UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

NUTRITION DISTRIBUTION, LLC, Plaintiff, v. NEW HEALTH VENTURES, LLC, Defendant.	Case No.: 16-cv-02338-BTM-MDD **ORDER DENYING PLAINTIFF'S MOTION FOR LEAVE TO AMEND COMPLAINT, GRANTING DEFENDANT'S MOTION TO DISMISS AND DENYING DEFENDANT'S MOTION TO STRIKE**

Before the Court are Defendant New Health Ventures, LLC's motion to dismiss and motion to strike, as well as Plaintiff Nutrition Distribution, LLC's motion for leave to file an amended complaint. (ECF Nos. 5–6, 13.) For the reasons discussed below, Plaintiff's motion for leave to amend is denied, Defendant's motion to dismiss is granted and its motion to strike certain portions of the Complaint is denied as moot.

I. BACKGROUND

On September 15, 2016, Plaintiff filed a Complaint against Defendant alleging a single cause of action of false advertisement in violation of Section 43(a)(1)(B) of the Lanham Act. (ECF No. 1 ("Compl.").) Plaintiff alleges that Defendant

falsely advertised and marketed products containing various "Selective Androgen Receptor Modulators ("SARMS")" such as "Ostarine." (Compl. ¶ 27.) On October 26, 2016, Defendant filed a motion to dismiss for failure to state a claim and a motion to strike Plaintiff's request for injunctive relief. In response, on December 12, 2016, Plaintiff filed a proposed First Amended Complaint (ECF No. 8 ("FAC")) asserting three causes of action including a violation of the Lanham Act, a violation of the Civil Racketeer Influenced and Corrupt Organizations Act ("RICO"), and a violation of the California Business and Professions Code Section 17200. Unlike Plaintiff's original Complaint, its proposed FAC is based on Defendant's sale of products containing Dimethazine ("DMZ").

Defendant subsequently filed a request for entry of dismissal with prejudice, arguing that because Plaintiff did not oppose the motion to dismiss and instead filed an untimely FAC without leave from the Court, the case should be dismissed with prejudice. (ECF No. 9.) On January 3, 2017, Plaintiff filed a motion for leave to amend its Complaint.

II. STANDARD

A. Leave to Amend

Pursuant to Federal Rule of Civil Procedure 15(a)(2), "a party may amend its pleading only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). "The court should freely give leave when justice so requires." Id. "Liberality in granting a plaintiff leave to amend is subject to the qualification that the amendment not cause undue prejudice to the defendant, is not sought in bad faith, and is not futile." *Bowles v. Reade*, 198 F.3d 752, 757 (9th Cir. 1999). Additionally, a court may consider the factor of undue delay. *Id.* at 757–58.

These factors are not given equal weight. *Bonin v. Calderon*, 59 F.3d 815, 845 (9th Cir. 1995). "Futility of amendment can, by itself, justify the denial of a motion for leave to amend." *Id.* The test for futility is the same one used when considering the sufficiency of a pleading under Rule 12(b)(6). *Miller v. Rykoff-Sexton, Inc.*, 845 F.2d 209, 214 (9th Cir. 1988).

B. Rule 12(b)(6)

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) should be granted only where a plaintiff's complaint lacks a "cognizable legal theory" or sufficient facts to support a legal claim. *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1988). When reviewing a motion to dismiss, the allegations of material fact in plaintiff's complaint are taken as true and construed in the light most favorable to the plaintiff. *Parks Sch. of Bus., Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Although detailed factual allegations are not required, factual allegations "must be enough to raise a right to relief above the speculative level." *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007). "A plaintiff's obligation to prove the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not show[n] that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (internal quotation marks omitted). Only a complaint that states a plausible claim for relief will survive a motion to dismiss. *Id.*

C. Rule 9(b)

Under Federal Rule of Civil Procedure 9(b), a plaintiff "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. Proc. 9(b). A plaintiff alleging fraud "must state the time, place, and specific content of the false representations as well as the identities of the parties to the

misrepresentations." *Alan Neuman Prods., Inc. v. Albright*, 862 F.2d 1388, 1392–93 (9th Cir. 1988) (quoting *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986)).

II. DISCUSSION

A. Plaintiff's Motion to Amend

Defendant opposes Plaintiff's motion for leave to file its FAC on grounds of bad faith, undue prejudice, and futility. First, Defendant argues that Plaintiff acted in bad faith because it completely abandoned its original claim and evaded an unfavorable ruling and possible attorney's fees. Second, Defendant argues that it would be prejudiced if an amendment is permitted because the original claims will never be adjudicated and it would be deprived of seeking its attorneys' fees. Finally, Defendant contends that the Court should deny Plaintiff leave to amend because the proposed amendments are futile.

At this juncture, no ENE has taken place and discovery has not yet commenced. Though the motion is procedurally defective, given the early stage of this litigation, the Court does not find that Plaintiff acted in bad faith, caused undue delay, or that granting Plaintiff leave to file an FAC would prejudice Defendants. Therefore, leave to amend turns on whether the proposed amendments would be futile.

1. Lanham Act Claim

Defendant argues that Plaintiff's Lanham Act claim is futile because it is barred under the primary jurisdiction doctrine and fails to satisfy Rules 12(b)(6) and 9(b).

Section 43(a) of the Lanham Act "allows one competitor to sue another if it alleges unfair competition arising from false or misleading product descriptions." *POM Wonderful LLC v. Coca-Cola Co.*, __ U.S. __, 134 S. Ct. 228, 1879 (2017). A plaintiff seeking to establish a prima facie case under the Lanham Act must show that:

> (1) the defendant made a false statement either about the plaintiff's or its own product; (2) the statement was made in commercial advertisement or promotion; (3) the statement actually deceived or had the tendency to deceive a substantial segment of its audience; (4) the deception is material; (5) the defendant caused its false statement to enter interstate commerce; and (6) the plaintiff has or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to the defendant, or by a lessening of goodwill associated with the plaintiff's product.

Newcal Indust. V. Ikon Office Solution, 513 F.3d 1038, 1052 (9th Cir. 2008).

i. Futility Under the Primary Jurisdiction Doctrine

Defendant argues that Plaintiff's Lanham Act claim—based on its failure to disclose DMZ's health effects—is futile because it is barred under the primary jurisdiction doctrine.

The primary jurisdiction doctrine allows federal courts, under limited circumstances, to defer to a relevant agency "when a claim is cognizable in federal court but requires resolution of an issue of first impression, or of a particularly complicated issue that Congress had committed to a regulatory agency." *Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002) (citations omitted). Though discretionary, in evaluating primary jurisdiction a court should consider "(1) the need to resolve an issue that, (2) has been placed by the United States Congress within the jurisdiction of an administrative body having regulatory authority, (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that, (4) requires expertise or uniformity in administration." *Id.* at 781.

Relying on *Aaronson v. Vital Pharmaceuticals, Incorporation*, No. 9–cv-1333-W, 2010 WL 625337, at *2–3 (S.D. Cal. Feb. 17, 2010), Defendant argues that Plaintiff's allegations concerning Defendant's omissions about DMZ's health effects falls within the FDA's primary jurisdiction. In *Aaronson*, the court determined that the plaintiff's claims rested on the question of whether the product was in fact safe. *Id.* at * 2. The court, therefore, dismissed the plaintiff's

claims under the primary jurisdiction doctrine and deferred to the FDA because it found that the agency was in a better position to make that determination. *Id.* at * 3.

Unlike the claims in *Aaronson*, Plaintiff's claim does not depend on whether DMZ is safe or not. Plaintiff alleges that "Defendant markets DMZ to body builders, gym users, fitness enthusiasts and athletes, promising consumers numerous purported physical benefits without mentioning the overwhelming clinical evidence that such products pose extreme health risks." (FAC ¶ 18.) Here, Plaintiff's claim instead requires the Court to determine whether Defendant misled consumers by failing to disclose the alleged severe health effects associated with taking DMZ. Therefore, the FDA's technical and policy expertise is not necessary to determine whether Defendant's advertisements are misleading. *See Nutrition Distribution LLC v. Custom Nutraceuticals LLC*, 194 F. Supp. 3d 952, 955–956 (D. Ariz. 2016) (holding that nearly identical allegations, including whether Defendant made false and misleading statements about Ostarine's side effects, were not barred under the primary jurisdiction doctrine); *see also Thermolife Int'l, LLC v. Gaspari Nutrition Inc.*, 648 Fed. Appx. 609, 612 (9th Cir. Apr. 14, 2016) (finding that whether a nutritional supplement distributor "falsely advertised its product as 'safe' and 'natural' require[d] no interpretation of the FDCA").

Accordingly, Plaintiff's claim based on Defendant's alleged omission of DMZ's side effects is not barred by the primary jurisdiction doctrine.

ii. Futility under 12(b)(6)

Defendant also argues that Plaintiff has not sufficiently alleged a claim under the Lanham Act.

First, Defendant maintains that Plaintiff fails to allege how DMZ is a "controlled substance" under the Controlled Substance Act ("CSA"), 21 U.S.C. § 802(41)(C). The CSA classifies more than a dozen drugs and hormonal

substances as Schedule III controlled substances. § 802(41)(A). Additionally, it provides that:

> a drug or hormonal substance . . . that is not listed in subparagraph (A) and is derived from, or has a chemical structure substantially similar to, 1 or more anabolic steroids listed in subparagraph (A) shall be considered to be an anabolic steroid for purposes of this Act if—(I) the drug or substance has been created or manufactured with the intent of producing a drug or other substance that either (aa) promotes muscle growth; or (bb) otherwise causes a pharmacological effect similar to that of testosterone; or (II) the drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

§ 802(41)(C).

Plaintiff alleges that DMZ is a controlled substance because it is derived from, and structurally similar to, Methastorone—a chemical already deemed to be an anabolic steroid under the Act. (FAC ¶ 14.) It claims that DMZ is "composed of two Methastorone molecules ba bonded at the center by two nitrogen atoms." (Id.) DMZ breaks down into Methastorone when it gets in contact with stomach acid. (Id.) As a result, the two molecules of Methastorone act on your body as they would if you had taken the drug on its own. (Id.) At this stage, the Court finds that Plaintiff has sufficiently pled that DMZ falls within the definition of a "controlled substance" under Section 802(41)(C) of the CSA.

Second, Defendant argues that Plaintiff's claim regarding Defendant's alleged failure to disclose that DMZ is banned by anti-doping organizations is legally insufficient because it is not an actionable omission.

Under the Lanham Act, a statement is actionable "if it is affirmatively misleading, partially incorrect, or untrue as a result of a failure to disclose a material fact." *U.S. Healthcare, Inc. v. Blue Cross of Greater Phila.*, 898 F.2d 914, 921 (3d. Cir. 1990) (quoting J. Thomas McCarthy, *Trademarks and Unfair Competition*, § 27.7B (2d ed. 1984)). Federal courts have held that while

omissions can be actionable under the Lanham Act if they render affirmative statements false or misleading, a plaintiff must point to such statements at the pleading stage. *See id.*; *see also Casper Sleep, Inc. v. Mitcham*, 204 F. Supp. 3d 632, 638 (S.D.N.Y. 2016); *Oil Heat Ins. V. Northwest Natural Gas*, 708 F. Supp. 1118, 1123 (D. Or. 1988) (holding that a reasonable fact finder could reasonably conclude that Northwest failed to disclose material facts about its product, making the statement untrue).

Defendant contends that the proposed FAC fails to state how the alleged omission contradicts a representation made by Defendant or that Defendant was obligated to disclose such omission. Plaintiff alleges that Defendant marketed its product, Fury DMZ, as "hands down the strongest anabolic Pre-Workout on the market today!" (FAC ¶ 21.) Defendant advertised that "Fury DMZ is an extremely potent, high-intensity, high-stimulant and highly anabolic pre-workout concoction." (Id.) However, Plaintiff fails to point to any statement that would be rendered misleading or untrue as a result of Defendant's alleged omission that DMZ is banned by competitive anti-doping organizations. Accordingly, to the extent that Plaintiff's Lanham Act claim is based on this alleged omission, it would not survive a motion to dismiss under Rule 12(b)(6).

iii. Futility Under Rule 9(b)

Lastly, Defendant argues that Plaintiff's Lanham Act claim is futile because it fails to meet Rule 9(b)'s particularity requirements.

Lower federal courts have applied this heightened pleading standard to claims under the Lanham Act that are grounded in fraud. *See Seoul Laser Dieboard Sys. Co. v. Serviform, S.R.L.*, 957 F. Supp. 2d 1189, 1200 (S.D. Cal. 2013); *see also EcoDisc Tech. AG v. DVD Format/Logo Licensing Corp.*, 711 F. Supp. 2d 1074, 1085 (C.D. Cal. 2010). Though the standard is somewhat relaxed for claims that are based on fraudulent omissions, a plaintiff must still plead the omission or concealment with particularity. *Kearns v. Ford Motor Co.*,

567 F.3d 1120, 1127 (9th Cir. 2009) (dismissing fraudulent omission claim under Rule 9(b) where plaintiff's claims of nondisclosure were couched in general pleadings); *see Davidson v. Apple, Inc.*, 16-cv-04942-LHK, 2017 WL 976048, at *9–10 (N.D. Cal. Mar. 14, 2017) (dismissing plaintiffs' fraudulent omission claims as "too vague to provide Defendants with the 'who, what, when, and where' of the allegedly fraudulent omissions, as required by Rule 9(b).").

Here, Plaintiff alleges that "Defendant has purposely made false and misleading descriptions of fact concerning the nature, characteristics and qualities of its DMZ products by . . . failing to disclose their status as controlled substances and failing to disclose the overwhelming clinical evidence that such products pose extreme health risks." (FAC ¶ 25.) Plaintiff fails to plead with particularity Defendant's alleged misleading advertisement. Rather than describe with particularity Defendant's alleged misleading descriptions of its DMZ products, Plaintiff merely makes general allegations about its advertisements—which are insufficient under Rule 9(b).

2. RICO Claim

Defendant also argues that Plaintiff's RICO claim is futile because it fails to allege facts supporting each of the claim's elements.

RICO under 18 U.S.C. § 1961 et seq., makes it unlawful for "any person employed by or associated with any enterprise engaged in . . . interstate or foreign commerce, to conduct or participate . . . in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c). In order to plead a claim under RICO, a plaintiff must demonstrate that a defendant participated in "(1) conduct (2) of an enterprise that affects interstate commerce (3) through a pattern (4) of racketeering activity or collection of unlawful debt." *Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 997 (9th Cir. 2014). The Supreme Court has clarified that while the same evidence may be used to prove both the existence of an "enterprise" and a

"pattern of racketeering," they are separate elements that a plaintiff must prove. *United States v. Turkette*, 452 U.S. 576, 583 (1981) ("The 'enterprise' is not the 'pattern of racketeering activity''; it is an entity separate and apart from the pattern of activity in which it engages.").

First, Defendant contends that Plaintiff fails to sufficiently allege the enterprise element of its RICO claim. An enterprise may be a legal entity or it may be a group of individuals associated-in-fact. 18 U.S.C. § 1961(4). An associated-in-fact enterprise is defined as "a group of persons associated together for a common purpose of engaging in a course of conduct." *United States v. Christensen*, 828 F.3d 763, 780 (9th Cir. 2016) (quoting *United States v. Turkette*, 452 U.S. at 583). To prove the existence of an associated-in-fact enterprise, a plaintiff must show: (1) a common purpose, (2) an ongoing organization, and (3) a continuing unit. *Id.* Contrary to what Defendant argues, RICO does not require that an "associated-in-fact enterprise have a structure beyond that necessary to carry out its racketeering activity." *Odom v. Microsoft Corp.*, 486 F.3d 541, 551 (9th Cir. 2007). Nevertheless, the Court finds that Plaintiff has not pled sufficient facts to demonstrate that Defendant and its unknown co-conspirators constitute an ongoing and continuing enterprise.

Second, Defendant argues that Plaintiff has failed to sufficiently allege any pattern of racketeering activity. A "'pattern of racketeering activity' requires at least two acts of racketeering activity . . . ." 18 U.S.C. § 1961(5). "'Racketeering activity' is any act indictable under several provisions of Title 18 of the United States Code . . ." *Sanford v. MemberWorks, Inc.*, 625 F.3d 550, 557 (9th Cir. 2010). The plaintiff must adequately plead the elements of each predicate act, satisfying the pleading standard that would apply if the predicate act were to stand-alone. *Alan Neuman Prods., Inc. v. Albright*, 862 F.2d 1388, 1392 (9th Cir. 1988). The proposed FAC generally alleges that Defendant and co-conspirators have violated 21 U.S.C. § 841 because they have sold products containing DMZ,

which is allegedly a controlled substance under the CSA. These general allegations alone are not enough to plead a RICO case. *See Nutrition Distribution LLC*, 194 F. Supp. 3d at 958 (dismissing plaintiff's RICO claim because "it fail[ed] to identify any particular instance in which Defendants engaged in such [a pattern of racketeering] activity."). Therefore, Plaintiff's RICO claim is futile, as it would not survive a motion to dismiss.

After reviewing the proposed FAC and finding that the proposed claims are futile[1], the Court denies Plaintiff's motion to amend.

B. Defendant's Motion to Dismiss

Defendant moves to dismiss Plaintiff's original Complaint, arguing that its claim is barred by the primary jurisdiction doctrine and that it fails to allege an actionable false statement. As already mentioned, Plaintiff filed no opposition to Defendant's motion to dismiss.

1. Primary Jurisdiction Doctrine

First, Defendant argues that Plaintiff's Lanham Act claim is barred under the primary jurisdiction doctrine because it urges the Court to determine whether its Ostarine products are safe—a determination that should be made by the FDA. As already discussed above, the primary jurisdiction doctrine allows a federal court to abstain from deciding a case if it determines that the "initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor Co.*, 307 F.3d at 780.

Here, the Court reads Plaintiff's Lanham Act claim to be based on namely three issues: 1) whether Defendant engaged in false advertising by mislabeling its products as natural "dietary supplements;" (2) whether Defendant engaged in

[1] Plaintiff's third proposed claim under California Business and Professions Code § 17200 is based on the same allegations set forth under its Lanham Act and RICO claims. As already discussed above, the Court finds that those claims are futile. As such, the Court similarly finds that Plaintiff's California Unfair Competition Claim is futile.

false advertising by failing to disclose any of the recognized side effects and dangers of using SARMS; and (3) whether Defendant engaged in false advertising by failing to disclose that SARMS are specifically prohibited for use in sporting events by the World Anti-Doping Agency and the U.S. Anti-Doping Agency. The Court finds that the FDA's technical and policy expertise is not required to determine whether Defendant's advertisements are false and misleading. *See Dabish v. Brand New Energy, LLC*, 16-cv-400-BAS, 2016 WL 7048319, at *5 (S.D. Cal. Dec. 5, 2016) (finding that because the FDA has already issued a guidance as to what a dietary supplement is and what dietary ingredients may be legally added to a dietary supplement and how, the issue of false advertising did not require the FDA's expertise or implicate concerns about uniformity in administration).

Plaintiff's Complaint does rest, in part, on Defendant's misrepresentations "to consumers that such products are purportedly safe and have little to no adverse health and safety consequences." (Compl. ¶ 27.) However, Plaintiff's claim does not require the Court to determine whether the product is safe under the FDA's standards. Instead it requires a determination of whether Defendant made false and misleading statements by representing the product as safe while failing to disclose the product's health effects—a finding that does not require the FDA's expertise. As the Supreme Court stated in *Pom Wonderful LLC*, 134 S.Ct. at 2238, though both the FDCA and Lanham Act touch on food and beverage labeling, "the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." Because a review of the Complaint reveals that Plaintiff's Lanham Act claim rests on Defendant's alleged misleading advertisements, it is not barred under the primary jurisdiction doctrine.

2. Rule 9(b)

Defendant also moves to dismiss Plaintiff's Complaint by arguing that it

fails to identify any actionable false or misleading statements or explain why these statements are false or misleading.

As already discussed above, Lanham Act claims that are grounded in fraud are subject to the heightened pleading standard under Rule 9(b). *Seoul Laser Dieboard Sys. Co.*, 957 F. Supp. 2d at 1200. Here, Plaintiff fails to provide sufficient facts to support its claim. Though Plaintiff alleges that Defendant made false and misleading statements, it fails to provide the Court with any of those alleged misleading statements or how Defendant's alleged omissions render affirmative statements misleading or untrue. Thus, Plaintiff's Lanham Act claim fails to satisfy Rule 9(b). As a result, Defendant's motion to dismiss is granted.

IV. CONCLUSION

For the reasons discussed above, Plaintiff's motion to amend its complaint (ECF No. 13) is **denied.** Defendant's motion to dismiss (ECF No. 5) is **granted** and motion to strike certain portions of the Complaint (ECF No. 6) is **denied as moot**.

The Court grants Plaintiff leave to file a First Amended Complaint ("FAC") that complies with Local Rule 15.1(c), remedying the defects identified above. Plaintiff must file its FAC within 20 days of the entry of this Order.

IT IS SO ORDERED.

Dated: June 13, 2017

Barry Ted Moskowitz, Chief Judge
United States District Court