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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GILBERT TRAVIS HERNANDEZ,
on behalf of himself and others similarly situated,

Plaintiff,

v.

BLUE DIAMOND GROWERS, a California corporation,

Defendant.

Case No.:

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff GILBERT TRAVIS HERNANDEZ (herein "Plaintiff HERNANDEZ" or "Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, pursuant to this Class Action Complaint against the Defendant, BLUE DIAMOND GROWERS ("Defendant" or "Blue Diamond"), alleges the following:

NATURE OF THE ACTION

1. This is a consumer protection action seeking redress for, and a stop to, Defendant's unfair and deceptive practice of advertising and marketing its "Bold Wasabi & Soy Sauce" almonds (herein the "Product"). *See* **Exhibit A**.

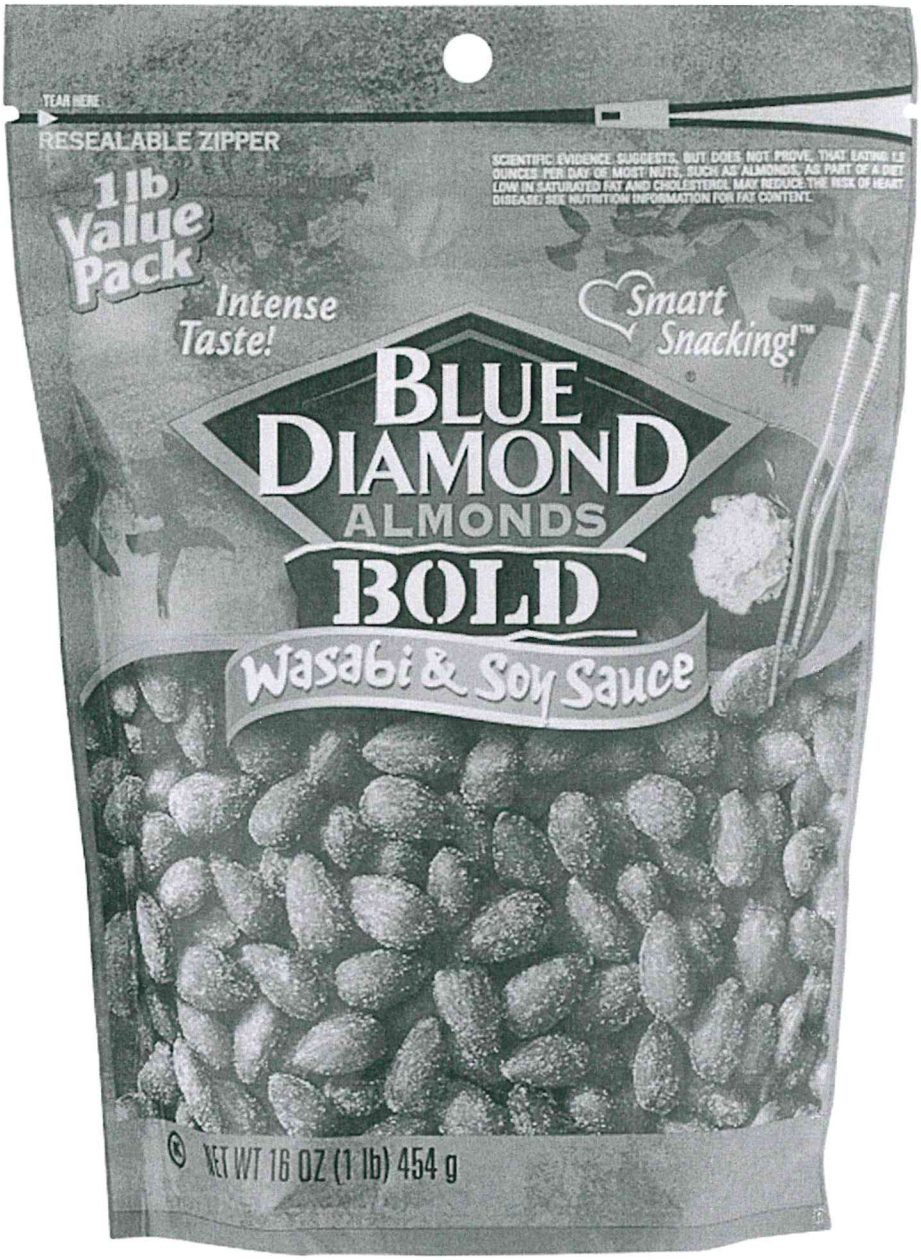
2. The wasabi plant is native to Japan. The plant's stem has a unique pungent flavor and is a distinctive green color. This stem is made into the food also called "wasabi" by grinding, grating, or powdering it.[1] Wasabi usually accompanies sushi and sashimi either as a condiment or within the sushi itself. Wasabi can either be prepared fresh by a chef or pre-prepared as a paste or powder.

3. Wasabi plants are scientifically referred to as "*Wasabia japonica*."[2] "*Wasabia*"[3] refers to the plant's scientific genus, of which the Japanese plant species used as a condiment (*Wasabia japonica*) is just one of several species.

4. Real wasabi products are in high demand and are generally expensive. Consequently, cheap substitutes for wasabi that are inferior to real wasabi are manufactured and sold at a price far below the price of genuine wasabi. To emulate real wasabi, wasabi substitutes contain various spicy vegetables, and sometimes additives that dye the food green.

5. Defendant distributes, manufactures, and sells the Product. Defendant has labeled the Product as "wasabi" and purports that the Product contains authentic wasabi. See below:

[1] Except where specifically noted, all subsequent uses of the word "wasabi" refer to the condiment wasabi.
[2] Or, synonymously, "Eutrema japonicum" or "Eutrema wasabi.
[3] Or "Eutrema."



However, in reality, the Product does not contain the wasabi plant at all and so it is not a wasabi food item. The Product is flavored by horseradish to imitate the taste of wasabi. *See* **Exhibit B**. The Product labels are misleading because they state that the Product is a wasabi product, when in reality it is not.

6. Defendant's mislabeling of the Product as wasabi deceives consumers into believing the Product is a wasabi product, when in reality horseradish is the ingredient in the

Product that gives it its flavor. Horseradish is not closely related to wasabi, as its scientific name *Armoracia rusticana*[4] reveals—the horseradish plant is not only a different species of plant than the wasabi plant, it is in a different genus altogether. *Wasabia* is the genus of wasabi; *Armoracia* is the genus of horseradish.

7. Defendant's Product is attractive to its target market due to its deceptive and/or materially misleading wasabi claim. Plaintiff and Class members were exposed to Defendant's deceptive wasabi claims because these claims appeared conspicuously on the label of every Product.

8. As the manufacturer, seller and/or distributor of the Product, Defendant possesses specialized knowledge regarding the ingredients contained in the Product.

9. Plaintiff brings this proposed consumer class action on behalf of himself and all other persons who, from the applicable limitations period up to and including the present (the "Class Period"), purchased the Product for consumption and not resale.

10. Defendant markets the Product in a way that is deceptive to consumers under consumer protection laws of New York, the other 49 states, and the District of Columbia.

11. Defendant violates statutes enacted in each of the fifty states and the District of Columbia that are designed to protect consumers against unfair, deceptive, fraudulent, unconscionable trade and business practices, and false advertising. These statutes include:

1) Alabama Deceptive Trade Practices Act, Ala. Statues Ann. §§ 8-19-1, *et seq.;*
2) Alaska Unfair Trade Practices and Consumer Protection Act, Ak. Code § 45.50.471, *et seq.;*
3) Arizona Consumer Fraud Act, Arizona Revised Statutes, §§ 44-1521, *et seq.;*
4) Arkansas Deceptive Trade Practices Act, Ark. Code § 4-88-101, *et seq.;*
5) California Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.,* and California's Unfair Competition Law, Cal. Bus. & Prof Code § 17200, *et seq.;*
6) Colorado Consumer Protection Act, Colo. Rev. Stat. § 6 - 1-101, *et seq.;*
7) Connecticut Unfair Trade Practices Act, Conn. Gen. Stat § 42-110a, *et seq.;*

[4] Or, synonymously, "*Armoracia lapathifolia* Gilib."

8) Delaware Deceptive Trade Practices Act, 6 Del. Code § 2511, *et seq.;*
9) District of Columbia Consumer Protection Procedures Act, D.C. Code § 28 3901, *et seq.;*
10) Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, *et seq.;*
11) Georgia Fair Business Practices Act, § 10-1-390 *et seq.;*
12) Hawaii Unfair and Deceptive Practices Act, Hawaii Revised Statues § 480 1, *et seq.*, and Hawaii Uniform Deceptive Trade Practices Act, Hawaii Revised Statutes § 481A-1, *et seq.;*
13) Idaho Consumer Protection Act, Idaho Code § 48-601, *et seq.;*
14) Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.;*
15) Indiana Deceptive Consumer Sales Act, Indiana Code Ann. §§ 24-5-0.5-0.1, *et seq.;*
16) Iowa Consumer Fraud Act, Iowa Code §§ 714.16, *et seq.;*
17) Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50 626, *et seq.;*
18) Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.;*
19) Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. § § 51:1401, *et seq.;*
20) Maine Unfair Trade Practices Act, 5 Me. Rev. Stat. § 205A, *et seq,,* and Maine Uniform Deceptive Trade Practices Act, Me. Rev. Stat. Ann. 10, § 1211, *et seq.,*
21) Maryland Consumer Protection Act, Md. Com. Law Code § 13-101, *et seq.;*
22) Massachusetts Unfair and Deceptive Practices Act, Mass. Gen. Laws ch. 93A;
23) Michigan Consumer Protection Act, §§ 445.901, *et seq.;*
24) Minnesota Prevention of Consumer Fraud Act, Minn. Stat §§ 325F.68, *et seq.;* and Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.43, *et seq.;*
25) Mississippi Consumer Protection Act, Miss. Code Ann. §§ 75-24-1, *et seq.;*
26) Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.;*
27) Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code §30-14-101, *et seq.;*
28) Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59 1601, *et seq.,* and the Nebraska Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301, *et seq.;*
29) Nevada Trade Regulation and Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.;*
30) New Hampshire Consumer Protection Act, N.H. Rev. Stat. § 358-A:1, *et seq. ;*
31) New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8 1, *et seq.;*
32) New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57 12 1, *et seq.;*
33) New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.;*
34) North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51 15 01, *et seq.;*
35) North Carolina Unfair and Deceptive Trade Practices Act, North Carolina General Statutes §§ 75-1, *et seq.;*
36) Ohio Deceptive Trade Practices Act, Ohio Rev. Code. Ann. §§ 4165.01. *et seq.;*
37) Oklahoma Consumer Protection Act, Okla. Stat. 15 § 751, *et seq.;*
38) Oregon Unfair Trade Practices Act, Rev. Stat § 646.605, *et seq.;*
39) Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Penn. Stat. Ann. § § 201-1, *et seq.;*
40) Rhode Island Unfair Trade Practices And Consumer Protection Act, R.I. Gen. Laws § 6-13.1-1, *et seq.;*

41) South Carolina Unfair Trade Practices Act, S.C. Code Laws § 39-5-10, *et seq.;*
42) South Dakota's Deceptive Trade Practices and Consumer Protection Law, S.D. Codified Laws §§ 37 24 *1, et seq.;*
43) Tennessee Trade Practices Act, Tennessee Code Annotated §§ 47-25-101, *et seq.;*
44) Texas Stat. Ann. §§ 17.41, *et seq.,* Texas Deceptive Trade Practices Act, *et seq.;*
45) Utah Unfair Practices Act, Utah Code Ann. §§ 13-5-1, *et seq.;*
46) Vermont Consumer Fraud Act, Vt. Stat. Ann. tit.9, § 2451, *et seq.;*
47) Virginia Consumer Protection Act, Virginia Code Ann. §§59.1-196, *et seq.;*
48) Washington Consumer Fraud Act, Wash. Rev, Code § 19.86.010, *et seq.;*
49) West Virginia Consumer Credit and Protection Act, West Virginia Code § 46A-6-101, *et seq.;*
50) Wisconsin Deceptive Trade Practices Act, Wis. Stat. §§ 100. 18, *et seq.;*
51) Wyoming Consumer Protection Act, Wyoming Stat. Ann. §§ 40-12-101, *et seq.*

JURISDICTION AND VENUE

12. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332, because this is a class action, as defined by 28 U.S.C § 1332(d)(1)(B), in which a member of the putative Class is a citizen of a different state than Defendant, and the amount in controversy exceeds the sum or value of $5,000,000, excluding interest and costs. *See* 28 U.S.C. § 1332(d)(2).

13. Alternatively, the Court has jurisdiction over all claims alleged herein pursuant to 28 U.S.C § 1332 because the matter in controversy exceeds the sum or value of $75,000 and is between citizens of different states.

14. Furthermore, this court has personal jurisdiction over Defendant because its Product are advertised, marketed, distributed, and sold throughout New York State. Defendant engages in the wrongdoing alleged in this Complaint throughout the United States, including New York State. Defendant is authorized to do business in New York State, and Defendant has sufficient minimum contacts with New York and/or otherwise has intentionally availed itself of the markets in New York State, rendering the exercise of jurisdiction by the Court permissible under traditional notions of fair play and substantial justice. Moreover, Defendant engages in substantial and not isolated activity within New York State.

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) and (b), because a substantial part of the events giving rise to Plaintiff's claims occurred in this District, and Defendant is subject to personal jurisdiction in this District.

PARTIES

Plaintiff

16. Plaintiff HERNANDEZ is, and at all times relevant hereto has been, a citizen of New York and a resident of New York County. On September 12, 2018, Plaintiff HERNANDEZ viewed the Product on Amazon.com and was exposed to Defendant's false wasabi claims.

17. Relying on Defendant's misrepresentations, Plaintiff HERNANDEZ decided to purchase a pack of the 16 oz. Product on Amazon.com for $7.98 that day. He would not have paid this premium price for the Product had he known that the it did not contain any wasabi and actually contains horseradish. As a result, Plaintiff HERNANDEZ was injured when he was denied the benefit of his bargain and paid a premium price for the Product whose value was deceptively inflated by Defendant.

Defendant

18. Defendant Blue Diamond Growers is a corporation organized under the laws of California with its principal executive office at 1802 C Street, Sacramento, CA 95811. Defendant's Agent for Service and Process is Dean LaVallee, located at 1802 C Street, Sacramento, CA 95811.

19. Defendant develops and markets the Product throughout the United States. The Product is available at numerous retail and online outlets.

20. The advertising for the Product, relied upon by Plaintiff, is approved by Defendant and its agents, and is disseminated by Defendant and its agents through advertising containing the misrepresentations alleged herein. The advertising for the Product is designed to encourage

consumers to purchase the Product, and misleads the reasonable consumer, i.e. Plaintiff and the Class. Defendant owns, manufactures and distributes the Product, and/or authorizes the unlawful, fraudulent, unfair, misleading and/or deceptive labeling and advertising for the Product.

FACTUAL ALLEGATIONS

Defendant Claims the Product Is a Wasabi Product

21. Defendant manufactures, markets and sells "Bold Wasabi & Soy Sauce" almonds under its Blue Diamond brand. *See* **Exhibit A**.

22. Every consumer who saw the packaging, whether in person or online, was exposed to Defendant's false label representation that the Product contains "wasabi."

23. The Product is sold on its online store and other online retailers such as Amazon.com. *See* **Exhibit C**.

24. All representations shown on the packaging prominently display "wasabi" on the front label.

Defendant's Product Does Not Contain Wasabi

25. Defendant's false and misleading wasabi claims begin with its deceptive product label and packaging. On each and every Product package label, Defendant prominently represents that the Product is a wasabi food item.

26. Defendant claims that the product is a wasabi food item, but "wasabi" specifically refers to a food made from the stem of the wasabi plant—or the wasabi plant itself. Defendant claiming its Product contains wasabi implies that the Product contains an ingredient prepared from the stem of the wasabi plant. However, the ingredient imparting the advertised flavor of the Product is actually horseradish.

27. The listed ingredients do not list wasabi, but only horseradish. *See* **Exhibit B**. Horseradish is a common substitute for wasabi because of its similar pungency.

28. Naming the Product "wasabi" deceives consumers into believing they are purchasing a product with real wasabi, when in reality they are not. The Product is named "wasabi & soy sauce," and this description states to consumers that the Product contains wasabi. The Product would have been more appropriately named "imitation wasabi & soy sauce," or "horseradish & soy sauce."

Wasabi and Horseradish Are Different Products

29. The wasabi plant and horseradish plant greatly differ in flavor, as they are neither the same species nor in the same genus. According to a study comparing the flavor compounds in wasabi and horseradish:

> The main difference between [wasabi and horseradish] is the green odor of wasabi as both of them possess a strong pungent flavor. Horseradish is a distant cousin of wasabi and is sometimes used as a substitute for wasabi with an added green food colour in it (Chadwick et al., 1993).
> ....
> Seven isothiocyanates (ITCs) were identified and measured as flavor compounds in New Zealand grown wasabi rhizomes and horseradish roots. These were iso-propyl ITC, sec-butyl ITC, allyl ITC (AITC), 3-butenyl ITC (3-BITC), 4-pentenyl ITC (4-PITC), 5- hexenyl ITC (5-HITC) and 2-phenylethyl ITC (2-PEITC). The concentration of each ITC except 3-BITC was different in the two plant species and their relative values are given.
> ....
> AITC was the highest concentration ITC in both wasabi (1937.8 mg/kg of fresh rhizome) and horseradish (1658.1 mg/kg fresh root). Its concentration was significantly lower in horseradish (14%) than in wasabi. However, AITC comprised a higher proportion of the total ITC concentration of wasabi (93.7%) than of horseradish (87.2%).
> The level of 4-PITC in wasabi was 47.97 mg/kg of rhizome, (2.32% of the total ITC concentration in wasabi) whereas in horseradish the level was only 8.99 mg/kg of the root, which was significantly lower (81%) than for wasabi.

"Comparison of Flavour Compounds in Wasabi and Horseradish." Food, Agriculture & Environment, vol. 1, no. 2, 27 Apr. 2003, pp. 117–121.

30. The Product is imitation wasabi and is inferior to real wasabi, with a noticeably different flavor. Real wasabi sells at a premium price above imitation wasabi. It is clear that

claiming the Product contains wasabi is meant to mislead consumers and deceive consumers into buying the Product for a premium price.

A Reasonable Consumer Would Be Deceived

31. Plaintiff and other reasonable consumers have been deceived and/or materially misled by Defendant's deceptive wasabi claims.

32. A reasonable consumer would not interpret the Product label to mean that the Product contains horseradish because Defendant's product label states that the Product is "wasabi," falsely communicating that it is authentic wasabi.

33. Defendant knew that due to its deceptive and/or materially misleading label and packaging, a reasonable customer would expect the Product to contain authentic wasabi.

34. Plaintiff purchased the Product from Amazon.com during the Class period and in doing so, read and considered the Product description on the front label, and in reliance thereof decided to buy the Product and pay the premium price based on Defendant's false representations.

35. Defendant's wasabi claims were the primary factor in inducing Plaintiff's purchase of the Product at the advertised price. Plaintiff would not have purchased the Product at that premium price had he known that Defendant's wasabi claims were false and misleading.

36. These deceptions are especially egregious, because the reasonable consumer in the United States rely on proper labeling for purchase of wasabi products. When a reasonable consumer purchases a wasabi product, they expect a wasabi product, not horseradish. There are numerous articles posted by both the media and regular bloggers that show surprise at such deceptive practices:

> Most wasabi paste is fake!
> Yes, it's true. Over 95% of wasabi served in sushi restaurants does not contain any real wasabi. Most fake wasabi is made from a blend of horseradish, mustard flour, cornstarch and green food colorant. This means that most people who think they know wasabi have actually never tasted the stuff![5]

> The little ball of neon-green stuff — it has the consistency of Play-Doh — perched on the edge of your platter of sushi rolls is wasabi, right? In most area sushi restaurants, the condiment called wasabi is almost always an imitation version, made from mixing water with a powdered "wasabi" that's concocted, typically, from horseradish, mustard, tapioca starch and green food coloring (or dried spinach powder).[6]

> Spicy news, sushi lovers: No longer is artificial crab meat the primary impostor invading our beloved rice-and-seaweed feasts. It turns out, the alleged wasabi we slather on our tuna sashimi is likely fake.[7]

> Besides being neon-hued and sinus clearing-hot, what exactly is that bright green blob served alongside sashimi? If you're putting it into your soy sauce Stateside, chances are it's a mix of horseradish powder, mustard and green food coloring (yellow dye no. 5 and blue dye no. 1, for those keeping track), and not actual wasabi.[8]

37. The content and tone of such articles indicate that the deceptive use of horseradish to imitate the presence of wasabi is unknown to most people, thus a reasonable consumer cannot and should not be expected to know this. These articles would be of no interest to the general public if the marketing of horseradish as wasabi was common knowledge.

38. Class members were deceived by Defendant's deceptive wasabi claims for the same reasons.

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[5] *See* "Real wasabi paste", Make Sushi, http://www.makesushi.com/real-wasabi-paste/ (last visited Feb. 14, 2019)
[6] *See* Charles Ferruzza, "Hot stuff: the difference between real and powdered wasabi," The Pitch, https://www.thepitchkc.com/food-drink/article/20574151/hot-stuff-the-difference-between-real-and-powdered-wasabi (last visited Feb. 14, 2019)
[7] *See* Cristen Conger, "That Isn't Wasabi On Your Sushi," Refinery29, https://www.refinery29.com/en-us/2016/07/117033/sushi-wasabi-paste-fake (last visited Feb. 14, 2019)
[8] *See* Liz Grossman, "What's the Deal with Fake Wasabi?", Plate, http://plateonline.com/food/whats-deal-fake-wasabi?allowguest=true (last visited Feb. 14, 2019)

The Relevant Food Regulations Prohibit the Species Substitution in the Products

39. Both the FDA and the New York Attorney General have issued warning letters against manufacturers that use substitute species. *See* **Exhibit D**, discussing the substitution of *Ursus arctos* for *Ursus americanus*, and **Exhibit E**, discussing the substitution of *Harpagophytum zeyheri* for *Harpagophytum procumbens* ("Devil's Claw").

40. Wasabi and horseradish are more distantly related than the products at issue in the warning letters, which concerned different species within the same genus. *Eutrema japonicum* and *Armoracia lapathifolia* Gilib. are not just different species, they are members of different genera.

Federal Law Prohibits Misbranded Foods Such as Defendant's Product

41. Federal law, agency regulation, and state law identically prohibit Defendant's misleading labeling practices.

42. Under the FDCA, 21 U.S.C. § 343(c), a food shall be deemed to be misbranded "[i]f it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated." The Products are misbranded regardless of whether or not Defendant intended to mislead consumers: "FDA advises that the term "misleading" does not require any clear implication regarding intent." 58 FR 64123, 64128.

State Laws Mirror and Incorporate Federal Law and FDA Regulations

43. Food labeling laws and regulations of the fifty states and the District of Columbia impose requirements which mirror and incorporate federal law.

44. New York State law broadly prohibits the misbranding of food in language identical to that found in regulations promulgated pursuant to the FDCA § 403, 21 U.S.C. 343. Under New York Agm. Law § 201, the law specifically provides that "[f]ood shall be deemed to be misbranded

…If it is an imitation of another food, unless its label bears the word "imitation" and immediately thereafter the name of the food imitated in type of uniform size and equal prominence, followed by a statement showing the constituents thereof."

45. Courts have noted the incorporation of FDA regulations into New York law in evaluating claims brought under NY GBL § 349. *See Ackerman v. Coca-Cola Co.*, No. CV-09-0395 (JG) (RML), 2010 U.S. Dist. LEXIS 73156, at *13 (E.D.N.Y. July 21, 2010) ("New York's Agriculture and Marketing law similarly provides in relevant part that food shall be deemed misbranded '[i]f its labeling is false or misleading in any particular, and incorporates the FDCA's labeling provisions."); *Izquierdo v. Mondelez Int'l, Inc.*, No. 16-cv-04697 (CM), 2016 U.S. Dist. LEXIS 149795, at *11 (S.D.N.Y. Oct. 26, 2016) ("Here [in a slack-fill case brought under NY GBL § 349], New York law expressly incorporates the standard imposed by the FDCA."); *N. Am. Olive Oil Ass'n v. Kangadis Food Inc.*, 962 F. Supp. 2d 514, 519 (S.D.N.Y. 2013) (evaluating claims under New York Gen. Bus. Law §§ 349 and 350 and finding that "New York law deems any product or label that fails to conform to [New York Agm. Law] definitions 'adulterated' or 'misbranded,' and thus unlawful.").

46. New York Agm. Law § 201 specifically provides that "[f]ood shall be deemed to be misbranded … If it is an imitation of another food, unless its label bears the word "imitation" and immediately thereafter the name of the food imitated in type of uniform size and equal prominence, followed by a statement showing the constituents thereof." Moreover, Part 259.1 of Title 1 of the New York Codes, Rules and Regulations of the State of New York (1 NYCRR § 259.1), incorporates by reference the regulatory requirements for food labeling under the FDCA:

> For the purpose of the enforcement of article 17 of the Agriculture and Markets Law, and except where in conflict with the statutes of this State or with rules and regulations promulgated by the commissioner, the commissioner hereby adopts the current regulations as they appear in title 21 of the *Code of Federal Regulations*

> (revised as of April 1, 2013) … in the area of food packaging and labeling as follows: … (2) Part 100 of title 21 of the *Code of Federal Regulations* [21 C.F.R. 100 *et seq*.], containing Federal definitions and standards for food packaging and labeling *General* at pages 5-10….

1 NYCRR § 259.1(a)(2).

The Product Label Violates Prohibitions Against Falsely Advertising Horseradish Products

47. The above paragraphs discussed the strength of Plaintiff's claims under regulations that address fake products. These have characterized the Product as a *fake wasabi product* inasmuch as it purports to contain wasabi and does not.

48. However, the Product also violates consumer protection regulations that prohibit false advertising inasmuch as the Product is a *falsely advertised horseradish product*.

49. The horseradish used in the Product has a precise definition under applicable regulations. 21 C.F.R. § 182.10 defines horseradish as "*Armoracia lapathifolia* Gilib." The Product name is simply erroneous as displayed on the label because the name does not refer to the Product's characterizing ingredient—horseradish—by its common or usual name: "horseradish." *See* 21 U.S.C. § 343; 21 C.F.R. § 102.5(a).

The Product Label Is Deceptive, Even Assuming that Wasabi Can Be Made of Horseradish

50. Even assuming that the Product's mix of spices and flavorings qualified as "real" wasabi for some or all legal purposes, which it does not, regulations would still require that the absence of *Eutrema japonicum* be prominently declared on the label, but it is not. *Eutrema japonicum* is a characterizing ingredient of wasabi products that commands a premium over horseradish on the spice market, and FDA regulations prohibit labels, such as the Product's label,

that create an erroneous impression that characterizing ingredients are in a Product when they are not:

> The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) . . . when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. . . .

21 C.F.R. § 102.5(c).

Plaintiff and the Class Were Injured as a Result of Defendant's Misrepresentations

51. As a result of Defendant's false wasabi claims, Plaintiff and the Class members have been injured through their purchase of the Product. Plaintiff and Class members have been deceived into purchasing a Product that they reasonably believed, based on Defendant's representations, to contain authentic wasabi, when it does not.

52. Plaintiff and Class members were thus injured when they paid the full price of the Product and received an inferior Product than what was represented to them by Defendant.

53. Plaintiff was thus deprived of the benefit of their bargains, injured in an amount up to the purchase price, to be determined by expert testimony at trial.

CLASS ACTION ALLEGATIONS

54. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of the following Class:

> All persons or entities in the United States who made retail purchases of Product during the applicable limitations period, and/or

> such subclasses as the Court may deem appropriate ("the Nationwide Class").[9]

In the alternative, Plaintiff seeks to represent a Class or Subclass consisting of:

> All persons or entities who made retail purchases of the Product in New York during the applicable limitations period, and/or such subclasses as the Court may deem appropriate ("the New York Class").

55. The proposed Classes exclude current and former officers and directors of Defendant, members of the immediate families of the officers and directors of Defendant, Defendant's legal representatives, heirs, successors, assigns, any entity in which it has or has had a controlling interest, and the judicial officer to whom this lawsuit is assigned.

56. Plaintiff reserves the right to revise the Class definition based on facts learned in the course of litigating this matter.

57. This action is proper for Class treatment under Rules 23(b)(1)(B) and 23(b)(3) of the Federal Rules of Civil Procedure. While the exact number and identities of other Class members are unknown to Plaintiff at this time, Plaintiff is informed and believes that there are millions of Class members. Thus, the Class members are so numerous that individual joinder of all Class members is impracticable.

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[9] See Fitzhenry-Russell v. Dr. Pepper Snapple Grp., No. 17-cv-00564 NC, 2017 U.S. Dist. LEXIS 155654, at *15 (N.D. Cal. Sep. 22, 2017) ("Yet the Supreme Court did not extend its reasoning to bar the nonresident plaintiffs' claims here, and Bristol-Myers is meaningfully distinguishable based on that case concerning a mass tort action, in which each plaintiff was a named plaintiff.");In re Chinese-Manufactured Drywall Prods. Liab. Litig., No. 09-2047, 2017 U.S. Dist. LEXIS 197612, at *52-53 (E.D. La. Nov. 28, 2017) ("it is clear and beyond dispute that Congress has constitutional authority to shape federal court's jurisdiction beyond state lines to encompass nonresident parties" and interpreting Bristol-Meyers as barring nationwide class actions where jurisdiction over defendant is specific "would require plaintiffs to file fifty separate class actions in fifty or more separate district courts across the United States — in clear violation of congressional efforts at efficiency in the federal courts."); Horton v. USAA Cas. Ins. Co., 266 F.R.D. 360, 364 (D. Ariz. 2009) ("Objectors argue that this Court lacks jurisdiction to certify a nationwide class. This argument is frivolous. A federal court applying Rule 23 of the Federal Rules of Civil Procedure may certify a nationwide class if the requirements for certification are satisfied.").

58. Common questions of law and fact arise from Defendant's conduct described herein. Such questions are common to all Class members and predominate over any questions affecting individual Class members. These include:

i. Whether Defendant labeled, packaged, marketed, advertised and/or sold the Product to Plaintiff and Class members, using false, misleading and/or deceptive packaging and labeling;

ii. Whether Defendant's actions constitute violations of the consumer protection laws of New York, and the other states;

iii. Whether Defendant omitted and/or misrepresented material facts in connection with the labeling, ingredients, marketing, advertising and/or sale of Products;

iv. Whether Defendant's labeling, packaging, marketing, advertising and/or selling of the Products constituted unfair, unlawful or fraudulent practices;

v. Whether, and to what extent, injunctive relief should be imposed on Defendant to prevent such conduct in the future;

vi. Whether the members of the Classes have sustained damages as a result of Defendant's wrongful conduct;

vii. The appropriate measure of damages and/or other relief; and

viii. Whether Defendant should be enjoined from continuing their unlawful practices.

59. Plaintiff's claims are typical of those of the Class members because Plaintiff and the other Class members sustained damages arising out of the same wrongful conduct, as detailed herein. Plaintiff and Class members purchased Defendant's Product and sustained similar injuries arising out of Defendant's conduct in violation of Federal and New York state law. Defendant's unlawful, unfair, and fraudulent actions concern the same business practices described herein

irrespective of where they occurred or were experienced. The injuries of the Class were caused directly by Defendant's unfair and deceptive practices. In addition, the factual underpinning of Defendant's misconduct is common to all Class members and represents a common thread of misconduct resulting in injury to all Class members. Plaintiff's claims arise from the same practices and course of conduct that give rise to the claims of Class members and are based on the same legal theories.

60. Plaintiff will fairly and adequately represent and pursue the interests of the Class. Plaintiff understands the nature of his claims herein, has no disqualifying conditions, and will vigorously represent the interests of the Class members. Neither Plaintiff nor Plaintiff's counsel have any interests that conflict with or are antagonistic to the interests of the Class members.

61. Plaintiff has retained highly competent and experienced class action attorneys to represent his interests and those of the Class members. Plaintiff and Plaintiff's counsel have the necessary financial resources to adequately and vigorously litigate this class action. Plaintiff and counsel are aware of their fiduciary responsibilities to the Class members and will diligently discharge those duties by vigorously seeking the maximum possible recovery for them.

62. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The damages suffered by any individual Class member are too small to make it economically feasible for an individual Class member to prosecute a separate action, and it is desirable for judicial efficiency to concentrate the litigation of the claims in this forum. Furthermore, the adjudication of this controversy through a class action will avoid the potentially inconsistent and conflicting adjudications of the claims asserted herein. There will be no difficulty in the management of this action as a class action.

63. The prerequisites to maintaining a class action for injunctive relief or equitable relief pursuant to Rule 23(b)(2) are met, as Defendant has acted or refuses to act on grounds generally applicable to the Classes, thereby making appropriate final injunctive or equitable relief with respect to the Classes as a whole.

64. The prerequisites to maintaining a class action for injunctive relief or equitable relief pursuant to Rule 23(b)(3) are met, as questions of law or fact common to the Classes predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

65. The prosecution of separate actions by members of the Class would create a risk of establishing inconsistent rulings and/or incompatible standards of conduct for Defendant. Additionally, individual actions may be dispositive of the interest of all members of the Class, although certain Class members are not parties to such actions.

66. Defendant's conduct is generally applicable to the Class as a whole and Plaintiff seeks, *inter alia*, equitable remedies with respect to the Class as a whole. As such, Defendant's systematic policies and practices make declaratory relief with respect to the Class as a whole appropriate.

CAUSES OF ACTION

COUNT I

INJUNCTION FOR VIOLATIONS OF NEW YORK GENERAL BUSINESS LAW § 349 (DECEPTIVE AND UNFAIR TRADE PRACTICES ACT)

(brought on behalf of the Nationwide Class, in conjunction with the substantively similar consumer protection laws of other states and the District of Columbia to the extent New York consumer protection laws are inapplicable to out-of-state Class members, or, in the alternative, on behalf of the New York Class)

67. Plaintiff realleges and incorporates herein by reference the allegations contained in all preceding paragraphs, and further alleges as follows:

68. Plaintiff brings these claims on behalf of himself and the other members of the Class for an injunction for violations of New York's Deceptive Acts or Practices Law ("NY GBL § 349").

69. Alternatively, should the Court not certify Plaintiff's proposed Nationwide Class, Plaintiff brings this claim individually and on behalf of the members of the New York Class for an injunction for violations of New York's Deceptive Acts or Practices Law ("NY GBL § 349").

70. NY GBL § 349 provides that "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are . . . unlawful."

71. Under the NY GBL § 349, it is not necessary to prove justifiable reliance. ("To the extent that the Appellate Division order imposed a reliance requirement on General Business Law [§] 349 … claims, it was error. Justifiable reliance by the plaintiffs is not an element of the statutory claim." *Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940, 941 (N.Y. App. Div. 2012) (internal citations omitted)).

72. Any person who has been injured by reason of any violation of the NY GBL § 349 may bring an action in their own name to enjoin such unlawful act or practice, an action to recover

their actual damages or fifty dollars, whichever is greater, or both such actions. The court may, in its discretion, increase the award of damages to an amount not to exceed three times the actual damages up to one thousand dollars, if the court finds the Defendant willfully or knowingly violated this section. The court may award reasonable attorney's fees to a prevailing plaintiff.

73. The practices employed by Defendant, whereby it advertises, promotes, and markets its Product as a "wasabi" food, are unfair, deceptive, misleading, and in violation of the NY GBL § 349.

74. The foregoing deceptive acts and practices were directed at consumers.

75. Defendant should be enjoined from representing the Product as "wasabi" on the Product's labels pursuant to NY GBL § 349.

76. Plaintiff, on behalf of himself and all others similarly situated, respectfully demands a judgment enjoining Defendant's conduct, awarding costs of this proceeding and attorneys' fees, as provided by NY GBL § 349, and such other relief as this Court deems just and proper.

COUNT II

DAMAGES FOR VIOLATIONS OF NEW YORK GENERAL BUSINESS LAW § 349

(DECEPTIVE AND UNFAIR TRADE PRACTICES ACT)

(brought on behalf of the Nationwide Class, in conjunction with the substantively similar consumer protection laws of other states and the District of Columbia to the extent New York consumer protection laws are inapplicable to out-of-state Class members, or, in the alternative, on behalf of the New York Class)

77. Plaintiff realleges and incorporates herein by reference the allegations contained in all preceding paragraphs, and further alleges as follows:

78. Plaintiff brings these claims on behalf of himself and other members of the Nationwide Class for Defendant's violations of NY GBL § 349.

79. Alternatively, should the Court not certify Plaintiff's proposed Nationwide Class, Plaintiff brings this claim individually and on behalf of the other members of the New York Class for Defendant's violations of NY GBL § 349.

80. Defendant's business act and practices and/or omissions as alleged herein constitute deceptive acts or practices under NY GBL § 349, which were enacted to protect the consuming public from those who engage in unconscionable, deceptive, and unfair acts or practices in the conduct of any business, trade, or commerce.

81. Defendant's Practices described throughout this Complaint, were specifically directed to consumers and violate the NY GBL § 349 for, *inter alia*, the following reasons:

a. Defendant misrepresents or misleadingly advertises that the Product contains "wasabi" with an intent to cause Plaintiff and Class members to believe that the Product contains some wasabi;

b. Defendant misleadingly fails to disclose that its "wasabi" in fact consists of horseradish;

c. Defendant caused Plaintiff and Class members to suffer a probability of confusion and a misunderstanding of legal rights, obligations and/or remedies by and through their conduct;

d. Defendant made material representations and statements of fact to Plaintiff and Class members that resulted in them reasonably believing the represented or suggested state of affairs to be other than what they actually were.

82. The practices employed by Defendant, whereby Defendant advertises, promotes, and markets its Product as a "wasabi" Product are unfair, deceptive, and misleading, and in violation of NY GBL § 349.

83. Under the circumstances, Defendant's conduct in employing these unfair and deceptive trade practices is malicious, willful, wanton and outrageous such as to shock the conscience of the community and warrant the imposition of punitive damages.

84. Defendant's actions impact the public interest because Plaintiff was injured in exactly the same way as millions of others purchasing the Product as a result of and Defendant's generalized course of deception.

85. The foregoing deceptive acts and practices are directed at consumers.

86. The foregoing deceptive acts and practices proximately caused Plaintiff and Class members to suffer actual damages in the form of, *inter alia*, monies spent to purchase the Product. Plaintiff and Class members are entitled to recover compensatory damages, statutory damages, punitive damages, attorneys' fees and costs, and any other relief the Court deems appropriate. Damages can be calculated through expert testimony at trial.

COUNT III

DAMAGES FOR VIOLATIONS OF NEW YORK GENERAL BUSINESS LAW § 350 (FALSE ADVERTISING LAW)

(brought on behalf of the Nationwide Class, in conjunction with the substantively similar consumer protection laws of other states and the District of Columbia to the extent New York consumer protection laws are inapplicable to out-of-state Class members, or, in the alternative, on behalf of the New York Class)

87. Plaintiff realleges and incorporates by reference the allegations contained in all preceding paragraphs and further alleges as follows:

88. Plaintiff brings this claim individually, as well as on behalf of members of the Nationwide Class, for violations of NY GBL § 350.

89. Alternatively, should the Court not certify Plaintiff's proposed Nationwide Class, Plaintiff brings this claim individually and on behalf of the members of the New York Class for violations of NY GBL § 350.

90. Defendant has been and/or is engaged in the "conduct of … business, trade or commerce" within the meaning of N.Y. Gen. Bus. Law § 350.

91. New York Gen. Bus. Law § 350 makes unlawful "[f]alse advertising in the conduct of any business, trade or commerce." False advertising includes "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect," taking into account the extent to which the advertising fails to reveal facts material in light of … representations [made] with respect to the commodity …" N.Y. Gen. Bus. Law § 350-a(1).

92. Defendant caused to be disseminated throughout New York and the United States, through advertising, marketing and other publications, statements that were untrue and/or misleading.

93. Defendant's affirmative misrepresentations or deceptions of the Product being "wasabi" is material and substantially uniform in content, presentation, and impact upon consumers at large. Consumers purchasing the Product were, and continue to be, exposed to Defendant's material deceptions.

94. Defendant's denial of the Product being "horseradish" is material and substantially uniform in content, presentation, and impact upon consumers at large. Consumers purchasing the Product were, and continue to be, exposed to Defendant's material deceptions.

95. Defendant has violated N.Y. Gen. Bus. Law § 350 because its labeling of the Products as "wasabi" Product is material and likely to deceive a reasonable consumer.

96. Plaintiff and Class members have suffered an injury, including the loss of money or property, as a result of Defendant's false and misleading advertising.

97. Pursuant to N.Y. Gen. Bus. Law § 350-e, Plaintiff and Class members seek monetary damages (including actual damages and minimum, punitive, or treble and/or statutory damages pursuant to GBL § 350-a(1)), injunctive relief, restitution and disgorgement of all monies obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.

COUNT IV

COMMON LAW FRAUD

(brought on behalf of the Nationwide Class, in conjunction with the substantively similar common law of other states and the District of Columbia to the extent New York common law is inapplicable to out-of-state Class members, or, in the alternative, on behalf of the New York Class)

98. Plaintiff realleges and incorporates herein by reference the allegations contained in all preceding paragraphs and further alleges as follows:

99. Defendant intentionally makes materially false and misleading representations regarding the nature of the Product.

100. Plaintiff and Class members reasonably relied on Defendant's false and misleading representations. They did not know, and had no reason to know, that the Product does not contain real wasabi. They would not have purchased the Product, or paid an appropriately lesser amount, had they known the truth.

101. Defendant knew and intended that Plaintiff and the Class members would rely on its misrepresentations.

102. Plaintiff and Class members have been injured as a result of Defendant's fraudulent conduct.

103. Defendant is liable to Plaintiff and Class members for damages sustained as a result of Defendant's fraud.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all other similarly situated, seek judgment against Defendant, as follows:

a. An Order that this action be maintained as a class action, appointing Plaintiff as representative of the Nationwide Class or, in the alternative, the New York Class;

b. An Order appointing the undersigned attorney as Class Counsel in this action;

c. Restitution and disgorgement of all amounts obtained by Defendant as a result of its misconduct, together with interest thereon from the date of payment, to the victims of such violations;

d. All recoverable compensatory and other damages sustained by Plaintiff and Class members;

e. Actual and/or statutory damages for injuries suffered by Plaintiff and Class members in the maximum amount permitted by applicable law;

f. An order (i) requiring Defendant to immediately cease their wrongful conduct as set forth in this Complaint; (ii) ordering Defendant to engage in a corrective advertising campaign; and (iii) requiring Defendant to reimburse Plaintiff and all Class members, up to the amounts paid for the Product;

g. Statutory pre-judgment and post-judgment interest on any amounts;

h. Payment of reasonable attorneys' fees and costs; and

i. Such other relief as the Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff, on behalf of themselves and all others similarly situated, demand a trial by jury on all questions of fact raised by the Complaint.

Dated: February 15, 2019

Respectfully submitted,

By: */s/ C.K. Lee*
C.K. Lee, Esq.

LEE LITIGATION GROUP, PLLC
C.K. Lee (CL4086)
Anne Seelig (AS3976)
30 East 39th Street, Second Floor
New York, NY 10016
Tel.: 212-465-1188
Fax: 212-465-1181
Attorneys for Plaintiff and the Class

Exhibit A

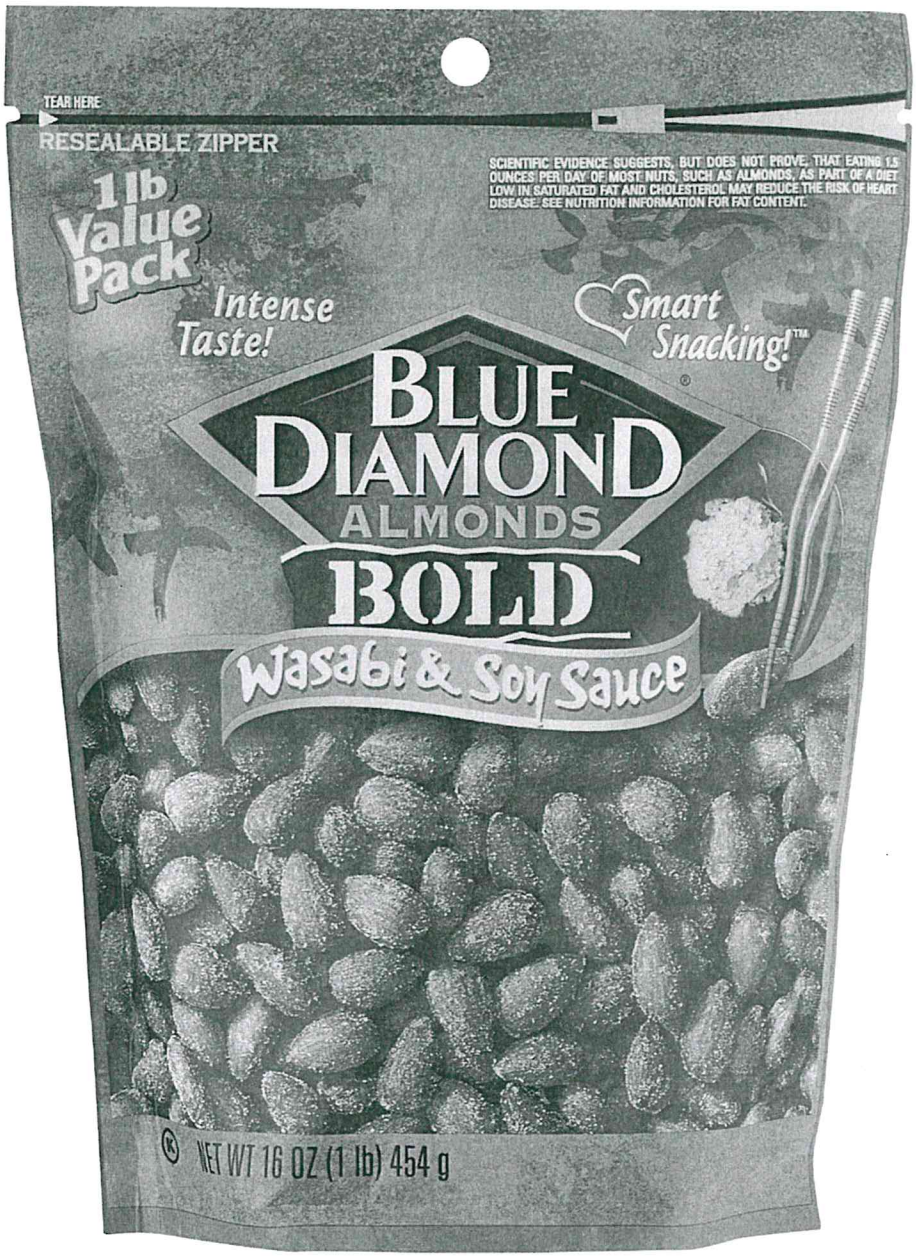

TEAR HERE
RESEALABLE ZIPPER
1lb Value Pack
SCIENTIFIC EVIDENCE SUGGESTS, BUT DOES NOT PROVE, THAT EATING 1.5 OUNCES PER DAY OF MOST NUTS, SUCH AS ALMONDS, AS PART OF A DIET LOW IN SATURATED FAT AND CHOLESTEROL MAY REDUCE THE RISK OF HEART DISEASE. SEE NUTRITION INFORMATION FOR FAT CONTENT.
Intense Taste!
Smart Snacking!™
BLUE DIAMOND
ALMONDS
BOLD
Wasabi & Soy Sauce
NET WT 16 OZ (1 lb) 454 g

Exhibit B


TEAR HERE
RESEALABLE ZIPPER
BLUE DIAMOND ALMONDS
Consistent Quality, Bold New Flavors and Great Value!
Nutrition Facts
Serving Size 1 oz (28g/about 28 nuts)
Servings Per Package 16
Amount Per Serving
Calories 170 Calories from Fat 140
% Daily Value*
Total Fat 15g 24%
Saturated Fat 1g 6%
Trans Fat 0g
Cholesterol 0mg 0%
Sodium 115mg 5%
Potassium 180mg 5%
Total Carbohydrate 6g 2%
Dietary Fiber 3g 11%
Sugars 2g
Protein 6g
Vitamin A 0% • Vitamin C 0%
Calcium 8% • Iron 6%
Vitamin E 95% • Magnesium 20%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:
Calories: 2,000 2,500
Total Fat Less than 65g 80g
Sat Fat Less than 20g 25g
Cholesterol Less than 300mg 300mg
Sodium Less than 2,400mg 2,400mg
Potassium 3,500mg 3,500mg
Total Carbohydrate 300g 375g
Dietary Fiber 25g 30g
Blue Diamond Growers' naturally nutritious Wasabi & Soy Sauce almonds are roasted and seasoned with spicy BOLD flavors, so satisfying that you just can't put them down. Combining the distinctive flavor of Asian style horseradish with the savory taste of soy sauce, these almonds pack a mouthwatering punch for your snacking enjoyment. And our convenient, resealable bag gives you the option to save some for later – if you can!
ALMONDS ARE CALORIE SMART
No Cholesterol
Good Source of Fiber
Good Source of Protein
No Artificial Ingredients
From the Almond People
6g – 3g = 3g NET CARBS
TOTAL CARBS FIBER
Questions or Comments?
WRITE BLUE DIAMOND GROWERS SACRAMENTO, CA 95812 PLEASE INCLUDE CODE NUMBER FOUND ON THE PACKAGE WITH ALL INQUIRIES.
INGREDIENTS: ALMONDS, VEGETABLE OIL (CANOLA, SAFFLOWER AND/OR SUNFLOWER), SUGAR, MODIFIED CORN STARCH, SALT, SOY SAUCE (SOYBEAN, WHEAT, SALT), HORSERADISH, ONION, SPICE, FRACTIONATED COCONUT AND/OR PALM KERNEL OIL, GARLIC, MALTODEXTRIN, YEAST EXTRACT, NATURAL FLAVOR, CITRIC ACID, DISODIUM GUANYLATE AND DISODIUM INOSINATE.
PEANUT FREE. MAY CONTAIN OTHER TREE NUTS.
FROM CALIFORNIA
PACKED BY: BLUE DIAMOND GROWERS
SACRAMENTO, CA 95812 U.S.A.
0 41500 00553 3
P-15748 002

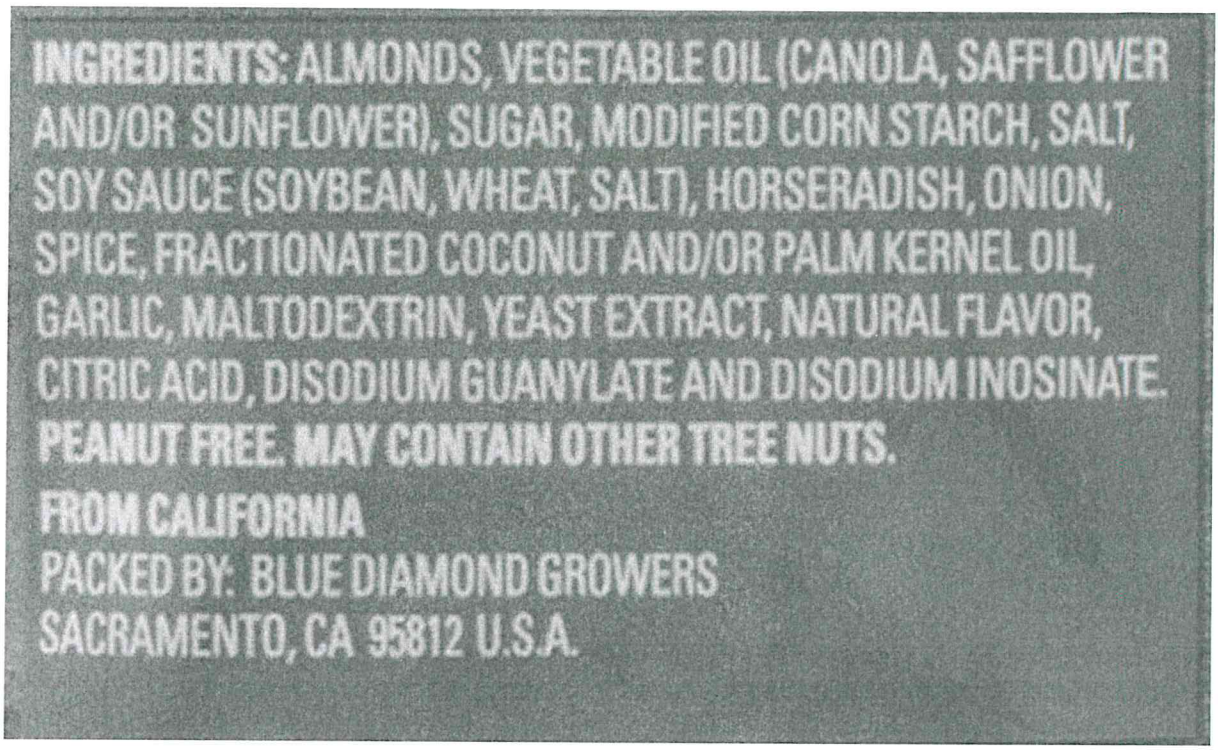
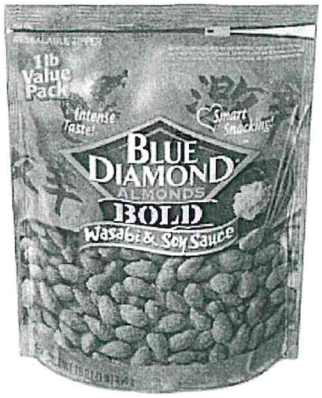

INGREDIENTS: ALMONDS, VEGETABLE OIL (CANOLA, SAFFLOWER AND/OR SUNFLOWER), SUGAR, MODIFIED CORN STARCH, SALT, SOY SAUCE (SOYBEAN, WHEAT, SALT), HORSERADISH, ONION, SPICE, FRACTIONATED COCONUT AND/OR PALM KERNEL OIL, GARLIC, MALTODEXTRIN, YEAST EXTRACT, NATURAL FLAVOR, CITRIC ACID, DISODIUM GUANYLATE AND DISODIUM INOSINATE.
PEANUT FREE. MAY CONTAIN OTHER TREE NUTS.
FROM CALIFORNIA
PACKED BY: BLUE DIAMOND GROWERS
SACRAMENTO, CA 95812 U.S.A.

Exhibit C

Go to Main Site | Sign In or Create Account | Cart

BLUE DIAMOND ALMONDS

Continue Shopping



Wasabi & Soy Sauce

No reviews Write a Review

Kosher

When we first heard the idea, we were a little skeptical, too. Then we tried one and tasted the great wasabi kick with a salty, sweet finish and we were hooked.

6 oz. can (Case of twelve) | 1 lb. bag (Single bag)

1 lb. bag (Case of six) | 1.5 oz. foils (Caddie of twelve)

$8.89 Qty 1 + Add to cart

Nutrition Facts

Ingredients

smartlabel

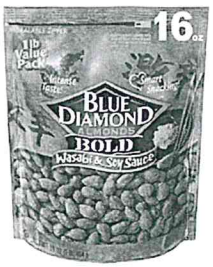
Deliver to New York 10016 | Departments | Your Amazon.com | Today's Deals | Gift Cards | Registry | Sell | Treasure Truck | Help | EN | Hello, Sign in Account & Lists | Orders | Try Prime

Grocery | Deals | Snacks | Breakfast | Warm Beverages | Cold Beverages | Cooking Staples | Baby Food | Candy & Chocolate | Prime Pantry | Subscribe & Save | International Foods

Healthy & tasty snacks delivered monthly

Blue Diamond Almonds, Bold Wasabi & Soy Sauce, 16 Ounce by Blue Diamond Almonds

542 customer reviews | 3 answered questions | Amazon's Choice for "blue diamond almonds wasabi"



About the product

- Contains 1 - 16 ounce resealable bag
- Cholesterol free
- 6g of protein per serving, 3g fiber, 0g trans fat
- A good source of fiber, Smart Snacking on-the-go
- Great wasabi kick with a salty, sweet finish

Add-on Item Ships with any qualifying order over $25. Details

Price: $9.32 ($0.58 / Ounce) & FREE Shipping on orders over $25 shipped by Amazon. Details

In Stock. Ships from and sold by Amazon.com. Gift-wrap available.

4 Sizes: 16 Ounce

1.5 Ounce (Pack of 12)	4 Ounce (Pack of 12)	16 Ounce
$10.09 ($0.84 / Count)	$26.91 ($0.56 / Ounce)	$9.32 ($0.58 / Ounce)

Want it tomorrow, Sept. 27? Add it to a qualifying order within 2 hrs 8 mins and choose One-Day Shipping at checkout. Details

Deliver to New York 10016

Qty: 1 1-Click ordering is not available for this item

Add to Cart

Add to List

OR

Delivery available via Fresh. Get this item with your weekly groceries, delivered as early as same day or early next morning.

Other Sellers on Amazon 10 new from $9.32

$17.09 ($1.07 / Ounce) + Free Shipping Add to Cart

Exhibit D

Inspections, Compliance, Enforcement, and Criminal Investigations

Czimer's Foods, Inc 2/4/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

February 4, 2011

WARNING LETTER
CHI-03-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Richard J. Czimer, Jr.
Owner
Czimer Foods, Inc.
13136 West 159th Street
Homer Glen, Illinois 60491

Dear Mr. Czimer:

The Food and Drug Administration (FDA) inspected your food processing facility, located at 13136 West 159th Street, Homer Glen, IL, on July 8, July 12, August 25, and September 16, 2010. We found that you have serious violations c the Federal Food, Drug, and Cosmetic Act (the Act) and associated regulations. You can find the Act and regulations on FDA's website at www.fda.gov[1].

On July 12, 2010, during the inspection, FDA collected samples of a number of your products, including your Black Bear Burger and your Black Bear Steak products. These products are adulterated within the meaning of Section 402(b)(2) of the Act [21 U.S.C. § 342(b)(2)] in that a valuable constituent (Black Bear) has been omitted from the products and another ingredient has been substituted wholly therefore. Specifically, your Black Bear Burger product was found to contain Elk/Red Deer *(Cervus sp.)* rather than Black Bear *(Ursus americanus)*, and your Black Bear Steak product was found to contain Brown Bear *(Ursus arctos)* rather than Black Bear.

Furthermore, your Black Bear Burger and Black Bear Steak products are misbranded within the meaning of Section 403(b) of the Act [21 U.S.C. § 343(b)] in that they are offered for sale under the name "Black Bear Burgers" and "Black Bear Steak" but are in fact Elk/Red Deer *(Cervus sp.)* and Brown Bear *(Ursus arctos)* , respectively.

During our inspection, we also found that you have serious violations of the Current Good Manufacturing Practice (CGMP) regulation, Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). Because the food products produced in your facility have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health, these products are adulterated withii the meaning of section 402(a)(4) of the Act [21 U.S.C. § 342(a)(4)].

During the inspection, our investigators observed the following significant violations of 21 CFR 110:

1. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials did not conform to hygienic practices to the extent necessary to protect against contaminations of food, as required by 21 CFR 110.10(b), including maintaining adequate personal cleanliness [21 CFR 110.10(b)(2)] and washing hands thoroughly to protect against contamination [21 CFR 110.10(b)(3)]. Specifically, an employee removed Ready-To-Eat (RTE) cheese products with his bare hands, from your retail display case, without washing and sanitizing his hands prior to handling the RTE cheese and without wearing gloves. The employee then portioned the cheese products with bare hands for a consumer and placed the RTE cheese product back into the display case.

2. You did not manufacture, package, and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and the contamination of food, as required by 21 CFR 110.80(b)(2). Specifically,

- You do not have a set thermal process for the smoking of exotic meat slim jims and meat jerky products, and do not monitor the smoking operation for processing time or smoking temperature. Further you do not calibrate the thermometers used in the facility. These conditions and controls are necessary to minimize the potential for growth of microorganisms during the smoking process.
- You do not monitor the pH or water activity of refrigerated, smoked vacuum packed exotic meat slim jims and meat jerky products. These properties can affect the time and temperature necessary to properly smoke the meat products, which would minimize the potential for growth of microorganisms during the smoking process.

3. Your facility failed to use cleaning compounds and sanitizing agents that are safe and adequate under the conditions of use, as required by 21 CFR 110.35(a). Specifically, your facility used a **(b)(4)** based sanitizer, but the sanitizer was not produced or maintained at the concentration specified on the label, which could render the sanitizer unsafe. An employee twice attempted to mix the sanitizer to the appropriate concentration, and on both attempts the **(b)(4)** concentration was significantly greater then the maximum strength specified on the label.

4. Your facility failed to maintain equipment and utensils in an acceptable condition through appropriate cleaning and sanitizing as necessary, as required by 21 CFR 110.80(b)(1). Specifically, on a day that no meat was being cut, the band saw used to cut and section frozen meat pieces had dried particles of meat scraps on the blade, the handle, and in the grooves of the saw's processing table.

This letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. You should investigate and determine the causes of the violations and take prompt actions to correct the violations to bring your products into compliance. Failure to promptly correct these violations may result in legal action without further notice including seizure and injunction.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Rosemary Sexton, Compliance Officer, at the address above. If you have any questions regarding any issues in this letter, please contact Ms. Sexton at 312-596-4225 or rosemary.sexton@fda.hhs.gov.

Sincerely,

/s/

Scott J. MacIntire
District Director

10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Links on this page:

1. https://wayback.archive-it.org/7993/20170112193958/http://www.fda.gov/

Exhibit E

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

EXECUTIVE DIVISION
SPECIAL COUNSEL

September 9, 2015

Bishop Dr. Truman Berst
Alternative Remedies Health & Herbs
425 Ellsworth Street SW
Albany, Oregon 45202-1100

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

Dear Bishop Dr. Berst,

This letter constitutes a demand that Alternative Remedies Health & Herbs cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* ("Devil's Claw")—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden ("NYBG") concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the "Substitute Plant"). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.[1] The NYBG study revealed widespread substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant

[1] DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbAtrnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG extracted identifiable DNA from all but two of the products. (Only one of the two is labeled as an "extract" in the "supplement facts" panel.)

source could be identified—produced by 14 separate companies, including large and small firms—**100%** were found to contain the Substitute Plant, either alone (81%) or in combination with Devil's Claw (19%). According to subpoenaed documents, this included a product sold by your company as "Devil's Claw Root," Lot No. C0239 (the "Tested Lot"). Your product's label did not disclose the presence of the Substitute Plant. The NYBG study concluded, however, that your company's product contained the Substitute Plant, not Devil's Claw.

Because of the implications for consumers, we are contacting your company prior to publication of the NYBG study. This analysis, however, is far from the first to draw attention to serious quality control and compliance problems in the supplement industry. Nor is it the first red flag indicating fraud, misidentification, or other serious problems in the supply chain for Devil's Claw, a popular and scarce plant indigenous to the Kalahari Desert; reports of raw material suppliers mixing or replacing dried Devil's Claw root tubers with the similar-looking dried root tubers of the Substitute Plant—a cheaper plant in the same genus—are common. In this context, the results of the NYBG study are especially troubling; they suggest an industry-wide failure to take necessary steps to comply with law and ensure the accuracy of claims concerning the quality and authenticity of the supplements marketed to consumers.

As a matter of commerce, science, and law, Devil's Claw (*Harpagophytum procumbens*) and the Substitute Plant (*Harpagophytum zeyheri*) are distinct species:

- Commercially, Devil's Claw is preferred in virtually all respects, is scarcer, and commands a higher market price. After contacting several suppliers, the Office of the New York Attorney General received price quotes for Devil's Claw root that were *two- to three-times higher* than a similar quote for the Substitute Plant.

- Scientifically, the two plants are separate species that can be easily distinguished in the wild. Herbalists link the purported therapeutic properties of Devil's Claw—which are not generally accepted in the medical community or approved by the FDA—to certain naturally-occurring chemical compounds, specifically iridoid glycosides. These chemicals tend to occur naturally in Devil's Claw at much higher concentrations. They also appear in different ratios in the two plants, and at least one chemically potent phenol glycoside in Devil's Claw (6-acetylacteoside) is missing from the Substitute Plant. Moreover, supplements derived from the Substitute Plant—even those "standardized" to deliver a promised percentage of certain iridoid glycosides—are also likely to expose users to other chemicals that are either absent from Devil's Claw or present at lower concentrations.[2]

[2] Certain overseas jurisdictions allow the Substitute Plant to be sold as part of the same product as Devil's Claw. This approach has been criticized in the scientific literature due, in part, to the distinct chemical profiles of the two plants and the lack of evidence that the two are pharmacologically equivalent. *See, e.g.,* Nontobeko P. Mncwangi, et al., *What the devil is in your phytomedicine? Exploring species substitution in* Harpagophytum *through chemometric modeling of* ^{1}*H-NMR and UHPLC-MS datasets,* 106 Phytochemistry 104-115 (October 2014) ("[O]ur results clearly demonstrate a phytochemical disparity between the two species which may impact on their biological properties. . . . The chemometric analysis results showed that the two species are not chemically equivalent, particularly, that harpagoside is not always present in H. zeyheri, suggesting that the therapeutic outcome may be different, thus they should not be used interchangeably until pharmacological equivalence has been confirmed.")

- Legally, the 1992 Edition of Herbs of Commerce supplies the list of plants that may be sold in the United States commercially under particular common names. 21 C.F.R. 101.4(h).[3] The relevant definition—which was reaffirmed in the more recent edition—defines devil's claw as *Harpagophytum procumbens*, *i.e.* as Devil's Claw. Representing any plant other than Devil's Claw as "devil's claw" is inconsistent with the definition codified in the Herbs of Commerce and is misleading as a matter of law. Misapplying the common name is all the more problematic where, as here, the scientific name of the non-standard species appears nowhere on the label.

Nor are we convinced that the Substitute Plant would be lawful for sale in New York or elsewhere in the United States under its proper scientific name, *i.e.* as *Harpagophytum zeyheri*. Under federal law, a manufacturer may legally sell a "new dietary ingredient"—or an ingredient that was first marketed in the United States after October 15, 1994—if it was (i) used as a source of food; or (ii) submitted to the federal Food and Drug Administration as part of a new dietary ingredient notification at least 75 days prior to initial sale. *See* 21 U.S.C. § 350b; 21 U.S.C. § 331(a); *see also* FDA Draft Guidance on New Dietary Ingredient Notifications, Docket No. FDA-2011-D-0376 76, Fed. Reg. 39111 (July 5, 2011). First, Devil's Claw has long been marketed in the United States, including as "grapple" and "harpagophytum root." We have seen no comparable evidence establishing that the Substitute Plant, *i.e. Harpagophytum zeyheri*, was sold in the United States prior to 1994, except as an unwanted adulterant.[4] Second, the Substitute Plant appears to satisfy neither of the requirements for new dietary ingredients.[5]

In connection with an investigation arising under N.Y. Exec. Law § 63(12), N.Y. Gen. Bus. Law § 349, N.Y. Agric. & Mkts. Law § 8, and other authorities, we therefore request a detailed, written response to this letter within *10* business days. In addition to offering you an opportunity to respond to, or dispute any of the analysis above, we ask that your response cover the topics and incorporate the materials identified in the attached Appendix, including but not limited to:

(i) The methodology and results of any testing your company performs or has performed by a third party on the Tested Lot to independently verify the results of the NYBG study;

(ii) Your company's plans for identifying and, where appropriate, recalling any and all non-complying devil's claw supplements;

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[3] Herbs of Commerce seeks to avoid confusion in the herbal supplements marketplace by applying "a single common name in trade . . . to only one botanical name." *Id.* at I (introduction). The common name "devil's claw" perfectly illustrates the problem. Overseas and in non-commercial settings, that name has been used loosely to refer to numerous species, including the Substitute Plant as well as other wholly unrelated plants like *Pisonia aculeate*, *Proboscidea altheaefolia,* and *Senegalia greggii.*

[4] To the contrary, various sources dating back many years identify the Substitute Plant as an unwanted adulterant, which was not legally exported internationally until European standards were loosened in 2003.

[5] Like many traditional herbal supplements, Devil's Claw may be administered orally, including as a tea. This does not convert it or the Substitute Plant into a source of food for purposes of the new dietary ingredient requirements.

(iii) Your company's proposal for identifying and, where appropriate, compensating any defrauded or otherwise harmed consumers; and

(iv) Any and all new reforms your company will implement to ensure the quality and authenticity of the herbal supplements it manufactures or distributes, including new analytical testing methods.

Notwithstanding this response, we further advise you to preserve and retain any and all documents and communications concerning the subjects addressed in this letter, including but not limited to: (i) the sourcing of ingredients for devil's claw and other herbal dietary supplements; (ii) the measures used to verify the reliability of suppliers of devil's claw and other herbal ingredients; (iii) quality control for devil's claw and other herbal dietary supplements, including awareness of misidentification of herbal products and financially motivated adulteration, with respect to raw materials or finished products; (iv) the labeling and marketing of devil's claw and other herbal supplements; and (v) the manufacturing protocols and testing methods employed to ensure the accuracy of all label and marketing claims relating to the identity, purity, potency, or other characteristics of devil's claw and other herbal supplements.

Please do not hesitate to reach out to our office with any questions or concerns.

Respectfully,

Simon G. Brandler
Senior Advisor & Special Counsel
212-416-6544 / Simon.Brandler@ag.ny.gov

APPENDIX

Request for Additional Documentation and Information

With your response, please furnish the following information or documentation:

(1) For each shipment of ingredients or products your company received since January 1, 2012 that were purportedly derived, in whole or in part, from Devil's Claw and/or the Substitute Plant (the "DC Ingredients"):

a. The name, address, telephone number, email address, and other contact information for the supplier from whom your company obtained the shipment;

b. The supplier's descriptions of the content of the shipment, as they appeared on order forms, packing slips, contracts, and other written materials;

c. The date your company received the shipment;

d. The address where your company received the shipment;

e. The form in which the DC Ingredients arrived (e.g. powdered extract, cut-and-dried tubers, powdered whole herbs, etc.);

f. The address or addresses of the manufacturing facilities that produced any finished supplements containing the DC Ingredients;

g. The volume in kilograms of DC Ingredients received;

h. The total price your company paid for the DC Ingredients in the shipment in U.S. dollars; and

i. Copies of all product labels (front and back) for all supplements produced using the DC Ingredients in that shipment.

(2) Copies of all audits, reviews, or other documents or communications prepared by your company or a third party to assess the reliability of any supplier who sold DC Ingredients to your company from January 1, 2012 to the present, and a description of any other verification measures not reflected in such documents and communications;

(3) Copies of all documents and communications, including but not limited to order forms, contracts, packing slips, contracts, correspondence, or other written or electronic materials, concerning the shipment or shipments of DC Ingredients used in manufacturing the Tested Lot;

(4) A complete description of the methodology and copies of the results of any testing or analyses your company performed or had performed from January 1, 2012 to the present on DC Ingredients or on finished dietary supplements containing DC Ingredients for identity, potency, purity, or any other characteristic, along with a

statement indicating whether any such testing could distinguish between Devil's Claw and the Substitute Plant;

(5) A complete description of the testing or other measures your company undertook, is undertaking, or intends to undertake to determine the degree to which the products it sold since January 1, 2012 purporting to contain DC Ingredients were adulterated or misbranded, including but not limited to the Tested Lot;

(6) The results of any and all testing described in response to Item 5 or of any other testing performed on the Tested Lot;

(7) Copies of any and all documents or communications concerning the Tested Lot or its sale;

(8) Copies of all documents and communications your company sent to, received from, or exchanged with any employee or agent of the federal Food and Drug Administration ("FDA") since January 1, 2012 concerning inspections of the company facilities identified in response to Item 1(f) above, including but not limited to Form 483s and your company's response thereto.

(9) For each year from January 1, 2012 to the present, the total annual revenue or, for 2015, the year-to-date revenue your company received respectively from the sale of dietary supplements containing DC Ingredients in (i) retail sales in New York State; (ii) Internet sales to New York State residents; and (iii) the United States overall;

(10) A proposal for identifying and, as appropriate, compensating any purchasers of devil's claw supplements your company manufactured who may have received adulterated or misbranded products; and

(11) A complete description of improvements, safeguards, or reforms your company will implement to avoid adulteration or misbranding of herbal dietary supplements in the future, including but not limited to testing or other measures to detect and prevent the adulteration or misbranding of supplement's containing DC Ingredients.