt complaint. (Dkt. No. 103-2, P's Reply NOL, Ex. 39, Giffhorn Depo. at 30:19-31:17 (UNDER SEAL).)

Defendant responds by providing evidence that the failure to BioGuard was due to its failed marketing efforts and the product being too expensive. BioGuard was pulled from Costco because it did not meet projected sales. In a December 29, 2010 email, a representative from Costco to Imagenetix wrote it "is time to discontinue BioGuard from Imagenetix." (Dkt. No. 90-7, D's NOL, Ex. AN at 27.) In January 2011, an email stated that sales at Costco are only at 30 to 50% from target." (Dkt. No. 90-3, D's NOL, Ex. L.) In an email of April 2011, Costco wrote that BioGuard "is not selling and the coupon we ran did not help sell much product." (Dkt. No. 90-7, D's NOL, Ex. AT at 32.) Costco's decision to discontinue BioGuard was due to "continued underperformance." (Dkt. No. 101-6 at 18, D's NOL, Ex. AQ (UNDER SEAL).)

BioGuard sales in the winter of 2010/2011 winter season were poor at Rite Aid. (Dkt. No. 101-2, D'NOL, Ex. F, Sajovic Depo. at 147:13-17.) Imagenetix was rejected at Walgreen, CVS and Walmart based on the high price. (Dkt. No. 90-3, D's NOL, Ex. N.) Plaintiff could not support advertising expense for both BioGuard and Celadrin. (Dkt. No.101-1 at 30, D's NOL, Ex. D, Giffhorn Depo. at 35:24-36:21.) On December 17, 2012, Plaintiff filed for Chapter 11 bankruptcy which was converted to a Chapter 7 bankruptcy. (Dkt. No. 98-1, P's Response to D's SSUF, Nos. 159-60.) Defendant has raised a genuine issue of material fact as to whether Plaintiff was damaged due to Defendant's alleged breach to the extent Plaintiff alleges.

Moreover, both parties present expert reports that provide conflicting conclusions as to Plaintiff's alleged lost profits and damages. Defendant's expert Fernando Torres concluded there were "no lost profit damages attributable to undertaking the SMA [Supply and Marketing Agreement] contract for the BioGuard product line." (Dkt. No. 90-10, D's NOL, Ex. BX, Torres Expert Report at 50.) In reply, Plaintiff presents its damages expert, Russell Mangum, who concluded that Plaintiff suffered "lost profits damages equal to approximately $20.98 million." (Dkt.

No. 103-3, Ex. 40, Mangum Expert Report at 17 (UNDER SEAL).)

Expert affidavits from both parties can create a genuine issue of fact that defeats summary judgment. See Garter–Bare Co. v. Munsingwear, Inc., 650 F.2d 975, 979-80, 982 (9th Cir. 1980) (reversing a district court's grant of summary judgment where the parties provided conflicting expert testimony and the district court granted summary judgment by relying solely on the moving party's expert testimony); DeLew v. Adamson, 293 F. App'x 504, 506 (9th Cir. Sept. 17, 2008) ("The existence of conflicting expert assessments suggests that neither party is entitled to summary judgment."); see also Ethyl Corp. v. Borden, Inc., 427 F.2d 206, 210 (3d Cir. 1970) (Courts may not resolve "disputed and relevant factual issues on conflicting affidavits of qualified experts."). "As a general rule, summary judgment is inappropriate where an expert's testimony supports the non-moving party's case." Provenz v. Miller, 102 F.3d 1478, 1490 (9th Cir. 1996) (quoting In re Worlds of Wonder Sec. Litig., 35 F.3d 1407, 1425 (9th Cir. 1994)).

Here, because the parties present conflicting expert reports, the Court concludes there are genuine issues of material fact whether Plaintiff was harmed due to Defendant's alleged breach. See Garter-Bare Co., 650 F.2d at 982 (conflicting expert testimony on issues of fact cannot be resolved on summary judgment).

3. Last Element - Whether Imagenetix Notified Frutarom of the Breach

In its motion to summary judgment, Imagenetix does not address the element of notice to the seller within a reasonable time as required under California law to recover on an express warranty claim. Instead, Plaintiff argues that it is not barred by the notice and cure provision in the Agreement because Defendant materially breached the Agreement. In response, Defendant contends that there is a genuine issue of fact as to whether Plaintiff took reasonable steps to notify Defendant of the breach under California law and also an issue of fact on the affirmative defense of notice and an

opportunity to cure as provided for in the Agreement.[5]

In this case, the Court notes that there is a notice to seller requirement under California law for breach of express warranty , and a contractual notice and cure provision in the Agreement, which provide for different legal obligations.

a. California Commercial Code § 2607(3)(A)

"To recover on a breach of warranty claim, the buyer must, within a reasonable time after he or she discovers or should have discovered any breach, notify the seller of any breach or be barred from any remedy." Cardinal Health 301, Inc. v. Tyco Elecs. Corp., 169 Cal. App. 4th 116, 135 (2008). The notice requirement is "designed to allow the seller the opportunity to repair the defective item, reduce damages, avoid defective products in the future, and negotiate settlements." Id. It is the buyer's burden of demonstrating reasonable notice. Id. "'The question whether notice was properly given must be 'determined from the particular circumstances and, where but one inference can be drawn from undisputed facts, the issue may be determined as a matter of law.'" Id. at 135-36. The Ninth Circuit has held that in order to effectuate these objectives, notice must be given "pre-suit." Alvarez v. Chevron Corp., 656 F.3d 925, 932 (9th Cir. 2011). To avoid dismissal of a breach of contract or breach of warranty claim in California, "[a] buyer must plead that notice of the alleged breach was provided to the seller within a reasonable time after discovery of the breach." Stearns v. Select Comfort Retail Corp., 763 F. Supp. 2d 1128, 1142 (N.D. Cal. 2010) (citations omitted)). The issue of whether a buyers' delayed notice of breach of warranty was unreasonable is a question for the jury. Webster v. Klassen, 109 Cal. App. 2d 583, 592 (1952).

In its motion for summary judgment, Plaintiff does not include analysis of the "notice" essential element to prove a breach of express warranty claim under California

[5]Defendant argues that the Court previously concluded that there were genuine issues of material fact precluding summary judgment; however, in the prior order, its ruling was based on the fact that it was not clear whether BLIS K12 was a drug or dietary supplement. Therefore, the Court's prior conclusion is not the law of the case.

law. On that basis alone, Plaintiff's motion for partial summary judgment is denied. See Federal Civil Procedure Before Trial, Calif & 9th Cir. eds., § 14:139 (plaintiff "demonstrate affirmatively . . . that there is no genuine dispute of material fact as to each element of its claim for relief, entitling it to judgment as a matter of law"). Rather, it appears that Plaintiff addresses "notice and cure" in the context of the Agreement which is relied upon by Defendant as an affirmative defense. The Court considers these arguments in the next section.

b. Notice and Cure Provision in the Agreement

The Agreement states, "[n]otwithstanding the foregoing, this Agreement may be terminated upon ninety (90) days' written notice in the following events: . . . (c) Either party fails to perform any obligation under this Agreement and fails to cure said default after ninety (90) days' written notice from the other specifically identifying the defaulted performance." (Dkt. No. 80-25, P's NOL, Ex 1 at ¶ 15(c).)

Defendant argues that Plaintiff is barred from bringing a claim under the Agreement because Plaintiff never notified Defendant that BLIS K12 did not comply with FDA regulations. Plaintiff argues that it was not required to provide notice and an opportunity to cure because there was a "vital" breach. (Dkt. No. 80-1 at 11.) Plaintiff contends that it was relieved of its obligations under the contract because Defendant materially breached the Agreement when it failed to comply with the FDCA. See Brown v. Grimes, 192 Cal. App. 4th 265, 277 (2011) ("[w]hen a party's failure to perform a contractual obligation constitutes a material breach of the contract, the other party may be discharged from its duty to perform under the contract.").

Here, Plaintiff admits that it never provided Frutarom notice at any time during the parties' agreement that BLIS K12 did not comply with the FDCA or that it was adulterated or misbranded. (Dkt. No. 98-1, P's Response to D's SSUF Nos. 54, 55.) Plaintiff claims it gave Frutarom written notice and an opportunity to cure on August 1, 2012 when it demanded that Frutarom remedy the breach by paying a small portion of its damages. Then, it waited 112 days, until November 21, 2012 before filing the

lawsuit when Defendant did not remedy the breach. However, Defendant argues that Plaintiff's notice in August 2012 did not provide Defendant an opportunity to cure the alleged defect given that the Plaintiff stopped purchasing BLIS K12, had returned unused BLIS K12 and mutually terminated the Agreement in April 2011. The Court concludes that these facts raise an issue whether Plaintiff's notice was reasonable. See id.

Both parties cite to Allied Health Ass'n v. Arthrocare Corp., No. C 05-4276 JF(RS), 2009 WL 1424509, at *6 (N.D. Cal. May 20, 2009) in support of their argument. In Allied Health, the district court found that a cosmetic products distributor's sale of a cosmetic device, without a physician's order, in violation of federal law, constituted a material breach that was sufficient to allow immediate termination of the distribution agreement without notice and an opportunity to cure. Id. at *8. The court explained that defendant's failure to distribute the products properly was not curable "because there was no realistic means to remedy any harm that could have been caused by such a breach." Id. The court also noted that the defendant's actions created a safety issue justifying the right of immediate termination. Id. at *9.

Plaintiff argues that the holding in Allied Health applies because its case also involves the sale of a product with a risk of harm to consumers as a consumer complained that BLIS 12 had made her seriously ill and a report revealed that S. Salivarius "has the potential to cause human disease and even death, this occurs very rarely and almost exclusively in patients with underlying immunocompromise, or when the organism is inoculated directly into a sterile site." (Dkt. No. 80-28, P's NOL, Ex. 24 at 10.) Plaintiff also argues that even if it provided notice, a breach was not curable within the 90 day cure period. In response, Defendant argues that Allied Health is distinguishable because the district court found that the material breach concerned a risk of harm to consumers that is far greater than in this case, and that Defendant could have easily cured the alleged breach by amending the marketing claims made on the

product's packaging. Defendant finally argues the late alleged notice of the breach defeated the purpose of the provision because by August 2012, there was no breach to cure because the parties mutually agreed to part ways in April 2011.

The Court concludes that Defendant has raised a genuine issue of material fact as to whether the alleged breach was material so that Plaintiff was relieved of complying with the notice and cure provision in the Agreement.

E. Affirmative Defense of Modification of Contract

Plaintiff argues there was no written amendment to the parties' Agreement terminating the Agreement in April 2011. Frutarom argues that there was a modification to the contract when the parties agreed to walk away from the Agreement in April 2011, therefore, Defendant is not under any contractual obligations to Plaintiff.

The Agreement provides that "This Agreement may be amended only by a writing signed by the parties which states that it is intended to amend this Agreement." (Dkt. No. 80-25, P's NOL, Ex. 1 ¶ 17(b).) California Civil Code section 1698(b) provides that,

> (b) A contract in writing may be modified by an oral agreement to the extent that the oral agreement is executed by the parties.
>
> (c) Unless the contract otherwise expressly provides, a contract in writing may be modified by an oral agreement supported by new consideration. . . .
>
> (d) Nothing in this section precludes in an appropriate case the application of rules of law concerning estoppel, oral novation and substitution of a new agreement, rescission of a written contract by an oral agreement, waiver of a provision of a written contract, or oral independent collateral contracts.

Cal. Civil Code § 1698. The Law Revision Commission Comments for section 1698 provides, "the principles described in subdivision (d) may be applied to permit oral modification although the written contract expressly provides that modifications must be in writing." A fully executed oral agreement may modify a written agreement. See MacIsaac & Menke Co. v. Cardox Corp., 193 Cal. App. 2d 661, 670 (1971) ("But under section 1698 of the Civil Code, an executed oral agreement may alter an agreement in writing, even though, as here, the original contract provides that extra

work must be approved in writing.") "Whether a written contract has been modified by an executed oral agreement is a question of fact." Id.

Here, Defendant argues the parties modified the Agreement when they agreed to walk away from the Agreement in April 2011. At the time, both parties agreed orally and in writing that Defendant would accept the return of certain amounts of remaining BLIS K12 for a reduced price. (Dkt. No. 98-1, P's Reply to D's SSUF No. 128.) Defendant maintains that Plaintiff fully performed on the modification when it returned the unused raw ingredient.

Plaintiff replies that the oral modification was never fully executed since Plaintiff refused to pay the fees Defendant demanded. There remained a balance due for the restocking fee and for product not accepted for return. (Id., No. 129.) Plaintiff made two payments, and after several requests to pay amounts past due, Defendant sent the account to collection on July 27, 2012. (Id., No. 130.) According to Plaintiff, the fact that it did not fully perform under the modification defeats Defendant's argument.

The parties do not dispute the facts of the alleged modification. Since Plaintiff did not fully execute the modification by failing to pay for the remaining amounts due, there was no modification of the Agreement. Thus, the Court concludes that Plaintiff has demonstrated that there are no genuine issues of fact whether the Agreement was modified.

Finally, Defendant, out of an abundance of cause, also summarily argues that there are triable issue of material fact as to its remaining twelve affirmatives defenses and provides one paragraph each as to the affirmative defense of breach of contract and waiver. Since the Court denies Plaintiff's motion for summary judgment, the Court declines to address the summary arguments on the remaining affirmative defenses especially as they were presented in a summary manner.

D. Defendant's Motion to Strike

Defendant filed a motion to strike a portion of Lowell Giffhorn's, Plaintiff's Chief Financial Officer ("CFO"), declaration stating,

> If Imagenetix had known that BLIS K12 was not lawful to sell in the United States, it would not have entered into the Agreement and it would not have invested in, marketed, and sold to its customers its BLIS K12-based product, Bioguard.

(Dkt. No. 80-26, P's NOL, Giffhorn Decl. ¶ 2.)

Federal Rule of Civil Procedure 56(c)(4) provides that an affidavit or declaration must "be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Fed. R. Civ. P. 56(c)(4). Statements that are "legal conclusions, speculative assertions, or statements of hearsay evidence do not satisfy the standards of personal knowledge, admissibility, and competence required by 56(c)(4)." Meador v. Hammer, No. 11cv3342 KJM AC P, 2015 WL 1238363, at *3 (E.D. Cal. Mar. 16, 2015) (citing Blair Foods, Inc. v. Ranchers Cotton Oil, 610 F.2d 665, 667 (9th Cir. 1980); Soremekun v. Thrifty Payless, Inc., 509 F.3d 978, 984 (9th Cir. 2007)). Also, a corporate officer's personal knowledge may be presumed from his or her position. See Self-Realization Fellowship Church v. Ananda Church of Self-Realization, 206 F.3d 1322, 1330 (9th Cir. 2000) (stating affiant's position as corporate officer allowed the court to presume the affiant had personal knowledge of the corporate activities at issue); Barthelemy v. Air Lines Pilots Ass'n, 897 F.2d 999, 1018 (9th Cir. 1990) (CEO's personal knowledge of various corporate activities could be presumed).

First, Defendant contends that Giffhorn's statement is based on a legal and factual impossibility. Giffhorn asserts that if Plaintiff had known that BLIS K12 "was not lawful to sell in the United States," it would not have entered into the Agreement. This statement, according to Defendant, is not legally or factually correct because the FDA's determination concluded that BLIS K12 was only unlawful to sell, as marketed. Since it was unlawful to sell as marketed, it could have been cured. Therefore, since it was curable, it is meaningless for Giffhorn to opine what Imagenetix would have done had it had known BLIS K12 was not legal to sell. In response, Plaintiff argues that the FDA not only found that BLIS K12 was being sold as an unapproved drug, it also found that it was "not a dietary ingredient." The FDA found that Defendant's

representation that BLIS K12 was deemed to be compliant with DHSEA since *S. Salivarius* is listed in the FDA listing of dietary ingredients in use before October 15, 1994 was false. Ultimately, BLIS K12 would still have been illegal to sell even if Frutarom's marketing claims had been cured. Therefore, Giffhorn's statement that had Plaintiff known that BLIS K12 was illegal to sell, it would not have entered into the Agreement, is still valid, even if the marketing claims were cured. In reply, Defendant does not address this response and appears to concede that Plaintiff's assertion that based on its claim that BLIS K12 is not a dietary ingredient, it would have been illegal to sell. Therefore, the Court finds Defendant's argument is not persuasive.

Next, Defendant contends that the statement is factually irrelevant because both parties agree that the marketing claims could have been cured. Therefore, it does not matter what Plaintiff would have done had it known BLIS K12 was "unlawful to sell." However, Plaintiff contends that Defendant did not cure its marketing claims and its argument is also based on a hypothetical scenario that did not occur. It was reasonable for Giffhorn, as the CFO, to opine on what Imagenetix would or would not do. The Court agrees that Defendant also responds with a hypothetical that had Plaintiff known that the product was illegal, it would have accepted a remedy from Defendant and does not support its argument that Giffhorn's statement is irrelevant. The issue, in fact, is relevant as it addresses whether the promise formed the basis of the bargain and the damages issues of a breach of express warranty claim, and a reasonable conclusion.

Lastly, Defendant contends that the statement is speculative because it is not made within Giffhorn's personal knowledge as the CFO since it was Bill Spencer, the President and CEO of Imagenetix, who made the decision to enter into and signed the Agreement. Plaintiff opposes arguing that Giffhorn attested that he was "fully knowledgeable of the facts here" and he was knowledgeable and involved in the events surrounding the execution of the Agreement. (Dkt No. 80-26, P's NOL, Ex. 22, Giffhorn Decl. ¶ 1.)

Contrary to Defendant's argument, a CFO is presumed to have personal

knowledge of the activities of the company and in this case, about the facts surrounding the decision to enter in an agreement with Frutarom. See Self-Realization Fellowship Church, 206 F.3d at 1130. Moreover, Plaintiff has provided facts demonstrating his personal knowledge concerning the Agreement. Giffhorn has been Imagenetix' Chief Financial Officer since 2005. (Dkt. No. 95-2, Ex. 2, Giffhorn Depo. at 8:22-9:1, Ex. 1.) He also served as the corporate secretary and interacted with the Board of Directors. (Id. at 9:13-15.) He had knowledge about the Agreement, reviewed the Agreement prior to execution, was intimately involved in compliance with SEC regulations and was aware of the FDA regulations. (Id. at 11:22-24; 13:18-20; 22:9-18; 49:15-23.) He testified that it would be material if the active ingredient in BioGuard was not approved for sale in the U.S. (Id. at 20:9-19.) The Court disagrees with Defendant's argument that Giffhorn did not have personal knowledge of the challenged statement.

In conclusion, the Court DENIES Defendant's motion to strike portions of Lowell Giffhorn's declaration.

Conclusion

Based on the above, the Court DENIES Plaintiff's motion for partial summary judgment on the claim for breach of warranty and DENIES Defendant's motion to strike. The Court also GRANTS Plaintiff's request for leave to file an amended complaint to add breach of express warranty. Plaintiff shall file an amended complaint within five days of the filing of this Order. The hearing set for March 24, 2017 shall be **vacated.**

IT IS SO ORDERED.

DATED: March 22, 2017

HON. GONZALO P. CURIEL
United States District Judge