UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FT. LAUDERDALE DIVISION

ASTORRIA SASSANO, Plaintiff, vs. PETSMART, INC., a Foreign For-Profit Corporation Defendant.	CASE NO.: _____ **NOTICE OF REMOVAL**

Pursuant to 28 U.S.C. §§ 1331, 1332, 1441, and 1446, Defendant PetSmart, Inc. ("PetSmart") hereby gives notice of removal of the above-entitled action, and all claims and causes of action therein, currently pending in the Circuit Court of the Seventeenth Judicial Circuit in and for Broward County, Florida (the "State Court Action"). Defendant PetSmart appears for the purposes of removal only, reserves all defenses and rights available to it, and as grounds for removal states as follows:

NOTICE OF REMOVAL

1. Plaintiff filed the above-entitled action on April 22, 2020 against PetSmart in the Circuit Court of the Seventeenth Judicial Circuit in and for Broward County, Florida. Plaintiff served PetSmart's registered agent with a copy of the Complaint via process server on May 1, 2020. A copy of the receipt of service of process from PetSmart's registered agent is attached hereto as Exhibit A.

2. Service of Process on May 1, 2020 constituted PetSmart's first receipt of a copy of the initial pleading setting forth the claim for relief upon which such action or proceeding is based. This Notice of Removal is being filed within 30 days of the same, and is therefore timely under 28 U.S.C. § 1446(b)(1).

3. Pursuant to 28 U.S.C. § 1446(d), PetSmart will file a copy of this Notice of Removal with the Clerk of the Circuit Court of the Seventeenth Judicial Circuit in and for Broward County, Florida, and will serve a copy of this Notice of Removal on Plaintiff to properly effect removal of this action to this Court.

4. A true and correct copy of the Complaint is attached hereto as Exhibit B. Pursuant to 28 U.S.C. § 1446(a), a true and correct copy of all other process, pleadings, and orders served upon PetSmart in the State Court Action is attached hereto as Exhibit C. A copy of the docket in the State Court Action is attached as Exhibit D. No substantive motions have been filed in the State Court Action.

5. In submitting this Notice of Removal, PetSmart reserves all rights and defenses, including as to venue, personal jurisdiction, the legal sufficiency of the claims alleged in Plaintiff's complaint, and all other objections and defenses.

FEDERAL QUESTION JURISDICTION OF THIS COURT

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 1441(a) because this action necessarily raises substantial and disputed federal issues. *See Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005). Suits alleging only state-law causes of action nevertheless "arise under" federal law if the "state-law claim[s] necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314. Applying this test "calls for a 'common-sense accommodation of judgment to the kaleidoscopic situations' that present a federal issue." *Id.* at 313.

7. The Eleventh Circuit has explained that "'[t]he substantiality inquiry under *Grable* looks to the importance of the issue to the federal system as a whole,' and the Supreme Court has identified three factors to assist in this inquiry. First, a pure question of law is more likely to be a substantial federal question. Second, a question that will control many other cases is more likely to be a substantial federal question. Third, a question that the government has a strong interest in litigating in a federal forum is more likely to be a substantial federal question." *MDS (Can.), Inc. v. RAD Source Techs., Inc.*, 720 F.3d 833, 842 (11th Cir. 2013).

8. This District has likewise followed the test set out by the Supreme Court in *Grable*, and also underscored that "[i]n making this determination, 'the removing court looks to the substance of the complaint, not the labels used in it.'" *Edwards v. Deloitte & Touche, LLP*, No. 16-21221-Civ-Scola, 2017 U.S. Dist. LEXIS 221984, at *10 (S.D. Fla. Jan. 18, 2017) (finding federal question jurisdiction over exclusively state law causes of action). This District has also made clear that, "even if it appears from the complaint that only state-law causes of action are actually pleaded, a federal question will be inferred where 'the vindication of a right under state law necessarily turns on some construction of federal law.'" *MSPA Claims 1, LLC v. Allstate Prop. & Cas. Ins. Co.*, No. 16-20443-Civ-Scola, 2016 U.S. Dist. LEXIS 92958, at *5-6 (S.D. Fla. June 29, 2016); *see also Korman v. IRS*, No. 06-81294-Civ-Marra, 2007 U.S. Dist. LEXIS 91046, at *10 (S.D. Fla. Feb. 20, 2007) ("That Plaintiff chose to cast his challenge to the propriety of the federal tax lien in state law terms is of no consequence. Under the artful pleading doctrine, federal courts may take jurisdiction over a complaint removed from state court where the plaintiff, although framing his action under state law, in actuality raises an essential federal question.'") (denying motion to remand state law claim).

9. Federal jurisdiction is also proper under the *Grable* framework "where federal law completely preempts the state law claims" or "where the plaintiff has attempted to defeat removal by 'artful pleading,' *i.e.* by failing to plead a necessary federal question in his complaint." *Quepasa Corp. v. Valdez*, No. 10-80698-Civ-Hurley, 2010 U.S. Dist. LEXIS 153817, at *13 (S.D. Fla. Nov. 19, 2010) (citations omitted). Under the "artful pleading" doctrine specifically, "[r]emoval will be held proper when the plaintiff has concealed a legitimate ground of removal by inadvertence, or artful pleading. The plaintiff may be said to have engaged in 'artful pleading' in particular when he pleads a state cause of action the merits of which turn on an important federal question." *Ayres v. GMC*, 234 F.3d 514, 518 n.7 (11th Cir. 2000) (quoting 14B Wright, Miller & Cooper, Federal Practice and Procedure: Jurisdiction § 3732, at 333 (3d ed. 1998) (emphasis added); *see also* 15A Moore's Federal Practice - Civil § 103.43; ("A plaintiff cannot avoid federal court simply by omitting a necessary federal question in the complaint; in such a case the necessary federal question will be deemed to be alleged in the complaint. This is a corollary to the well-pleaded complaint rule, sometimes called the 'artful pleading' exception, that a plaintiff may not frame the action solely under state law by omitting federal questions that are essential to recovery."); 15A Moore's Federal Practice - Civil § 107.73.

The Legal Issue in This Case Depends Exclusively On Federal Law Interpretation.

10. In this case, although Plaintiff pleads only a single state law cause of action, for violation of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.201 *et seq.*, her allegations derive *exclusively* from the claim that the Only Natural Pet Hemp Seed Oil with Krill and Cod Liver product sold by PetSmart (hereinafter, the "Product") violates the Federal Food Drug & Cosmetics Act ("FD&C Act") because it is an unapproved "new animal drug" under that law and is therefore "unsafe" and "adulterated." *See* Ex. B ¶¶ 15-23. Specifically,

Plaintiff alleges that the product "is not approved by the FDA or indexed and therefore the Product is considered unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5)," and as such, "the Product is an unapproved new animal drug and cannot lawfully be sold." (Compl., Ex. B ¶¶ 19, 21).

11. Plaintiff makes no other claims whatsoever regarding the efficacy of the Product or the truthfulness of the Product's advertised claims – her grievance is exclusively a matter of regulatory compliance under federal law. Plaintiff makes no claims, for example, regarding any alleged problems or deficiencies with the Product. Instead, the Complaint merely alleges that these alleged regulatory violations make the product "worthless" as a matter of law because it cannot lawfully be sold. *Id.* ¶¶ 21-23.[1] Accordingly, this Court has subject matter jurisdiction under *Grable* and the applications of Grable's principles in this Circuit and District, because the Complaint "necessarily raise a stated federal issue" that is "actually disputed and substantial."

12. A federal forum may entertain the issues presented in this case without disturbing any congressionally approved balance of federal and state judicial responsibilities because it impacts only the interpretation of federal FDA law, with the state FDUTPA statute serving as nothing more than a vehicle for a challenge premised solely on alleged violations of federal law. Indeed, there is greater federal interest in this case, because its outcome depends entirely on the interpretation of federal law.

13. The federal government has a strong interest in questions regarding the interpretation and application of the FD&C Act being litigated in a federal forum, so that these

[1] For the avoidance of doubt, even if such additional claims were made, this would not impact the Court's jurisdiction because the federal law claims would still be essential to Plaintiff's Complaint.

important questions of FDA law—to which the government devotes extensive regulatory resources—can be uniformly understood.[2]

14. Moreover, the resolution of the issues presented in Plaintiff's Complaint are a pure question of law as to how federal law regulates and applies to pet products containing hemp ingredients, and whether such products actually violate FDA laws, while the content of this Product's ingredients and advertising are clearly indicated in the Complaint and are not a matter of factual dispute. This heightens the federal interest in this dispute, because there is a likelihood that the outcome of this case would control or influence litigation involving a variety of other similar pet products that contain comparable hemp-based ingredients. In fact, Plaintiff's counsel has contemporaneously filed a nearly-identical action against PetSmart raising these same claims about an additional pet product, which PetSmart is also contemporaneously removing to this Court.[3]

The Claims are Preempted Under Federal Law.

15. There is also federal law preemption in this case,[4] as courts in this District have previously held that product claims under the FDUTPA can be preempted by FDA law and regulation. For example, in *Lombardo v. Johnson & Johnson Consumer Cos.*, No. 13-60536-Civ-SCOLA, 2013 U.S. Dist. LEXIS 189043 (S.D. Fla. 2013), the court held that Plaintiffs' challenges

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[2] By way of example, the FDA's 2020 operating budget totals $5.9 billion. *See* https://www.fda.gov/media/136036/download.

[3] *See Newell v. PetSmart, Inc.*, Case No. CACE-20-007163 (Broward Cty. Cir. Ct., filed April 28, 2020), for which PetSmart is contemporaneously filing a Notice of Removal to this Court today.

[4] PetSmart anticipates that FDA federal preemption will apply to this case, though not based on the precise provisions of FDA law that Plaintiff relies on. PetSmart disputes that the FDA-related statutes identified in Plaintiff's Complaint are the correct federal statutes applicable to the Product, but will raise other arguments based on preemption by FDA law and regulation in its forthcoming Motion to Dismiss. Under either analysis, FDA preemption will apply.

to the labeling of sunscreen products was preempted as of the time that an on-point FDA rulemaking guidance went into effect. *See also Bailey v. Janssen Pharmaceutica, Inc.*, No. 06-80702-Civ-RYSKAMP/VITUNAC, 2007 U.S. Dist. LEXIS 112568, at *17-18 (S.D. Fla. Apr. 11, 2007) ("The FDA has primary authority and expertise to regulate prescription drugs and services. As such, the FDA guidelines preempt state consumer fraud claims that constitute a 'requirement or prohibition imposed under state law with respect to advertising or promotion' . . . . FDA approved labeling for the patch cannot serve as a basis for the state law claim because such claim is preempted by FDA regulation.") (also explaining that "Plaintiff is correct in noting that neither of these cases expressly holds that federal law preempts the Florida statute, yet these cases do provide that state law claims that conflict with federal regulations are preempted. The FDA's determinations about the propriety of marketing materials regarding the patch deserve deference.").

16. Accordingly, this action involves disputed and substantial federal issues, including federal preemption, notwithstanding Plaintiff's attempts at "artful pleading" to restrict their causes of action to state law. It is abundantly clear from the face of the Complaint that Plaintiff's claims are entirely, and exclusively, premised on the construction and application of the Federal Food Drug & Cosmetics Act. The core and the crux of Plaintiff's Complaint is that the challenged product cannot be lawfully sold because it is an unauthorized animal drug that violates the FD&C Act. The resolution of this case thus depends, entirely and inherently, on construction of federal law. Therefore, Plaintiff's complaint raises a federal question and this Court has subject-matter jurisdiction.

DIVERSITY JURISDICTION OF THIS COURT

17. This Court also has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and the parties are completely diverse, and were completely diverse at the time Plaintiff filed the complaint.

A. There is Complete Diversity Between the Parties

18. Defendant PetSmart is, and at all relevant times has been, a Delaware corporation with its principal place of business in Phoenix, Arizona.[5] It is therefore deemed to be a citizen of Delaware and Arizona under 28 U.S.C. § 1332(c)(1).

19. Plaintiff and putative class representative Astorria Sassano is, and at the time of the filing of the Complaint was, a resident of Broward County, Florida. Compl., Ex. B ¶ 2.

B. The Amount in Controversy Exceeds $75,000, Exclusive of Interest and Costs

20. The amount-in-controversy requirement found in 28 U.S.C. § 1332 is satisfied. On the face of the Complaint, while Plaintiff only specifies that she seeks damages "in excess of" $30,000 (Compl., Ex. B ¶ 1), she also seeks to recover attorney's fees, as provided for under the Florida Deceptive and Unfair Trade Practices Act (FDUTPA). Compl., Ex. B ¶¶ 1, 74, 76, 77; Fla. Stat. §§ 501.211 & 501.2105. It is well-established that if attorneys' fees are provided for by statute, then a claim for attorneys' fees counts toward the amount in controversy. *See, e.g., Morrison v. Allstate Indem. Co.*, 228 F.3d 1255, 1265 (11th Cir. 2000) ("When a statute authorizes the recovery of attorney's fees, a reasonable amount of those fees is included in the amount in

[5] In the Complaint, Plaintiff alleges that "Defendant is a foreign for-profit corporation, doing business in Broward County, Florida." Compl., Ex. B ¶ 3.

controversy."); *Federated Mut. Ins. Co. v. McKinnon Motors, LLC*, 329 F.3d 805, 808 n. 4 (11th Cir. 2003).

21. The amount in controversy must include a reasonable estimation of attorneys' fees to be incurred and sought if the plaintiff ultimately prevails. *See, e.g.*, *Hall v. Am. Sec. Ins. Co.*, No. 09-21697-Civ-MORENO, 2009 U.S. Dist. LEXIS 130488, at *3-4 (S.D. Fla. July 23, 2009) (Moreno, J.) ("Plaintiff argues the Court must look to the amount of fees incurred up until the time of removal to determine whether the jurisdictional amount is met. . . . The court does not agree that this is the correct way to calculate a 'reasonable' amount of fees."); *Brown v. Cunningham Lindsey U.S., Inc.*, 3:05-cv-141-J-32HTS, 2005 U.S. Dist. LEXIS 38862, at *14 (M.D. Fla. May 11, 2005) (considering what would be "a fair estimate of Ms. Brown's attorneys' fees through trial"); *see also McGlynn v. Huston*, 693 F. Supp. 2d 585, 596 (M.D. La. 2010) (considering "fees likely to be incurred in this matter").

22. "The Eleventh Circuit Court of Appeals has held that it is appropriate for a federal court to look beyond the face of a complaint in assessing its jurisdiction when a notice of removal is filed." *Lewis v. AT&T Corp.*, 898 F. Supp. 907, 909 (S.D. Fla. 1995) (citing *Davis v. Cluet, Peabody & Co.*, 667 F.2d 1371, 1373 (11th Cir. 1982) (also stating that "a Court may properly look to a Notice of Removal to "suppl[y] the missing requisite [jurisdictional] facts."). Indeed, the Eleventh Circuit has chastised plaintiffs who attempt to obfuscate and deliberately avoid federal jurisdiction in their complaints.

23. This applies to the determination of the amount in controversy. As the Eleventh Circuit explained in *Roe v. Michelin N. Am., Inc.*, 613 F.3d 1058, 1064 (11th Cir. 2010), "when a district court can determine, relying on its judicial experience and common sense, that a claim satisfies the amount-in-controversy requirements, it need not give credence to a plaintiff's

representation that the value of the claim is indeterminate. Otherwise, a defendant could wrongly be denied the removal to which it is entitled." *Id.* The court explained that "preventing a district judge from acknowledging the value of the claim, merely because it is unspecified by the plaintiff, would force the court to abdicate its statutory right to hear the case…. Plaintiffs skilled in this form of artful pleading could, with this 'trick,' simply 'make federal jurisdiction disappear.'" *Id.* The court reasoned that "[b]oth policy and precedent counsel against rewarding such obfuscating tactics." *Id*.

24. Here, litigation will be costly. Plaintiffs' claims require analysis, research, and litigation of complicated federal statutory and regulatory requirements, as shown on the face of the Complaint, which cites at least six separate provisions of the Federal FD&C Act and various subsections thereof, in addition to FDA enforcement by way of warning letters. *See* Compl., Ex. B ¶¶ 15-22.

25. This will involve the litigation of federal preemption, which will require review of precedent from outside of the immediate jurisdiction. In addition, the parties will have to litigate the availability and propriety of the various forms of injunctive relief Plaintiff seeks. As a result of the complexity of Plaintiff's claims, attorneys' fees for litigating this action are likely ultimately to be quite high if Plaintiff ultimately prevails on her claims.

26. The previous conduct of Plaintiff's counsel in other putative class actions makes it highly likely that, even in the absence of class certification, Plaintiff's counsel will demand attorneys' fees on behalf of the single named Plaintiff that far exceed $75,000. In a previous putative class action also related to product claims brought under the FDUTPA, the same counsel representing Plaintiff in this action, Howard W. Rubenstein, made a settlement proposal that sought attorneys' fees in excess of $75,000. Counsel made this request early in the litigation of the

matter, before briefing or argument regarding class certification. As a result, the case was removed to this court on the basis of diversity jurisdiction. *See Perez v. Ralph Lauren Corp.* Case No. 9:18-cv-81631 (S.D. Fla), Dkt. No. 1 and Exhibit B thereto (Declaration of Jason Stiehl indicating that Mr. Rubenstein's settlement proposal "demanded in excess of $75,000 in damages and attorney's fees" to resolve that action). It is therefore highly likely that in this similar case, Plaintiff's counsel will likewise seek attorneys' fees in excess of $75,000, even on behalf of the single named plaintiff.

WHEREFORE, Defendant PetSmart respectfully requests, pursuant to 28 U.S.C. §§ 1331, 1332, 1441, and 1446, that this action be removed in its entirety from the Circuit Court of the Seventeenth Judicial Circuit in and for Broward County, Florida, to this Court, that this Court proceed with the case as if it was originally initiated in this Court, and that this Court make and enter such further orders as may be necessary and proper.

Dated: May 29, 2020

Respectfully submitted,

s/ Alec H. Schultz
Alec H. Schultz
Florida Bar No. 35022
León Cosgrove, LLP
255 Alhambra Circle, Suite 800
Coral Gables, Florida 33134
Telephone: 305-740-1975
Facsimile: 305-437-8158
Email: aschultz@leoncosgrove.com

Jason P. Stiehl
Nina Ruvinsky
pro hac vice to be filed
Loeb & Loeb LLP
321 N. Clark Street, Suite 2300
Chicago, Illinois 60654
Telephone: 312-464-3100
Facsimile: 312-464-3111
Email: jstiehl@loeb.com
Email: nruvinsky@loeb.com

Counsel for Defendant PetSmart, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 29, 2020, I electronically filed the foregoing with the Clerk of Court using CM/ECF system which in turn will serve a copy by electronic mail to all counsel of record.

s/ Alec H. Schultz
Alec H. Schultz

EXHIBIT B

IN THE CIRCUIT COURT, SEVENTEENTH JUDICIAL CIRCUIT,
IN AND FOR BROWARD COUNTY, FLORIDA

CASE NO.:
DIVISION:

ASTORRIA SASSANO,

Plaintiff,

CLASS REPRESENTATION

vs.

PETSMART, INC., a Foreign
For-Profit Corporation

Defendant.
_____/

CLASS ACTION COMPLAINT

Plaintiff, ASTORRIA SASSANO individually, and on behalf of all others similarly situated in Florida, by and through her undersigned counsel, hereby files this Class Action Complaint, against Defendant, PETSMART, INC. (hereinafter referred to as "Petsmart" or "Defendant"), and in support thereof alleges as follows:

I. PARTIES, JURISDICTION AND VENUE

1. This is a class action for damages pursuant to Florida Rule of Civil Procedure 1.220(b) in excess of Thirty Thousand Dollars ($30,000.00) exclusive of interest, costs and attorney's fees.

2. Plaintiff is an individual consumer over the age of eighteen, who resides in Broward County Florida. Plaintiff seeks injunctive relief and damages on behalf of Plaintiff and the Class, and respectfully requests a jury trial on damage claims.

3. Defendant is a foreign for-profit corporation, doing business in Broward County, Florida.

4. Venue for this action properly lies in Broward County, Florida, pursuant to

the provisions of Section 47.051, Fla. Stat. and Chapter 501.207 et seq. Fla. Stat. because Defendant transacts business in Broward County, Florida and the transactions out of which this action arose occurred in Broward County, Florida.

5. There is not federal jurisdiction of this Action under the Class Action Fairness Act of 2005 ("CAFA"), Pub. L. No. 109-2, 119 Stat. 4 (2005), which explicitly provides for the original jurisdiction of the Federal Courts of any class action in which any member of the plaintiff class is a citizen of a state different from any Defendant, and in which the matter in controversy exceeds in the aggregate the sum of $5,000,000.00, exclusive of interest and costs. The issue at hand does not exceed this requisite amount.

IV. FACTUAL ALLEGATIONS

6. On or about April 19, 2020, Plaintiff purchased Only Natural Pet Hemp Seed Oil with Krill and Cod Liver 8.0 FL OZ/237 ML bottle (hereinafter also referred to as "Product"), from PETSMART located at 1700 N. Federal Highway, Fort Lauderdale, Florida. A copy of the receipt is attached hereto as **Exhibit "A."**

7. The Product had not been altered between manufacture and point of sale. A photograph of the Product's packaging is attached hereto as composite **Exhibit "B."**

8. The back of the Product's packaging states "Only Natural Pet Hemp Seed Oil with Krill & Cod Liver provides a concentrated source of Omega 3 & 6's to support the immune system, cardiovascular health and vitality. **Hemp seed is packed with phytonutrients and antioxidants** while krill & cod liver oil delivers a healthy dose of phospholipids and astaxanthin, **all which work together to support overall health and wellness**." *See* Exhibit "B."

9. The product is also advertised on Defendant's website at: https://www.petsmart.com/dog/dental-care-and-wellness/vitamins-and-supplements/only-natural-pet-hemp-seed-dog-oil-immunity-skin-and-coat-support---krill-and-cod-liver-57057.html.

10. Screenshots of Defendant's website advertising and marketing the Product to consumers is attached hereto as composite **Exhibit "C."**

11. Defendant's website also advertises and represents that the Product "[h]elps support a healthy inflammatory response and immune system" and also [h]elps support cardiovascular health, healthy brain development & function." *See* Ex. "C."

12. Defendant's website also advertises and represents that the "**Health Consideration**" for which the Product is designed and intended for are "Immune system, Skin & Coat." See Ex. "C."

13. The Product's packaging, as well as Defendant's advertising and marketing of the Product, makes clear that the Product's contents are intended to treat, mitigate, or prevent disease and/or are intended to affect the structure or any function of the body; specifically, to support the immune system, cardiovascular system, and brain development or function.

14. At all material times, Defendant, Petsmart, was a retailer selling, marketing, and distributing the Product.

15. The Product, according to its explicit advertising, marketing, labeling and packaging, is clearly intended mitigate, treat, or prevent disease in animals, and therefore are drugs within the meaning of section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B).

16. Additionally, the Product, according to its explicit advertising, marketing, labeling and packaging, is a "new animal drugs" under section 201(v) of the FD&C Act, 21 U.S.C. 321(v), because it is not the subject of a final FDA regulation published through notice and comment rulemaking finding that the drug has been generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling.

17. To be legally marketed, a new animal drug must have an approved new animal drug application, conditionally approved new animal drug application, or a listing on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species ("index listing") under section 512, 571, or 572 of the FD&C Act [21 U.S.C. § 360b, 360ccc, or 360ccc-1], respectively

18. New animal drugs that lack the required approval or index listing are "unsafe" and "adulterated" under sections 512(a) and 501(a)(5) of the FD&C Act [21 U.S.C. §§ 360b(a) and 351(a)(5)]. Introduction of an adulterated animal drug into interstate commerce is prohibited under section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

19. The Product is not approved by the FDA or indexed and therefore the Product is considered unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5).

20. The FDA has sent numerous warning letters to companies manufacturing, advertising and marketing products that are intended mitigate, treat, or prevent disease in animals and/or "new animal drugs" Examples of some of these warning letters can be

viewed at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/curaleaf-inc-579289-07222019; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dr-gs-marine-aquaculture-inc-606979-04152020; and are also attached hereto as **Exhibit "D."**

21. For these reasons, the Product is an unapproved new animal drug and cannot lawfully be sold.

22. The introduction or delivery for introduction into interstate commerce of the Product, as a misbranded drug, violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

23. A Product that cannot lawfully be sold has no value. *Debernardis v. IQ Formulations, LLC*, D.C. Docket No. 1:17 – cv -21562-DPG (11th Cir. Nov. 14, 2019) (finding a claim under FDUTPA should survive a motion to dismiss where the plaintiff purchased a product which was subject to an FDA warning letter to the manufacturer that the product could not lawfully be sold).

24. Defendant, in its respective role as a distributor, was aware of and disregarded these laws when it advertised, marketed, and/or sole the Product at its stores.

25. Defendant's actions of advertising, marketing, and/or selling an unapproved and/or misbranded new drug constitutes false and deceptive conduct.

26. Defendant did not disclose to consumers, including Plaintiff and putative Class Members, that the Product could not lawfully be sold because it was an unapproved new animal drug and/or because it was misbranded.

27. When purchasing the Product, consumers were misled into believing Defendant had complied with applicable laws and regulations and that Defendant could lawfully sell the Product.

28. Defendants intended for Plaintiff and putative Class Members to be misled.

29. Defendant's misleading and deceptive practices proximately caused harm to Plaintiff and Class Members. Defendant has sold Products that are unapproved and/or misbranded and are worthless because they could not be lawfully sold to consumers.

30. The Product's labeling, marketing, and advertising, as outlined and explained above, contain representations which are misleading and deceptive and that are likely to mislead a consumer acting reasonably in the circumstances to her detriment by purchasing a Product the consumer would reasonably believe was legally sold, approved, and properly branded in accordance with applicable law and regulations.

31. In reliance on the Product label, marketing, and advertising, as well as Defendant's actions of offering the Product for sale, the Plaintiff, a consumer, reasonably believed she was purchasing a Product that was could legally be sold.

32. Plaintiff is aggrieved by the deceptively labeled and marketed Product as she relied on the misleading and deceptive marketing and advertising and she was deprived of the benefit of the bargain she reasonably anticipated from the Product's marketing, advertising, and sale; specifically, she was deprived of the benefit she paid for a Product she reasonably believed was legally sold and properly branded.

33. Reasonable consumers, such as the Plaintiff, will continue to be aggrieved by the deceptive and misleading marketing, advertising, and sale of the Product as reasonable consumers will continue to make the plausible connection that they are purchasing a Product that can legally be sold and that is properly branded.

34. Defendant unlawfully marketed, advertised, sold, and/or distributed the Product to Florida purchasers.

35. Defendant's false and misleading representations and omissions deceive Florida consumers for the reasons previously alleged, above.

36. Plaintiff has performed all conditions precedent to bringing this Action.

37. As an immediate, direct, and proximate result of Defendant's false, misleading, and deceptive representations and conduct, Defendant injured Plaintiff and the other Class members in that Plaintiff and other Class members:

a. paid a sum of money for the Products that was not as represented;

b. paid a premium price for the Products that was not as represented;

c. were deprived the benefit of the bargain because the Products they purchased was different than what Defendant warranted;

d. were deprived the benefit of the bargain because the Products they purchased had less value than what was represented by Defendant;

e. did not receive a Products that measured up to their expectations as created by Defendant;

f. purchased a Product that was other than what was represented by Defendant;

g. purchased a Product that Plaintiff and the other members of the Class did not expect or consent to;

h. purchased a Product that was of a lower quality than what Defendant promised;

i. were denied the benefit of knowing what they purchased.

38. Had Defendant not made the false, misleading, and deceptive representations and omissions, or engaged in false, misleading, and deceptive conduct, Plaintiff and the other Class members would not have been economically injured because Plaintiff and the other Class members would not have purchased the Product.

39. Accordingly, Plaintiff and the other Class members have suffered injury in fact and lost money or property as a result of Defendant's wrongful conduct.

40. Plaintiff and the other Class members did not obtain the full value of the advertised Product due to Defendant's misrepresentations and omissions.

41. Plaintiff and the other Class members purchased, purchased more of, or paid more for the Product than they would have done had they known the truth about the Product.

ANTICIPATED DEFENSE

42. In anticipation of a defense that may be raised by Defendant, and only in response to that anticipated defense, Plaintiff pleads that in addition to violating Florida consumer protection laws, the Product also fails to comply with applicable federal law, as alleged previously.

V. CLASS ALLEGATIONS

43. Plaintiff re-alleges and incorporates by reference the allegations set forth

in each of the preceding paragraphs of this *Class Action Complaint* as if fully set forth herein.

44. Pursuant to Rule 1.220, *Florida Rules of Civil Procedure,* Plaintiff brings this class action and seeks certification of the claims and certain issues in this action on behalf of a Class defined as:

> **All persons throughout Florida, who, within the four years preceding the filing the original Complaint ("Class Period"), purchased one or more of the Product from Defendant ("Class") with a credit or debit account.**

45. Excluded from the Class is Defendant, its subsidiaries, affiliates, and employees; all persons who make a timely election to be excluded from the Class; governmental entities; and the Judge(s) to whom this case is assigned and any immediate family members thereof.

46. Certification of Plaintiff's claims for class-wide treatment is appropriate because Plaintiff can prove the elements of Plaintiff's claims on a class-wide basis using the same evidence as would be used to prove those claims in individual actions alleging the same claims.

A. Numerosity

47. The members of the Class are so numerous that individual joinder of all class members is impracticable.

48. The precise number of members of the Class is unknown to Plaintiff, but it is clear that the number greatly exceeds the number that would make joinder practicable, particularly given Defendant's comprehensive distribution and sales network throughout Florida.

49. Members of the Class may be notified of the pendency of this action by

recognized, Court-approved notice dissemination methods, which may include U.S. Mail, electronic mail, Internet postings, and/or published notice.

B. Commonality and Predominance

50. This action involves common questions of law or fact, which predominate over any questions affecting individual members of the Class. All members of the Class were exposed to Defendant's deceptive and misleading advertising and marketing claims and omissions, and/or Defendant's deceptive and misleading conduct, alleged herein.

51. Furthermore, common questions of law or fact include:

a. whether Defendant engaged in the conduct as alleged herein;

b. whether Defendant's practices violate applicable law cited herein;

c. whether Plaintiff and the other members of the Class are entitled to actual, statutory, or other forms of damages, and/or other monetary relief; and

d. whether Plaintiff and the other members of the Class are entitled to equitable relief, including but not limited to injunctive relief.

52. Defendant engaged in a common course of conduct in contravention of the laws Plaintiff seeks to enforce individually, and on behalf of the other members of the Class. Similar or identical statutory legal violations, business practices, and injuries are involved. Individual questions, if any, pale by comparison, in both quality and quantity, to the numerous common questions that dominate this action. Moreover, the common questions will yield common answers.

C. Typicality

53. Plaintiff's claims are typical of the claims of the other members of the

Class because, among other things, all members of the Class were comparably injured through the same uniform misconduct described herein. Further, there are no defenses available to Defendant that are unique to Plaintiffs.

D. Adequacy of Representation

54. Plaintiff is an adequate representative of the members of the Class because Plaintiff's interests do not conflict with the interests of the other members of the Class that Plaintiff seeks to represent. Plaintiff has retained counsel competent and experienced in complex class action litigation and Plaintiff will prosecute this action vigorously. The Class' interests will be fairly and adequately protected by Plaintiff and Plaintiff's counsel. Undersigned counsel has represented consumers in a wide variety of actions where they have sought to protect consumers from fraudulent and deceptive practices.

E. Declaratory and Injunctive Relief

55. Defendant has acted or refused to act on grounds generally applicable to Plaintiff and the other members of the Class, thereby making appropriate final injunctive relief and declaratory relief, as described herein, with respect to the members of the Class as a whole.

F. Superiority

56. A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The damages or other financial detriment suffered by Plaintiff and the other members of the Class are relatively small compared to the burden and expense that would be required to individually litigate their

claims against Defendant, so it would be impracticable for members of the Class to individually seek redress for Defendant's wrongful conduct. Even if the members of the Class could afford individual litigation, the court system could not. Individualized litigation creates a potential for inconsistent or contradictory judgments, and increases the delay and expense to all parties and the court system and thereby unnecessarily clogging of dockets.

57. By contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court. Given the similar nature of the members of the Class' claims and the absence of material or dispositive differences in laws upon which the claims are based, the Class will be easily managed by the Court and the parties.

FIRST CAUSE OF ACTION:
VIOLATION OF THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, FLA. STAT. § 501.201 *et seq.*

58. Plaintiff re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs of this Complaint as if fully set forth herein verbatim.

59. This cause of action is brought pursuant to the Florida Deceptive and Unfair Trade Practices Act, Sections 501.201 to 501.213, *Florida Statutes*.

60. The express purpose of FDUTPA is to "protect the consuming public . . . from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Section 501.202(2), *Florida Statutes*.

61. Section 501.204(1), *Florida Statutes* declares as unlawful "unfair methods

of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce."

62. The sale of the Product at issue in this cause was a "consumer transaction" within the scope of FDUTPA.

63. Plaintiff is a "consumer" as defined by Section 501.203, *Florida Statutes*.

64. The Product sold by Defendant is a good within the meaning of FDUTPA and Defendant is engaged in trade or commerce within the meaning of FDUTPA.

65. For the reasons discussed herein, Defendant violated and continues to violate FDUTPA by engaging in unconscionable, deceptive, unfair acts or practices proscribed by Section 501.201, *Florida Statute*, et. seq.

66. Defendant's actions of misrepresenting and omitting material facts regarding the Product—that it could not lawfully be sold as it was an unapproved new animal drug and/or a misbranded drug—constitute unconscionable, deceptive, or unfair acts or practices, and are immoral, unethical, oppressive, and unscrupulous activities that are substantially injurious to consumers in violation of FDUTPA. Defendant knew or should have known that the product could not be lawfully sold to consumers, and Defendant failed to disclose this information to consumers.

67. Plaintiff and putative Class Members suffered damages when they purchased the Product, which could not lawfully be sold to consumers. Defendant's unconscionable, deceptive, and/or unfair practices caused actual damages to Plaintiff and putative Class Members who were unaware of this when they purchased the Product.

68. Defendant's affirmative misrepresentations, omissions, actions, and

practices described herein were likely to, and did in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

69. Consumers, including Plaintiff and putative Class Members, could not have purchased the Product had Defendant disclosed to them and the consuming public that the Product could not lawfully be sold to consumers because it was an unapproved new animal drug and because it was misbranded.

70. As a direct and proximate result of the unconscionable, unfair, and deceptive acts or practices alleged herein, Plaintiff and putative Class Members have been damaged and are entitled to recover actual damages to the extent permitted by law, including class action rules, in an amount to be proven at trial.

71. Plaintiff and Class Members have been aggrieved by Defendant's unfair and deceptive practices in violation of FDUTPA, in that they purchased Defendant's deceptively labeled, marketed, and advertised the Product.

72. Reasonable consumers rely on Defendant to honestly market and advertise the Product to consumers by selling a Product that can legally be sold and that is properly branded.

73. Defendant has deceived reasonable consumers, like Plaintiff and the Class, into believing the Product was something it was not; specifically that the Product could legally be sold and/or that it was properly branded.

74. In addition, Plaintiff and the putative Class seeks equitable relief and injunctive relief against Defendant on terms that the Court considers reasonable, and reasonable attorneys' fees, litigation costs, and expenses.

75. Plaintiff and the Class suffered damages and are entitled to injunctive relief.

76. Pursuant to sections 501.211(2) and 501.2105, *Florida Statutes*, Plaintiff and the Class make claims for damages, attorney's fees and costs. The damages suffered by the Plaintiff and the Class were directly and proximately caused by the deceptive, misleading and unfair practices of Defendant. Additionally, pursuant to Section 501.211(1), *Florida Statutes*, Plaintiff and the Class seek injunctive relief for, *inter alia*, the Court to enjoin Defendant's above-described wrongful acts and practices, and for restitution and disgorgement.

77. Plaintiff seeks all available remedies, damages, and awards as a result of Defendant violations of FDUTPA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually, and on behalf of all others similarly situated, prays for relief pursuant to each cause of action set forth in this Complaint as follows:

i. For an order certifying that the action may be maintained as a class action, certifying Plaintiff as representative of the Class, and designating Plaintiff's attorneys Class counsel;

ii. For an award of equitable relief for all causes of action as follows:

a. Enjoining Defendant from continuing to engage, use, or employ any unfair and/or deceptive business acts or practices related to the design, testing, manufacture, assembly, development, marketing, advertising, or sale of the Products for the purpose of selling the Products in such manner as set forth in detail above, or from

making any claims found to violate FDUTPA or the other causes of action as set forth above;

b. Restoring all monies that may have been acquired by Defendant as a result of such unfair and/or deceptive act or practices; and

iii. For actual damages in an amount to be determined at trial for all causes of action;

iv. For an award of attorney's fees and costs;

v. For any other relief the Court might deem just, appropriate, or proper; and

vi. For an award of pre- and post-judgment interest on any amounts awarded.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues so triable.

Submitted: April 22, 2020.

By: /s/ Howard W. Rubinstein
Howard W. Rubinstein, Esq.
The Law Office of Howard W. Rubinstein
1281 N. Ocean Dr. Apt. 198
Singer Island, FL 33404
Telephone: 832-715-2788
Fax: 561-688-0630
Email: howardr@pdq.net

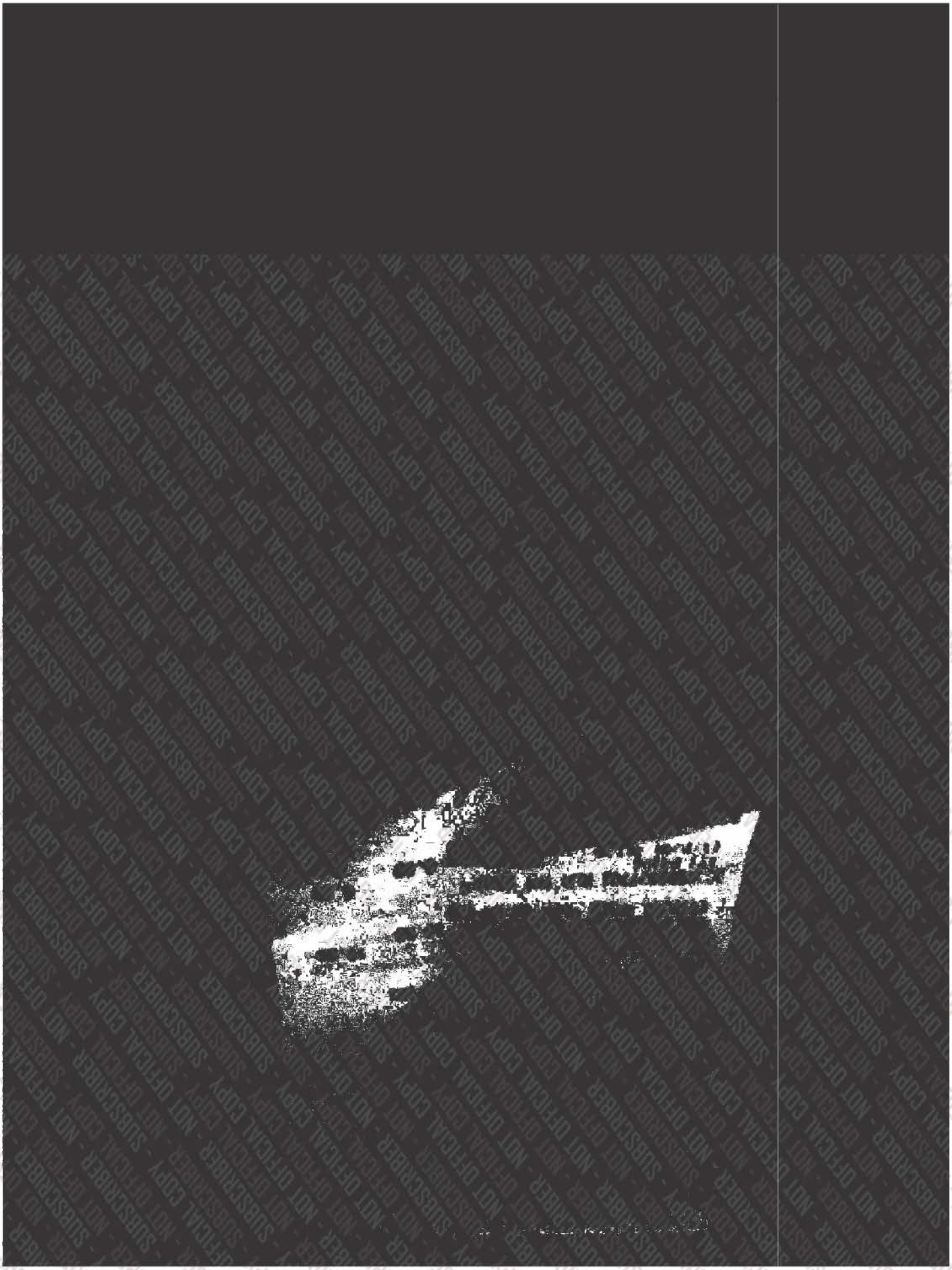


Exhibit A 1 of 1

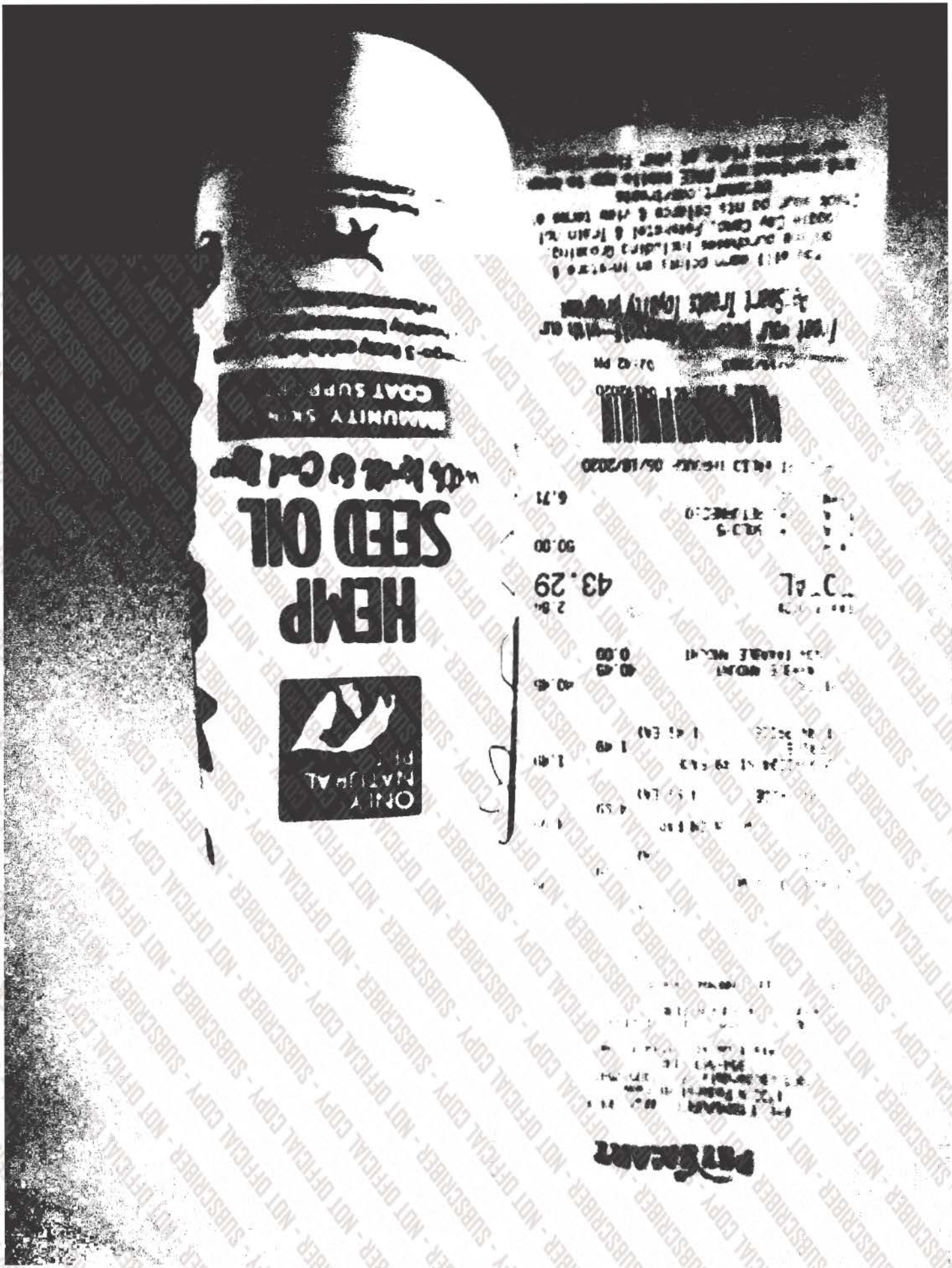


Exhibit B 1 of 2

Exhibit B 2 of 2

Dog / Dental Care & Wellness / Vitamins & Supplements

Only Natural Pet® Hemp Seed Dog Oil Immunity, Skin & Coat Support - Krill & Cod Liver

by Only Natural Pet

Item #5296082

$19.99

Earn Treats on this purchase! Sign Up

- Buy 1, Get 1 50% Off Supplements
  Details
- Sign In & Enjoy Free Shipping Over $49
  Details

Size **8 Fl Oz**

Buy online, pick up in-store
Take advantage of our Curbside service by calling the store when you arrive.

LOW STOCK AT
Lakeland
919 Lakeland Park Center Dr Unit 380
863-279-3923

Check other nearby stores

1 Buy & Pickup

Estimated 159 points earned

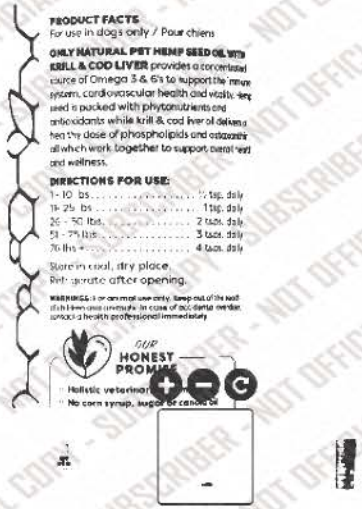
or

Ship to me

1 Ship

Estimated 159 points earned

Dog / Dental Care & Wellness / Vitamins & Supplements



Only Natural Pet® Hemp Seed Dog Oil Immunity, Skin & Coat Support - Krill & Cod Liver

by Only Natural Pet

Item #5296082

$19.99

Earn Treats on this purchase! Sign Up

- Buy 1, Get 1 50% Off Supplements
  Details
- Sign In & Enjoy Free Shipping Over $49
  Details

Size 8 Fl Oz

Buy online, pick up in-store

Take advantage of our Curbside service by calling the store when you arrive.

LOW STOCK AT

Lakeland
919 Lakeland Park Center Dr Unit 380
863-279-3923

Check other nearby stores

1 Buy & Pickup

Estimated 159 points earned

or

Ship to me

1 Ship

Estimated 159 points earned

WARNING LETTER

Curaleaf, Inc

MARCS-CMS 579289 – JULY 22, 2019

Delivery Method:

Via Overnight Delivery

Product:

Animal & Veterinary
Drugs

Recipient:

Joseph Lusardi
President
Curaleaf, Inc
301 Edgewater Place Suite 405
Wakefield, MA 01880
United States

Issuing Office:

Center for Drug Evaluation and Research
10903 New Hampshire Avenue,
Silver Spring, MD 20993
United States

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

July 22, 2019

Joseph Lusardi, President
Curaleaf, Inc.
301 Edgewater Place
Suite 405
Wakefield, MA 01880

RE: 579289

Dear Joseph Lusardi:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address https://curaleafhemp.com in April and June 2019 and has determined that you take orders there for the products "CBD Lotion," "CBD Pain-Relief Patch," "CBD Tincture" (5 versions), "CBD Disposable Vape Pen" (5 versions) and "Bido CBD for Pets" (3 versions), all of which you promote as products containing cannabidiol (CBD).[1] We have also reviewed your social media websites at www.facebook.com/CuraleafHemp and https://twitter.com/curaleafhemp; these websites direct consumers to your website, https://curaleafhemp.com, to purchase your products. FDA has determined that your "CBD Lotion," "CBD Pain-Relief Patch," "CBD Tincture," and "CBD Disposable Vape Pen" products are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, these products are misbranded drugs under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). FDA has also determined that your "Bido CBD for Pets" products are unapproved new animal drugs that are unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5). As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov.

Unapproved New and Misbranded Human Drug Products

Based on our review of your website, your "CBD Lotion," "CBD Pain-Relief Patch," "CBD Tincture," and "CBD Disposable Vape Pen" products are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the body.

Examples of claims observed on your website and social media accounts in April 2019 that establish the intended use of your products as drugs include, but may not be limited to, the following:

On your product webpage for CBD Disposable Vape Pen (Relieve):
• "[F]or chronic pain."

On your product webpage for CBD Tincture (Relieve):
• "[S]oothing tincture for chronic pain."

Additional claims observed on your website in June 2019 include, but are not limited to, the following:

On your webpage titled "Can CBD Oil be Used for ADHD?"
• "CBD oil is becoming a popular, all-natural source of relief used to address the symptoms of many common conditions, such as chronic pain, anxiety . . . ADHD."
• "The Benefits of CBD Oil for ADHD . . . It's not unusual for people with ADHD to feel anxious and on the edge. CBD is known for its anti-anxiety properties that can promote relaxation and stress relief. It can also help to restore focus and ability to concentrate on specific tasks, as well as reduce impulsivity."

On your webpage titled "How to Use CBD Oil for Anxiety"
• "CBD can successfully reduce anxiety symptoms, both alone and in conjunction with other treatments."
• "CBD oil can be used in a variety of ways to help with chronic anxiety."

On your webpage titled "CBD Benefits: Top 5 Research-Backed Benefits of CBD"
• "CBD has also been shown to be effective in treating Parkinson's disease."
• "CBD has been linked to the effective treatment of Alzheimer's disease . . .."
• "CBD is being adopted more and more as a natural alternative to pharmaceutical-grade treatments for depression and anxiety."
• "CBD can also be used in conjunction with opioid medications, and a number of studies have demonstrated that CBD can in fact reduce the severity of opioid-related withdrawal and lessen the buildup of tolerance."
• "CBD has been demonstrated to have properties that counteract the growth of spread of cancer."
• "CBD was effective in killing human breast cancer cells."
• "Heart disease is one of the leading causes of death in the United States each year, and CBD does a number of things to deter it. The two most important of these are the ability to lower blood pressure, and the ability to promote good cholesterol and lower bad cholesterol."

On your webpage titled "Hemp Oil vs. CBD Oil: Everything You Need to Know"
• "CBD . . . can be used to help manage a wide range of health conditions, such as . . . Anxiety and depression . . . Chronic or arthritic pain . . .."

On your webpage titled "How to Choose the Best CBD Oil for You"
• "Some of the most common reasons to use CBD oil include . . . Chronic pain . . . Mental conditions like anxiety, depression, and PTSD . . .."

On your webpage titled "Is CBD Oil Good for Depression?"
• "A 2014 study showed that participants who received CBD oil experienced anti-anxiety and anti-depression effects from the oil."
• "A 2018 study showed that CBD offers quick relief of depression and anxiety symptoms and that the residual effects can last up to seven days."

On your webpage titled "What are the Benefits of Hemp-Derived CBD Oil?"
• "What are the benefits of CBD oil? . . . Some of the most researched and well-supported hemp oil uses include . . . Anxiety, depression, post-traumatic stress disorders, and even schizophrenia . . . Chronic pain from fibromyalgia, slipped spinal discs . . . Eating disorders and addiction . . .."

On your Facebook Social Media Account:
• April 8, 2019 posting – "CBD Can be a powerful ally if you're suffering from chronic inflammation and pain."
• March 14, 2019 posting – "The top five research backed benefits of CBD include: 1) neuro[de]generative disease 2) depression and anxiety treatment 3) pain treatment 4) aids in the treatment of cancer and related symptoms to cancer . . .."

On your Twitter Social Media Account:
• March 27, 2019 posting – "#ICBD to help lower anxiety . . .."
March 25, 2019 posting – "CBD is being adopted more and more as a natural alternative to pharmaceutical-grade treatments for depression and anxiety."

Your "CBD Lotion," "CBD Pain-Relief Patch," "CBD Tincture," and "CBD Disposable Vape Pen" products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). New drugs may not be legally introduced or

delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

Your "CBD Lotion," "CBD Pain-Relief Patch," "CBD Tincture," and "CBD Disposable Vape Pen" products are also misbranded within the meaning of section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), in that their labeling fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended, 21 CFR 201.5. Your "CBD Lotion," "CBD Pain-Relief Patch," "CBD Tincture," and "CBD Disposable Vape Pen" products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. FDA-approved prescription drugs which bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson. However, your products are not exempt from the requirement that their labeling bear adequate directions for use, 21 CFR 201.100(c)(2) and 201.115, because no FDA-approved applications are in effect for them. It is prohibited to introduce or deliver for introduction into interstate commerce a misbranded drug under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Dietary Supplement Labeling

Information on your website and social media accounts suggests that you may intend to market your CBD products as dietary supplements. For example, a disclaimer on your website includes the statement "Cannabidiol (CBD) is a natural constituent of industrial hemp and is a dietary supplement." You also display a photo of a CBD product with a supplement facts panel that appears to be your "CBD Tincture" (Relax version) on your social media accounts. Furthermore, you state under the disclaimer section on your "CBD Lotion," "CBD Pain-Relief Patch," "CBD Tincture," and "CBD Disposable Vape Pen" products' webpages that "Cannabidiol (CBD) . . . is a dietary supplement." Based on these observations, it appears you intend to market your CBD products as dietary supplements. However, they cannot be dietary supplements because they do not meet the definition of a dietary supplement under sections 201(ff)(3)(B) and 201(ff)(2)(A)(i) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B) and 321(ff)(2)(A)(i).

FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(i) and (ii). Under those provisions, if an article (such as CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act, 21 U.S.C. 355, or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD.**2** FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, but you may present FDA with any evidence that has bearing on this issue.

Furthermore, your "CBD Lotion" product's labeling states that it is intended to be applied directly to the skin; your "CBD Pain-Relief Patch" product's labeling states that it is intended to be applied to the body for transdermal use; and your "CBD Disposable Vape Pen" products' labeling states that they are intended for inhalation. The FD&C Act defines the term "dietary supplement" in section 201(ff)(2)(A)(i) as a product that is

"intended for ingestion." Because these products are not intended for ingestion, this is an additional reason why your "CBD Lotion," "CBD Pain-Relief Patch," and "CBD Disposable Vape Pen" products do not meet the definition of a dietary supplement under the FD&C Act. Furthermore, with respect to your "CBD Tincture" products, the "Suggested Use" section of these products' labeling includes both "edible" uses and topical uses. To the extent that your "CBD Tincture" products are intended for a delivery method other than ingestion, as evidenced by the labeling describing topical uses, this is an additional reason why these products also do not meet the definition of a dietary supplement under the FD&C Act.

Unapproved New Animal Drugs

During a recent review of your firm's website (https://curaleafhemp.com/collections/pet-drops), FDA determined that your firm is marketing "Bido CBD for Pets" (Pure, Bacon and Salmon Flavor), which are unapproved new animal drugs. Based on our review of the information provided, we determined that these products are intended for use in the mitigation, treatment, or prevention of diseases in animals, which makes them drugs under section 201(g)(1)(B) of the Federal Food, Drug and Cosmetic Act (the FD&C Act), 21 U.S.C. 321(g)(1)(B). Further, as discussed below, these products are unapproved new animal drugs and marketing them violates the FD&C Act.

Examples of claims observed on your firm's website (https://curaleafhemp.com/blogs/cbd) that show the intended uses of these products include, but are not limited to, the following:

Found at: https://curaleafhemp.com/blogs/cbd/reasons-to-use-cbd-oil-for-dogs
• "Decrease compulsive behavior like biting, scratching, chewing, whining, eliminating, and other symptoms of dog separation anxiety"
• "Decrease autonomic arousal symptoms like fast/irregular heartbeat, panting, and general distressed feelings"
• "Alleviate fear feelings"
• "Prevent the longer-term health effects of anxiety"
• "CBD may help with cat anxiety" (https://curaleafhemp.com/blogs/cbd/cbd-oil-for-cats)
• "It's natural, safe and will allow your dog to play, eat, and do other things dogs enjoy without the symptoms of anxiety." (https://curaleafhemp.com/blogs/cbd/cbd-for-dog-separation-anxiety)
• "vets will prescribe puppy Xanax to pet owners which can help in certain instances but is not necessarily a desirable medication to give your dog continually. Whereas CBD oil is natural and offers similar results without the use of chemicals." (https://curaleafhemp.com/blogs/cbd/how-much-cbd-oil-should-i-give-my-dog)
• "Relief of seizures and neurological problems" (https://curaleafhemp.com/blogs/cbd?page=2)
• "Soothing of trauma and anxiety" (https://curaleafhemp.com/blogs/cbd?page=2)

Found at: https://curaleafhemp.com/blogs/cbd/reasons-to-use-cbd-oil-for-dogs

• "For dogs with arthritis and other joint issues, the American Kennel Club reports that CBD treats inflammation in the muscle tissue and joints—which works to improve the overall musculoskeletal system."
• "...this helps take pressure away from the surrounding nerve endings and directly reduces pain."

Found at: https://curaleafhemp.com/blogs/cbd?page=3

• "Pain relief from cancer or after surgery"
• "Relief of muscle spasms"
• "Recently published research confirms that CBD helps dogs with osteoarthritis. All dogs in the trial showed marked improvement in their overall activity levels and apparent pain levels. So it's believed that CBD would provide the same results for cats with arthritis or inflammation."

Found at: https://curaleafhemp.com/blogs/cbd/cbd-oil-for-cats
"•Diabetes"

Found at: https://curaleafhemp.com/blogs/cbd/is-cbd-oil-safe-for-dogs
"What are the benefits of using CBD oil for your pets?.....
•Pain relief from arthritis and aging"

Found at: https://curaleafhemp.com/blogs/cbd/cannabis-oil-dog-cancer
• "CBD oil can help relieve cancer pain and spasms"
• "CBD oil may slow the growth of cancer"

Found at: https://curaleafhemp.com/blogs/cbd?page=9
• "...it has been found to assist in the reduction of tumor size while stunting the potential spreading of cancer through the body."
• "Chemotherapy, radiation treatments, and surgery can quickly push into the tens of thousands of dollars. While you may not be able to afford such cancer treatments for your dog, CBD oil is a viable and inexpensive alternative."
• "For dogs experiencing pain, spasms, anxiety, nausea or inflammation often associated with cancer treatments, CBD (aka cannabidiol) may be a source of much-needed relief."
(https://curaleafhemp.com/blogs/cbd?page=3)
• "...CBD oil has been clinically shown to help manage the symptoms of cancer treatment, which can improve a patient's quality of life." (https://curaleafhemp.com/blogs/cbd?page=3)

Found at: https://curaleafhemp.com/blogs/cbd/how-much-cbd-oil-should-i-give-my-dog
• "Many dogs, especially those with thinner, shorter coats, suffer from skin conditions. Whether due to allergies or the weather, CBD oil can help improve the overall quality of your dog's skin."

Because the products are intended to mitigate, treat, or prevent disease in animals, they are drugs within the meaning of section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B). Further, these products are "new animal drugs" under section 201(v) of the FD&C Act, 21 U.S.C. 321(v), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling.

To be legally marketed, a new animal drug must have an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the FD&C Act, 21 U.S.C. 360b, 360ccc, and 360ccc-l. These products are not approved or index listed by the FDA, and therefore these products are considered unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5). Introduction of an adulterated drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your marketed products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance, 10903 New Hampshire Avenue, WO51, Silver Spring, MD 20993-0002 or by email to FDAADVISORY@fda.hhs.gov.

Sincerely,
/s/
Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
/s/
Eric Nelson
Director
Office of Compliance
Center for Veterinary Medicine
Food and Drug Administration

[1] Full product list: CBD Tincture Digest, CBD Tincture Uplift, CBD Tincture Relieve, CBD Tincture Revive, and CBD Tincture Relax; CBD Disposable Vape Pen Digest, CBD Disposable Vape Pen Uplift, CBD Disposable Vape Pen Relieve, CBD Disposable Vape Pen Revive, and CBD Disposable Vape Pen Relax; and Bido CBD for Pets Bacon, Bido CBD for Pets Pure, and Bido CBD for Pets Salmon.

[2] CBD is the active ingredient in the approved drug product Epidiolex. Furthermore, the existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex. (See Sativex Commences US Phase II/III Clinical Trial in Cancer Pain (https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome (http://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)). FDA considers a substance to be "authorized for investigation as a new drug"

if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations [21 CFR 312.2], unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

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WARNING LETTER

Dr. G's Marine Aquaculture, Inc.

MARCS-CMS 606979 – APRIL 15, 2020

Product:

Animal & Veterinary

Recipient:

Ms. Elena Ninoua-Gonzalez

Dr. G's Marine Aquaculture, Inc.

20841 Johnson Street, 110

Pembroke Pines, FL 33029

United States

drgsphyto@gmail.com (mailto:drgsphyto@gmail.com)

Issuing Office:

Center for Veterinary Medicine

United States

WARNING LETTER

Date: April 15, 2020

RE: Unapproved Chloroquine Phosphate Product

Dear Ms. Ninoua-Gonzalez:

This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the internet address http://www.drgsmarineaquaculture.com in April 2020. The FDA has observed that your website offers Dr. G's Anti-Parasitic Caviar for sale in the United States. Based on our review, this product is adulterated. The introduction or delivery for introduction into interstate commerce of any food or drug that is adulterated is a prohibited act. (Section 301(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 321(a)].)

Your Dr. G's Anti-Parasitic Caviar product is a drug under Section 201(g)(1)(B) of the FD&C Act [21 U.S.C. § 321(g)(1)(B)] because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals. Some examples of the claims on your website, where you sell Dr. G's Anti-Parasitic Caviar, http://www.drgsmarineaquaculture.com/anti-parasitic-caviar-detail.cfm, that establish the intended uses of your product include:

- "Treats Ich, Brooklynella, Uronema, Crypto, Oodinium and many more Ornamental Fish Parasites."
- "Effective new treatment for several forms of marine and freshwater Parasites, that can harm or kill your fish."
- "Treats your Fish, Not your Water!"
- "Our unique formula provides the Anti-Parasitic efficiency of Chloroquine plus the premium nutritional value of Dr.G's Caviar MAX, made with the finest and freshest ingredients."

Dr. G's Anti-Parasitic Caviar is intended for use in fish, a "minor species," as defined in section 201(oo) of the FD&C Act [21 U.S.C. § 321(oo)]. Therefore, your Dr. G's Anti-Parasitic Caviar product is a new animal drug under section 201(v) of the FD&C Act [21 U.S.C. § 321(v)] because it is not the subject of a final FDA regulation published through notice and comment rulemaking finding that the drug has been generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. To be legally marketed, a new animal drug must have an approved new animal drug application, conditionally approved new animal drug application, or a listing on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species ("index listing") under section 512, 571, or 572 of the FD&C Act [21 U.S.C. § 360b, 360ccc, or 360ccc-1], respectively. Dr. G's Anti-Parasitic Caviar has not been approved, conditionally approved, or index listed. New animal drugs that lack the required approval or index listing are "unsafe" and "adulterated" under sections 512(a) and 501(a)(5) of the FD&C Act [21 U.S.C. §§ 360b(a) and 351(a)(5)]. Introduction of an adulterated animal drug into interstate commerce is prohibited under section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

Your product's labeling includes the claim, "provides the Anti-Parasitic efficiency of Chloroquine," demonstrating the intended use of chloroquine as a drug. Chloroquine is a new animal drug under section 201(v) of the FD&C Act. It has not been approved, conditionally approved or index listed for use in ornamental fish. Therefore, chloroquine is an unsafe new animal drug within the meaning of section 512(a) of the FD&C Act.

Your Dr. G's Anti-Parasitic Caviar is accompanied by labeling including the statement, "To 'Treat' Parasitic infections, use as regular food twice a day for up to 3 weeks. To 'Prevent' Parasitic infections, use as regular food twice a day for up to 3 weeks." As defined by section 201(w) of the FD&C Act [21 U.S.C. § 321(w)], an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animals is an "animal feed." To the extent your Dr. G's Anti-Parasitic Caviar is an animal feed that contains the unsafe new animal drug chloroquine, it is an unsafe animal feed within the meaning of section 512(a)(2) of the FD&C Act [21 U.S.C. 360b(a)(2)]. Such an unsafe animal feed is an adulterated drug within the meaning of section 501(a)(6) of the FD&C Act [21 U.S.C. 351(a)(6)].

Finally, to the extent your Dr. G's Anti-Parasitic Caviar is a "food," as defined by section 201(f) of the FD&C Act [21 U.S.C. § 321(f)],[1] it is an adulterated food within the meaning of section 402(a)(2)(C)(ii) of the FD&C Act [21 U.S.C. 342(a)(2)(C)(ii)], which states that a food is adulterated if it bears or contains a new animal drug that is unsafe within the meaning of section 512 of the FD&C Act. As noted above, chloroquine is an unsafe new animal drug within the meaning of section 512(a) of the FD&C Act. Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within 48 hours, please send an email to the contact person below, describing the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the correction. If you do not believe that your products are in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Your response should be sent via e-mail to Dr. Vic Boddie at Vic.Boddie@fda.hhs.gov. If you have any questions about this letter, please contact Dr. Boddie at 240-402-5618.

Sincerely,
/S/

Mr. Eric M. Nelson
Director, Division of Compliance
Center for Veterinary Medicine
Food and Drug Administration

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[1] Your labeling states that your Dr. G's Anti-Parasitic Caviar contains Dr. G's Caviar MAX (capelin (Mallotus villosus) eggs), Dr. G's Reef Essentials vitamins and amino acids, and garlic.

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