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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

MICHELLE CHEN and JOHN DOES 1-100, *on behalf of themselves and others similarly situated*,

Plaintiffs,

-against-

OUTERNATIONAL BRANDS, INC.,

Defendant.

Case No.:

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs MICHELLE CHEN and JOHN DOES 1-100 (together, "Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, as and for their Complaint against the Defendant, OUTERNATIONAL BRANDS, INC. (hereinafter, "Defendant"), alleges the following based upon personal knowledge as to themselves and their own action, and, as to all other matters, respectfully alleges, upon information and belief, as follows (Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery):

NATURE OF THE ACTION

1. Plaintiffs, MICHELLE CHEN and JOHN DOES 1-100, on behalf of themselves and others similarly situated, by and through their undersigned attorneys, bring this class action

against Defendant, OUTERNATIONAL BRANDS, INC., for the deceptive practice of marketing the Vivaloe™ aloe vera drink products as "All Natural" and containing no preservatives when they contain citric acid, a non-natural, highly chemically processed ingredient regularly used as a preservative in juice products. Citric acid is used in all of the flavors of Defendant's Vivaloe™ 16.9 ounce and 50.7 ounce products, including:

(i) Vivaloe™ Original Aloe,
(ii) Vivaloe™ Peach Aloe,
(iii) Vivaloe™ Coconut Aloe,
(iv) Vivaloe™ Honeydew Aloe,
(v) Vivaloe™ Mango Aloe
(vi) Vivaloe™ Pink Lemonade Aloe, and
(vii) Vivaloe™ Watermelon Aloe (collectively, the "Products").

2. This case is about the deceptive manner in which the Defendant labeled, packaged and marketed its Products to the general public during the Class Period. Defendant's promotion of the Products is deceptive because it builds upon the fiction that the Products are natural, real aloe vera drinks with no added preservatives or artificial coloring whatsoever, when they are not.

3. Defendant's "All Natural" claims are deceptive. The term "All Natural" only applies to those products that contain no non-natural or synthetic ingredients and consist entirely of ingredients that are only minimally processed. Defendant, however, deceptively labeled Products as containing "No Preservatives," even though they all contain the synthetic ingredient citric acid (2-hydroxypropane-1,2,3-tricarboxylic acid), which is not extracted from citric fruits but industrially synthesized via complex chemical synthetic routes and thus cannot be considered "minimally processed."[1]

[1] *See, e.g.*, *Biotechnology in the chemical industry*, THE ESSENTIAL CHEMICAL INDUSTRY, March 18, 2013, *available at* http://www.essentialchemicalindustry.org/materials-and-applications/biotechnology-in-the-chemical-industry.html; Luciana P.S Vandenberghe et al., *Solid-state fermentation for the synthesis of citric acid by Aspergillus niger*, BIORESOURCE TECHNOLOGY, 74:2, 175–178, September 2000

4. Defendant also engaged in deceptive labeling practices by failing to disclose that the Products contain citric acid as a preservative and by expressly representing on the front label that the Products contain no preservatives. All of the Products contain citric acid, which is commonly used as preservatives in commercial juice drinks. Water containing fruit juices and essences is fertile ground for bacterial/mold growth. Without the addition of preservatives, a drink containing fruit, or in this instance, aloe vera pieces, would turn stale and moldy in a matter of days, and would certainly not last for months of the Products' shelf life.

5. By marketing the Products as having "All Natural" and containing no preservatives, Defendant wrongfully capitalized on and reaped enormous profits from consumers' strong preference for food products made entirely of natural ingredients and free of preservatives.

6. Plaintiffs bring this proposed consumer class action on behalf of themselves and all other persons nationwide, who, from the applicable limitations period up to and including the present ("Class Period"), purchased for consumption and not resale any of Defendant's Products.

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

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.;*
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.*

8. Defendant marketed its Vivaloe™ Products in a way that is deceptive to consumers under consumer protection laws of all fifty states and the District of Columbia. Defendant has been unjustly enriched as a result of its conduct. For these reasons, Plaintiffs seek the relief set forth herein.

JURISDICTION AND VENUE

9. 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).

10. The Court has jurisdiction over the federal claims alleged herein pursuant to 28 U.S.C. § 1331 because it arises under the laws of the United States.

11. The Court has jurisdiction over the state law claims because they form part of the same case or controversy under Article III of the United States Constitution.

12. 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.

13. The Court has personal jurisdiction over Defendant because its Products are advertised, marketed, distributed, and sold throughout New York State; Defendant engaged in the wrongdoing alleged in this Complaint throughout the United States; including in 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 is engaged in substantial and not isolated activity within New York State.

14. Pursuant to 28 U.S.C. § 1391, this Court is the proper venue for this action because a substantial part of the events, omissions, and acts giving rise to the claims herein occurred in this District. Plaintiff CHEN is a citizen of New York and has purchased the Products from Defendant in this District. Moreover, Defendant distributed, advertised, and sold the Products, which are the subject of the present Complaint, in this District.

PARTIES

Plaintiffs

15. Plaintiff MICHELLE CHEN is, and at all times relevant hereto has been, a citizen of the State of New York and resides in Kings County. During the Class Period, Plaintiff CHEN purchased numerous Vivaloe™ Products, including the Vivaloe™ Original Aloe Product, for personal consumption within the State of New York. Plaintiff CHEN purchased the Products in bulk from Amazon.com. The purchase price was $24.95 (or more) for a box of twelve Products. Plaintiff CHEN substantially relied on Defendant's "All Natural" and "Free of Preservatives" claims in deciding to purchase the Products. Plaintiff CHEN purchased the Products at a premium price and was financially injured as a result of Defendant's deceptive conduct as alleged herein. Further, should Plaintiff CHEN encounter the Product in the future, she could not rely on the truthfulness of the packaging, absent corrective changes to the packaging. However, Plaintiff CHEN would still be willing to purchase the current formulation of the Product, absent the price premium, so long as Defendant engages in corrective advertising.

16. Plaintiffs JOHN DOES 1-100 are, and at all times relevant hereto has been, citizens of the any of the fifty states and the District of Columbia. During the Class Period, Plaintiffs

JOHN DOES 1-100 purchased the Products for personal consumption or household use within the United States. Plaintiffs purchased the Products at a premium price and were financially injured as a result of Defendant's deceptive conduct as alleged herein.

Defendant

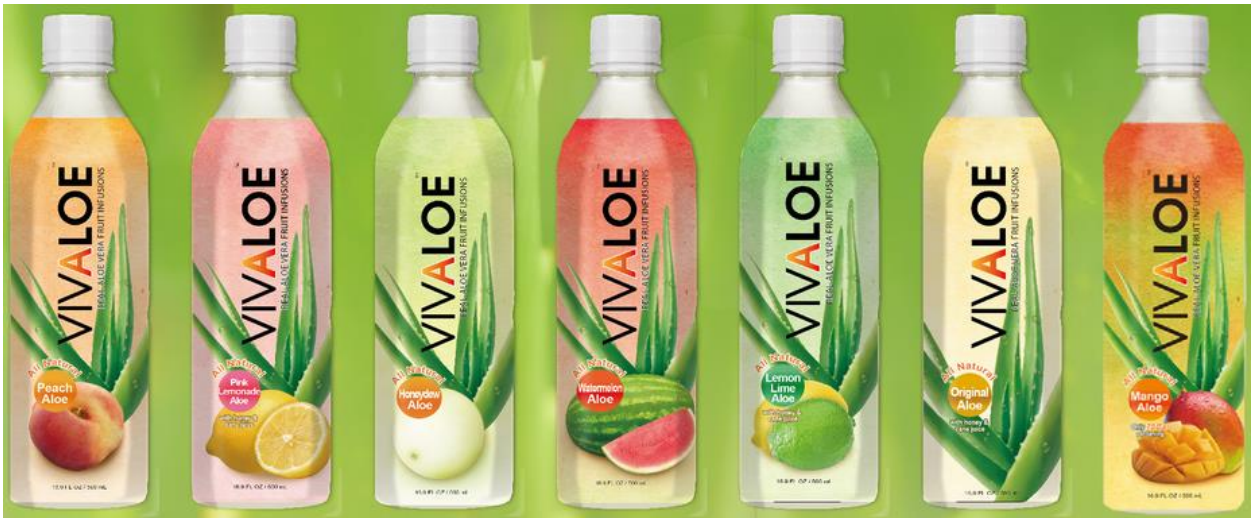
17. Defendant OUTERNATIONAL BRANDS, INC. is a foreign business corporation organized under the laws of Delaware with a principal executive office and an address for process at 234 Birch Drive, Roslyn, NY 11576. Outernational markets, distributes and sells beverage products under the brand Vivaloe™, which includes the Vivaloe™ Products.

18. Defendant distributes, markets and sells juice drink products throughout the fifty states and the District Columbia. The labeling, packaging, and advertising for the Vivaloe™ Products, relied upon by Plaintiffs, were prepared and/or approved by Defendant and its agents, and were disseminated by Defendant and its agents through advertising containing the misrepresentations alleged herein. Such labeling, packaging and advertising were designed to encourage consumers to purchase the Products and reasonably misled the reasonable consumer, i.e. Plaintiffs and the Class, into purchasing the Products. Defendant owned, marketed and distributed the Products, and created and/or authorized the unlawful, fraudulent, unfair, misleading and/or deceptive labeling, packaging and advertising for the Products.

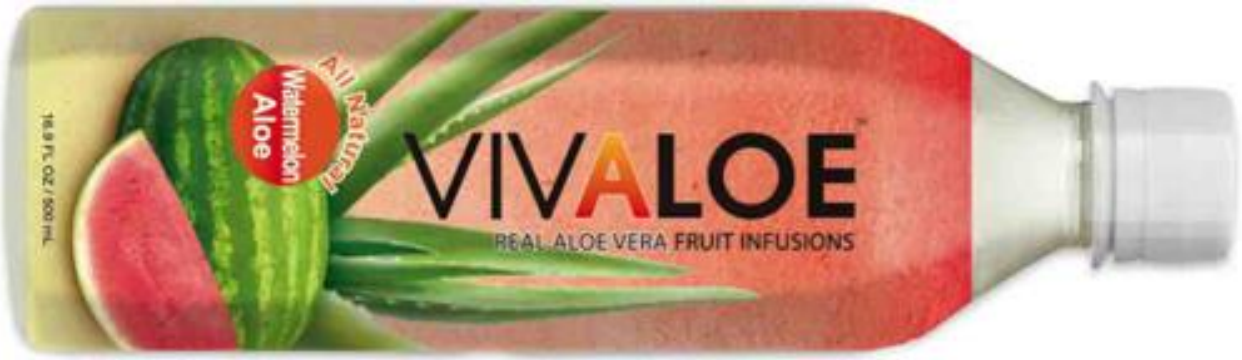
FACTUAL ALLEGATIONS

Vivaloe™ Aloe Drinks

19. Defendant markets the Viavloe™ Products under the brand name Vivaloe™. The Products are ready-to-drink aloe vera-based beverage products available at many supermarket chains, online retailers and other retail outlets throughout the United States, including but not limited to Amazon, Whole Foods, and Walgreens.



An enlarged version of the packaging of the watermelon-flavored Product is shown below:



20. Defendant has consistently conveyed the very specific message to consumers throughout the United States, including Plaintiffs and Class members, that the Products are "All Natural" and contain "No Preservatives," that it is a "Real Aloe Vera" drink with neither preservatives nor artificial coloring. Defendant would have the consumers to believe that, basically, drinking the Product is extremely beneficial as it contains "16 amino acids and 20 minerals with numerous health benefits."

Deceptive Labeling and Advertising

21. Defendant's misleading marketing campaign begins with its representations on the label of its Products, that the Product is "All Natural" and contains "No Preservatives." Such verbal representations, combined with images of fresh aloe and fruit (depending on the product

flavor) imply that the Products are fresh and contain natural fruit juices. Defendant's exhaustive advertising campaign builds on this deception.

Defendant's All Natural Claims Violate Identical State and Federal Law

22. Defendant's labeling and advertising of the Products as "All Natural" violate various state and federal laws against misbranding.

23. The federal Food, Drug, and Cosmetic Act (the "FDCA") provides that "[a] food shall be deemed misbranded – (a) (1) its labeling is false or misleading in any particular." 21 U.S.C. § 343 (a)(1).

24. Defendant's "All Natural" claim also violates various state laws against misbranding which mirror federal law. New York and other state law broadly prohibit the misbranding of food in language identical to that found in regulations promulgated pursuant to the FDCA, 21 U.S.C. §§ 343 *et seq.*:

> Pursuant to N.Y. Agm. Law § 201, "[f]ood shall be deemed to be misbranded: 1. If its labeling is false or misleading in any particular… ."

25. Under the FDCA, the term "false" has its usual meaning of "untruthful," while the term "misleading" is a term of art. Misbranding reaches not only false claims, but also those claims that might be technically true, although still misleading. If any one representation in the labeling is misleading, the entire food is misbranded. No other statement in the labeling cures a misleading statement. "Misleading" is judged in reference to "the ignorant, the unthinking and the credulous who, when making a purchase, do not stop to analyze." *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951). Under the FDCA, it is not necessary to prove that anyone was actually misled.

Definition of Natural

26. The FDA did not intend to and has repeatedly declined to establish a final rule with regard to a definition of the term "All Natural" in the context of food labeling. As such, Plaintiffs' state consumer protection law claims are not preempted by federal regulations. See *Jones v. ConAgra Foods, Inc.*, 2012 WL 6569393, *6 (N.D. Cal. Dec. 17, 2012). Additionally, the primary jurisdiction doctrine does not apply "because the FDA has repeatedly declined to adopt formal rule-making that would define the word 'natural.'" *Id.* at p. 8.

27. The "FDA has not developed a definition for use of the term natural or its derivatives," but it has loosely defined the term "All Natural" as a product that "does not contain added color, artificial flavors, or synthetic substances." According to federal regulations, an ingredient is synthetic if it is:

> [a] substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes. 7 C.F.R. §205.2.

28. Although there is not an exact definition of "All Natural" in reference to food, cosmetic or oral care ingredients, there is no reasonable definition of "All Natural" that includes ingredients that, even if sourced from "nature," are subjected to extensive transformative chemical processing before their inclusion in a product. For example, the National Advertising Division of the Better Business Bureau ("NAD") has found that a "All Natural" ingredient does not include one that, while "literally sourced in nature (as is every chemical substance), . . . is, nevertheless subjected to extensive processing before metamorphosing into the" ingredient that is included in the final product.

Citric Acid Is Not a Natural Ingredient

29. Citric acid (2-hydroxy-propane-1,2,3-tricarboxylic acid) is a synthetic, non-natural ingredient. While the chemical's name has the word "citric" in it, citric acid is no longer extracted from the citrus fruit but industrially manufactured by fermenting certain genetically mutant strains of the black mold fungus, *Aspergillus niger*.[2]

30. A technical evaluation report for the substance citric acid compiled by the United States Department of Agriculture, Agricultural Marketing Service ("USDA AMS") for the National Organic Program classified citric acid as "Synthetic Allowed". *See* **EXHIBIT A**, Page 4, *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067876. As one of the USDA AMS reviewers commented,

> "[Citric acid] is a natural[ly] occurring substance that commercially goes through numerous chemical processes to get to [its] final usable form. This processing would suggest that it be classified as synthetic." *Id.* at 3.

The report further explains, under the "How Made" question, that citric acid is made –

> "Traditionally by extraction from citrus juice, no longer commercially available. It is now extracted by fermentation of a carbohydrate substrate (often molasses) by citric acid bacteria, *Aspergillus niger* (a mold) or *Candida guilliermondii* (a yeast). Citric acid is recovered from the fermentation broth by a lime and sulfuric acid process in which the citric acid is first precipitated as a calcium salt and then reacidulated with sulfuric acid." *Id.* at 4.

31. Because citric acid is a synthetic acid and cannot be reasonably considered a natural ingredient, Defendant's claim that the Products are "All Natural" is false, deceptive, and misleading, and the Products are misbranded under federal and state law.

[2] *See, e.g.*, Belén Max, et al., *Biotechnological production of citric acid*, BRAZILIAN JOURNAL OF MICROBIOLOGY, 41.4 São Paulo (Oct./Dec. 2010).

Defendant's No Preservatives Claims Violate Identical State and Federal Law

32. Defendant's labeling, packaging and marketing practices are deceptive and or misleading because the Products fail to disclose that the citric acid is used as a preservative and/or that the Products prominently represent on the front label, that they contain "No Preservatives." All Products use citric acid (2-hydroxypropane-1,2,3-tricarboxylic acid), a non-natural, highly chemically processed ingredients regularly used as preservatives (due to their acidic pH level which creates an environment where bacteria cannot thrive) in many drink products.

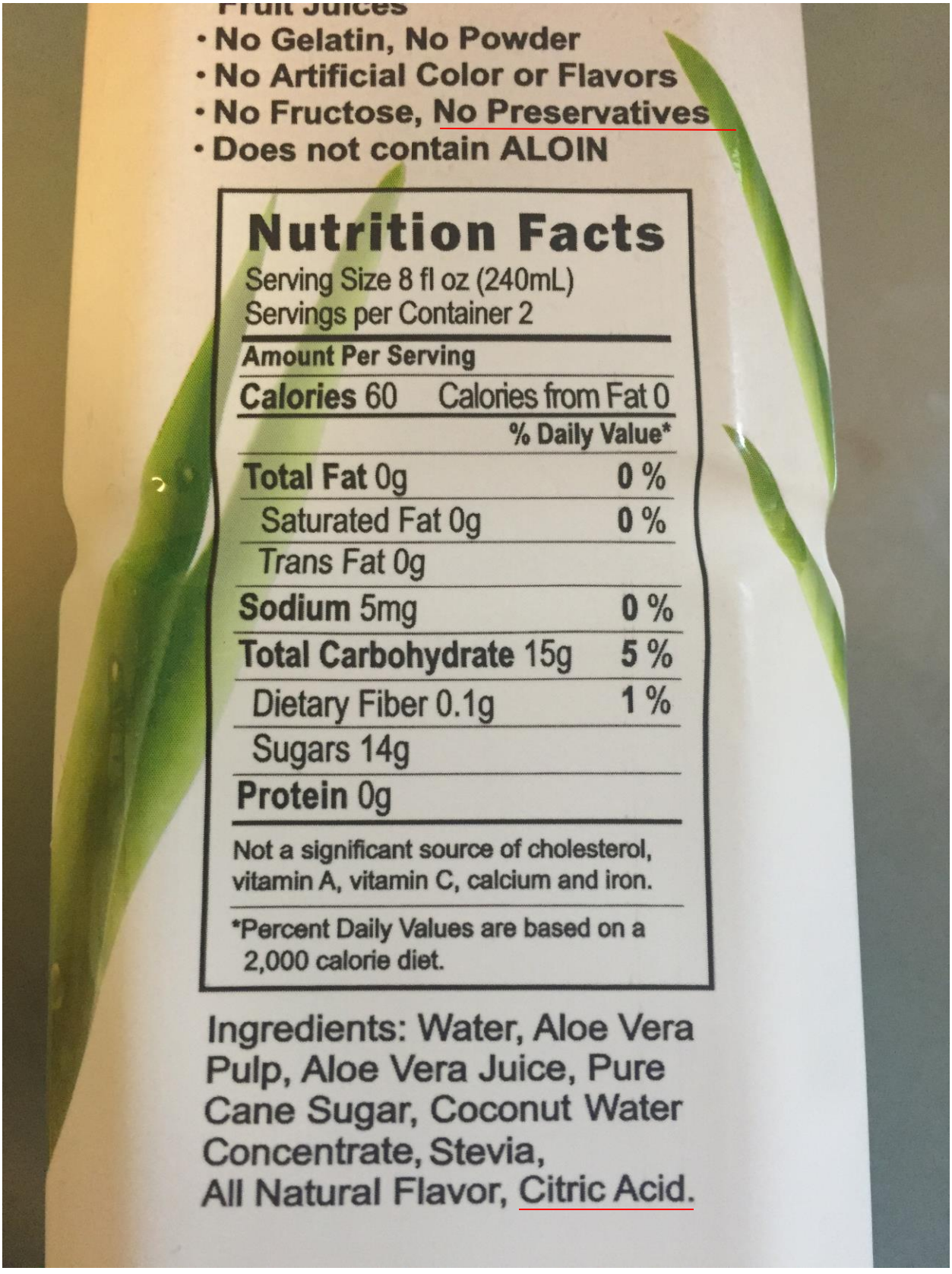
33. The FDCA provides that "[a] food shall be deemed misbranded – (a) (1) its labeling is false or misleading in any particular, or … (k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, *unless* it bears labeling stating that fact… ." 21 U.S.C. §§ 343 (a)(1), 343 (k).

34. Defendants' packaging and advertising of the Products also violate various state laws against misbranding which mirror federal law. New York state law broadly prohibit the misbranding of food in language identical to that found in regulations promulgated pursuant to the FDCA, 21 U.S.C. §§ 343 *et seq.*:

> Pursuant to N.Y. Agm. Law § 201, "[f]ood shall be deemed to be misbranded: 1. If its labeling is false or misleading in any particular…11. If it bears or contains any artificial flavoring, artificial coloring, or permitted chemical preservative, unless it bears labeling stating that fact."

35. The term "chemical preservative" means "any chemical that, when added to food tends to prevent or retard deterioration thereof[.]" 2l C.F.R. § 101.22(a)(5).

36. While citric acid is listed in the fine print on the label of the Product in the list of ingredients (see below), Defendant deliberately made no mention of the function of the citric acid in violation of state and federal laws:


Fruit Juices
• No Gelatin, No Powder
• No Artificial Color or Flavors
• No Fructose, No Preservatives
• Does not contain ALOIN
Nutrition Facts
Serving Size 8 fl oz (240mL)
Servings per Container 2
Amount Per Serving
Calories 60 Calories from Fat 0
% Daily Value*
Total Fat 0g 0 %
Saturated Fat 0g 0 %
Trans Fat 0g
Sodium 5mg 0 %
Total Carbohydrate 15g 5 %
Dietary Fiber 0.1g 1 %
Sugars 14g
Protein 0g
Not a significant source of cholesterol, vitamin A, vitamin C, calcium and iron.
*Percent Daily Values are based on a 2,000 calorie diet.
Ingredients: Water, Aloe Vera Pulp, Aloe Vera Juice, Pure Cane Sugar, Coconut Water Concentrate, Stevia, All Natural Flavor, Citric Acid.

37. The U.S. Food and Drug Administration ("FDA") routinely required that food manufacturers disclose the fact that citric acid is used as a preservative. In a Warning Letter dated October 6, 2010, the FDA warned the manufacturers of the Chiquita brand "Pineapple Bites with Coconut" and "Pineapple Bites" products, that they are in violation of the FDCA and the federal regulations promulgated pursuant to the FDCA:

> "The 'Pineapple Bites' and 'Pineapple Bites with Coconut' products are further misbranded within the meaning of section 403(k) of the Act [21 U.S.C. 343(k)] in that they contain the chemical preservatives ascorbic acid and citric acid but their labels fail to declare these preservatives with a description of their functions. 21 CFR 101.22."

See **EXHIBIT B**, FDA Warning Letter dated October 6, 2010 (emphasis added).

38. Defendant's misleading labeling practices go even further. Apart from not having disclosed the function of the citric acid, Defendant expressly labeled the Products as "Free from Preservatives" on the Product label, even though such was patently false.

39. Because the Products similarly contain citric acid and Defendant similarly "fail[ed] to declare [such] preservative with a description of [its] functions," *see id.*, and because the Products are expressly labeled as containing "No Preservatives, " the Products are misbranded food under the FDCA and state laws which incorporate by reference federal food labeling regulations. 21 U.S.C. §§ 343(a)(1), 343(k); N.Y. Agm. Law § 201; California Health and Safety Code §§ 110660, 110740.

The Impact of Defendant's Deceptive Conduct

40. By representing the Products as "All Natural" and containing "No Preservatives" Defendant sought to capitalize on consumers' preference for natural Products with no preservatives and the association between such Products and a wholesome way of life. Consumers are willing to pay more for natural Products because of this association as well as the perceived higher quality, health and safety benefits and low impact on the environment.

41. As a result of Defendant's deception, consumers – including Plaintiffs and members of the proposed Class – have purchased Products that claimed to be "All Natural" and "Free from Preservatives." Moreover, Plaintiffs and Class members have paid a premium for the Products over other aloe vera beverage products sold on the market.

42. Although Defendant represented that the Products are "All Natural" and contain "No Preservatives", they failed to also disclose material information about the Products; the fact that they contained unnatural, synthetic, and/or artificial ingredients which is used as a preservative. This non-disclosure, while at the same time branding the Products as "All Natural" and containing "No Preservatives" was deceptive and likely to mislead a reasonable consumer, including Plaintiffs and Class members.

43. A representation that a product is "All Natural" and "No Preservatives" is material to a reasonable consumer when deciding to purchase a product.

44. Plaintiffs did, and a reasonable consumer would, attach importance to whether Defendant's Products are "misbranded," i.e., not legally salable, or capable of legal possession, and/or contain highly processed ingredients.

45. Plaintiffs did not know, and had no reason to know, that the Products were not "All Natural," nor contain "No Preservatives."

46. Defendant's Product labeling and misleading online and otherwise marketing campaign was a material factor in Plaintiffs' and Class members' decisions to purchase the Products. Relying on Defendant's deceptive and/or misleading Product labeling and other promotional material, Plaintiffs and Class members believed that they were getting Products that and were "All Natural" and contain "No Preservatives." Had Plaintiffs known the truth about Defendant's Products, they would not have purchased them.

47. Defendant's Product labeling as alleged herein is deceptive and misleading and was designed to increase sales of the Products. Defendant's misrepresentations are part of their systematic Product packaging practice.

48. At the point of sale, Plaintiffs and Class members did not know, and had no reason to know, that the Products were misbranded as set forth herein, and would not have bought the Products had they known the truth about them.

49. Defendant's false and deceptive labeling is misleading and in violation of the FDCA, food labeling laws and consumer protection laws of each of the fifty states and the District of Columbia, and the Products at issue are misbranded as a matter of law. Misbranded products cannot be legally manufactured, advertised, distributed, held or sold in the United States. Plaintiffs and Class members would not have bought the Products had they known they were misbranded and illegal to sell or possess.

50. As a result of Defendant's misrepresentations, Plaintiffs and thousands of others throughout the United States purchased the Products.

51. Plaintiffs and the Class (defined below) have been damaged by Defendant's deceptive and unfair conduct in that they purchased Products with false and deceptive labeling and paid premium prices they otherwise would not have paid over other comparable products that did not claim to contain to be free of preservatives The following table indicates that the Products are sold at a premium price over other brand name aloe vera beverage products:

Brand	Product	Size	Price[3]
ALO	Exposed Aloe Vera Beverage, Honey	16.9 fluid ounce (pack of 12)	$1.69/bottle
AloeCure	Pomegranate Aloe Vera Drink	16.9 fluid ounce (pack of 12)	$2.00/bottle
Vivaloe	**Mango Flavor Aloe Beverage**	**16.9 fluid ounce (pack of 12)**	**$2.08/bottle**

Plaintiffs Were Injured as a Result of Defendant's Misleading and Deceptive Conduct

52. Defendant's labeling as alleged herein is false and misleading and was designed to increase sales of the Products at issue. Defendant's misrepresentations are part of their systematic labeling practice.

53. Plaintiffs and Class members were exposed to and relied on Defendant's labeling and packaging. At the time of purchase, Plaintiffs and Class members read the labels on Defendant's Products, including labels which represented that the Products were "All Natural" and contain "No Preservatives."

54. Defendant's labeling claims were a material factor in Plaintiffs and Class members' decisions to purchase the Products. Based on Defendant's claims, Plaintiffs and Class members believed that the Products were a better and healthier choice than other available aloe vera juice products.

55. Plaintiffs and Class members did not know that the Products were not "All Natural" nor contain "No Preservatives." Plaintiffs and Class members would not have bought the purchased Products had they known that the Products all contain citric acid, which is highly processed, industrially produced and used as a preservative.

56. Plaintiffs and Class members were exposed to these misrepresentations prior to purchase and relied on them. As a result of such reliance, Plaintiffs and Class members deemed

[3] Pricing information obtained from www.amazon.com as of June 9, 2015.

the Products to be more preferable to other products which do not claim to be "All Natural" or contain "No Preservatives." Plaintiffs and Class members would not have bought the Products had they not been misled by Defendant's misrepresentations into believing that the Products were better and healthier than they were.

57. At the point of sale, Plaintiffs and Class members did not know, and had no reason to know, that Defendant's Products were misbranded as set forth herein, and would not have bought the Products had they known the truth about them.

58. As a result of Defendant's misrepresentations, Plaintiffs and thousands of others throughout the United States purchased the Products.

59. Defendant's labeling, advertising, and marketing as alleged herein is false and misleading and designed to increase sales of the Products. Defendant's misrepresentations are a part of an extensive labeling and advertising campaign, and a reasonable person would attach important to Defendant's representations in determining whether to purchase the Products at issue. Plaintiffs and Class members would not have purchased Defendant's misbranded Products had they known they were misbranded.

60. Plaintiffs and the Class (defined below) have been damaged by Defendant's deceptive and unfair conduct in that they purchased Products with false and deceptive labeling and paid premium prices they otherwise would not have paid over other comparable products that did not claim to be "All Natural" and contain "No Preservatives."

CLASS ACTION ALLEGATIONS

The Nationwide Class

61. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of the following class (the "Class"):

> All persons or entities in the United States who made retail purchases of the Products during the applicable limitations period, and/or such subclasses as the Court may deem appropriate.

The New York Class

62. Plaintiff CHEN seeks to represent a class consisting of the following subclass (the "New York Class"):

> All New York residents who made retail purchases of the Products during the applicable limitations period, and/or such subclasses as the Court may deem appropriate.

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, and any entity in which they have or have had a controlling interest, and the judicial officer to whom this lawsuit is assigned.

63. Plaintiffs reserve the right to revise the Class definition based on facts learned in the course of litigating this matter.

64. 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 Plaintiffs at this time, Plaintiffs are informed and believe that there are thousands of Class members. Thus, the Class is so numerous that individual joinder of all Class members is impracticable.

65. 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 only individual Class members and include:

a. whether labeling "All Natural" on Products containing one or more highly processed ingredients, including citric acid, was false and misleading;

b. whether labeling "No Preservatives" and failing to disclose that the Products used preservatives on Products containing one or more highly processed preservatives, such as citric acid,was false and misleading;

c. whether Defendant engaged in a marketing practice intended to deceive consumers by labeling Products as "All Natural" and without preservatives, even though such Products contained one or more highly processed ingredients, including citric acid;

d. whether Defendant deprived Plaintiffs and the Class of the benefit of the bargain because the Products purchased were different than what Defendant warranted;

e. whether Defendant deprived Plaintiffs and the Class of the benefit of the bargain because the Products they purchased had less value than what was represented by Defendant;

f. whether Defendant caused Plaintiffs and the Class to purchase a substance that was other than what was represented by Defendant;

g. whether Defendant caused Plaintiffs and the Class to purchase Products that were artificial, synthetic, or otherwise unnatural;

h. whether Defendant have been unjustly enriched at the expense of Plaintiffs and other Class members by its misconduct;

i. whether Defendant must disgorge any and all profits they have made as a result of its misconduct; and

j. whether Defendant should be enjoined from marketing the Products as "All Natural" and containing "No Preservatives," and whether Defendant should be required to disclose the fact that an ingredient was used as a preservative.

66. Plaintiffs' claims are typical of those of the Class members because Plaintiffs and the other Class members sustained damages arising out of the same wrongful conduct, as detailed herein. Plaintiffs purchased Defendant's Products and sustained similar injuries arising out of Defendant's conduct in violation of 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 wrongful misconduct. 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 members of the Class. Plaintiffs' claims arise from the same practices and course of conduct that give rise to the claims of the members of the Class and are based on the same legal theories.

67. Plaintiffs will fairly and adequately represent and pursue the interests of the Class and have retained competent counsel experienced in prosecuting nationwide class actions. Plaintiffs understand the nature of their claims herein, have no disqualifying conditions, and will vigorously represent the interests of the Class. Neither Plaintiffs nor Plaintiffs' counsel have any interests that conflict with or are antagonistic to the interests of the Class. Plaintiffs have retained highly competent and experienced class action attorneys to represent their interests and those of the Class. Plaintiffs and Plaintiffs' counsel have the necessary financial resources to adequately

and vigorously litigate this class action, and Plaintiffs and counsel are aware of their fiduciary responsibilities to the Class and will diligently discharge those duties by vigorously seeking the maximum possible recovery for the Class.

68. 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.

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

70. 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 Class 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.

71. 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.

72. Defendant's conduct is generally applicable to the Class as a whole and Plaintiffs seek, *inter alia*, equitable remedies with respect to the Class as a whole. As such, Defendants' 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)

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

74. Plaintiff CHEN brings this claim on behalf of herself and the other members of the Class for an injunction for violations of New York's Deceptive Acts or Practices Law, General Business Law § 349 ("NY GBL").

75. 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."

76. Under the § 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 plaintiff 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)).

77. Any person who has been injured by reason of any violation of the NY GBL 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.

78. The practices employed by Defendant, whereby Defendant labeled, packaged, and marketed their Products as "All Natural" and contain "No Preservatives" were unfair, deceptive, and misleading and are in violation of the NY GBL § 349.

79. The foregoing deceptive acts and practices were directed at customers.

80. Defendant should be enjoined from labeling its Products as "All Natural" and containing "No Preservatives," and should be required to disclose that one or more ingredients were used as preservatives, as described above pursuant to NY GBL § 349.

81. Plaintiff CHEN, on behalf of herself 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, and such other relief as this Court deems just and proper.

COUNT II

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

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

83. Plaintiff CHEN brings this claim on behalf of herself and the other members of the Class for violations of NY GBL § 349.

84. By the acts and conduct alleged herein, Defendant committed unfair or deceptive acts and practices by misbranding its Products as "All Natural" and "No Preservatives."

85. The practices employed by Defendant, whereby Defendant advertised, promoted, and marketed that its Products are "All Natural" and "No Preservatives" were unfair, deceptive, and misleading and are in violation of NY GBL § 349.

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

87. Plaintiff CHEN and the other Class members suffered a loss as a result of Defendant's deceptive and unfair trade acts. Specifically, as a result of Defendant's deceptive and unfair trade acts and practices, Plaintiff CHEN and the other Class members suffered monetary losses associated with the purchase of Products, *i.e.*, the purchase price of the Product and/or the premium paid by Plaintiff CHEN and the Class for said Products.

COUNT III

NEGLIGENT MISREPRESENTATION
(All States)

88. Plaintiffs reallege and incorporate by reference the allegations contained in all preceding paragraphs, and further allege as follows:

89. Defendant, directly or through its agents and employees, made false representations, concealments, and nondisclosures to Plaintiffs and members of the Class.

90. In making the false, misleading, and deceptive representations and omissions, Defendant knew and intended that consumers would pay a premium for Products labeled as "All Natural" and "No Preservatives" over comparable products that are not so labelled, furthering Defendant's private interest of increasing sales for its Products and decreasing the sales of products that are truthfully offered as "All Natural" and containing "No Preservatives" by Defendant's competitors, or those that do not claim to be "All Natural" nor free of preservatives.

91. As an immediate, direct, and proximate result of Defendant's false, misleading, and deceptive representations and omissions, Defendant injured Plaintiffs and the other Class members in that they paid a premium price for Products that were not as represented.

92. In making the representations of fact to Plaintiffs and members of the Class described herein, Defendant has failed to fulfill its duties to disclose the material facts set forth above. The direct and proximate cause of this failure to disclose was Defendant's negligence and carelessness.

93. Defendant, in making the misrepresentations and omissions, and in doing the acts alleged above, knew or reasonably should have known that the representations were not true. Defendant made and intended the misrepresentations to induce the reliance of Plaintiffs and members of the Class.

94. Plaintiffs and members of the Class relied upon these false representations and nondisclosures by Defendant when purchasing the Products, upon which reliance was justified and reasonably foreseeable.

95. As a result of Defendant's wrongful conduct, Plaintiffs and members of the Class have suffered and continue to suffer economic losses and other general and specific damages, including but not limited to the amounts paid for the Products and any interest that would have been accrued on those monies, all in an amount to be determined according to proof at time of trial.

COUNT IV

BREACH OF EXPRESS WARRANTIES
(All States)

96. Plaintiffs reallege and incorporate by reference the allegations contained in all preceding paragraphs, and further allege as follows:

97. Defendant provided Plaintiffs and other members of the Class with written express warranties, including, but not limited to, warranties that their Products are "All Natural" and "No Preservatives."

98. This breach resulted in damages to Plaintiffs and the other members of the Class who bought Defendant's Products but did not receive the goods as warranted in that the Products were not as healthy nor as pure as they appear to be.

99. As a proximate result of Defendant's breach of warranties, Plaintiffs and the other Class members have suffered damages in an amount to be determined by the Court and/or jury, in that, among other things, they purchased and paid for Products that did not conform to what Defendant promised in its promotion, marketing, advertising, packaging and labeling, and they were deprived of the benefit of their bargain and spent money on products that did not have any value or had less value than warranted or products that they would not have purchased and used had they known the true facts about them.

COUNT V

UNJUST ENRICHMENT
(All States)

100. Plaintiffs reallege and incorporate by reference the allegations contained in all preceding paragraphs, and further allege as follows:

101. As a result of Defendant's deceptive, fraudulent and misleading labeling, packaging, advertising, marketing and sales of Products, Defendant was enriched, at the expense of Plaintiffs and members of the Class, through the payment of the purchase price for Defendant's Products.

102. Plaintiffs and members of the Class conferred a benefit on Defendant through purchasing the Products, and Defendant has knowledge of this benefit and has voluntarily accepted and retained the benefits conferred on it.

103. Defendant will be unjustly enriched if it is allowed to retain such funds, and each Class member is entitled to an amount equal to the amount they enriched Defendant and for which Defendant have been unjustly enriched.

104. Under the circumstances, it would be against equity and good conscience to permit Defendant to retain the ill-gotten benefits that it received from Plaintiffs, and all others similarly situated, in light of the fact Defendant has misrepresented that the Products are "All Natural" and "No Preservatives," when in fact, the Products contain synthetic, unnatural ingredients such as citric acid, which is used as a preservative.

105. Defendant profited from its unlawful, unfair, misleading, and deceptive practices and advertising at the expense of Plaintiffs and Class members, under circumstances in which it would be unjust for Defendant to be permitted to retain said benefit.

106. Plaintiffs have standing to pursue this claim as Plaintiffs have suffered injury in fact and has lost money or property as a result of Defendant's actions, as set forth herein. Defendant is aware that the claims and/or omissions that it made about the Products are false, misleading, and likely to deceive reasonable consumers, such as Plaintiffs and members of the Class.

107. Plaintiffs and Class members do not have an adequate remedy at law against Defendant (in the alternative to the other causes of action alleged herein).

108. Accordingly, the Products are valueless such that Plaintiffs and Class members are entitled to restitution in an amount not less than the purchase price of the Products paid by Plaintiffs and Class members during the Class Period.

109. Plaintiffs and Class members are entitled to restitution of the excess amount paid for the Products, over and above what they would have paid if the Products had been adequately advertised, and Plaintiffs and Class members are entitled to disgorgement of the profits Defendant derived from the sale of the Products.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, seek judgment against Defendant, as follows:

A. For an order certifying the nationwide Class and under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as representatives of the Class and Plaintiffs' attorneys as Class Counsel to represent members of the Class;

B. For an order declaring the Defendant's conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiffs and the nationwide Class;

D. For compensatory and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief;

G. For injunctive relief as pleaded or as the Court may deem proper;

H. For an order awarding Plaintiffs and the Class their reasonable attorneys' fees and expenses and costs of suit; and

I. Any other relief the Court may deem appropriate.

DEMAND FOR TRIAL BY JURY

Plaintiffs, on behalf of themselves and all others similarly situated, hereby demand a jury trial on all claims so triable.

Dated: April 4, 2016

Respectfully submitted,

LEE LITIGATION GROUP, PLLC
C.K. Lee (CL 4086)
Anne Seelig (AS 3976)
30 East 39th Street, Second Floor
New York, NY 10016
Tel.: 212-465-1188
Fax: 212-465-1181
Attorneys for Plaintiffs and the Class

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

EXHIBIT A

Non 5
Syn 5

allowed

NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: **Citric Acid**

CATEGORY: Synthetic Allowed **Complete?:** 3/16

✓ **NOSB Database Form**

✓ **References**

✓ **MSDS (or equivalent)**

✓ **FASP (FDA)**

✓ **Date file mailed out:** 1/8/95

✓ **TAP Reviews from:** Steve Taylor
Steven Harper
Bob Durst

Supplemental Information:

Microbial form only ...
because of substrate might be
ag product

MISSING INFORMATION: _____

NOSB/NATIONAL LIST COMMENT FORM/BALLOT

Use this page to write down comments and questions regarding the data presented in the file of this National List material. Also record your planned opinion/vote to save time at the meeting on the National List.

Name of Material Citric Acid

Type of Use: ____ **Crops;** ____ **Livestock;** ✓ **Processing**

TAP Review by:

1. Steve Taylor
2. Steven Harper
3. Bob Durst

Comments/Questions:

My Opinion/Vote is:

Signature _____ **Date** _____

USDA/TAP REVIEWER COMMENT FORM

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Attach additional sheets if you wish.

This file is due back to us within 30 days of: Jan 7

Name of Material: Citric Acid

Reviewer Name: Steve Taylor

Is this substance Natural or Synthetic? Explain (if appropriate)

Natural

Please comment on the accuracy of the information in the file:

This material should be added to the National List as:

____ **Synthetic Allowed** ____ **Prohibited Natural**

or, ____ **This material does not belong on the National List because:**

Are there any restrictions or limitations that should be placed on this material by use or application on the National List?

Made by fermentation. Fermentation is natural but process does ~~not~~ involve use of other substances: substrates: corn syrup, sucrose ammonium bicarbonate

Any additional comments or references?

Need to find out more about process and processing aids to make determination.

Signature Steve Taylor **Date** 3-5-95

2.

USDA/TAP REVIEWER COMMENT FORM

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Attach additional sheets if you wish.

This file is due back to us within 30 days of: Jan 7

Name of Material: Citric Acid

Reviewer Name: Steven Harper

Is this substance Natural or Synthetic? Explain (if appropriate)

Synthetic

Please comment on the accuracy of the information in the file:

Good

This material should be added to the National List as:

__x__ **Synthetic Allowed** ____ **Prohibited Natural**

or, ____ **This material does not belong on the National List because:**

Are there any restrictions or limitations that should be placed on this material by use or application on the National List?

No.

Any additional comments or references?

Signature Steven Harper **Date** 3/10/95

3.

USDA/TAP Reviewer Comment Form

Material: Citric acid

Reviewer: Bob Durst

Is this substance Natural or Synthetic? Explain (if appropriate)

It is a natural occurring substance that commercially goes through numerous chemical processes to get to it's final usable form. This processing would suggest that it be classified as synthetic.

Please comment on the accuracy of the information in the file:

The file is accurate.

This material should be added to the National List as:

__X__ Synthetic Allowed,

_____ Prohibited Natural, or

_____ This material does not belong on the National List because:

Are there any restriction or limitations that should be placed on this material by use or application on the National List?

Must be listed on the ingredient label if it used used.

Unless it is actually derived from a natural source the labeling must not indicate that it is a natural compound.

Any additional comments or references?

As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic element concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adopted.

Since citrus juices are a high natural source of citric acid, it might be advisable to find a manufacturer that is willing to isolate citric acid from organically grown fruit in an organically acceptable manner, and get a natural citric acid.

Signature Robert W. Durst Date 3/4/95

NOSB Materials Database

4.

Identification

Common Name	**Citric Acid**	**Chemical Name**	B-hydroxy-tricarboxylic acid C6H8O7
Other Names	Citric Acid, Anhydrous USP/FCC		
Code #: CAS	77-92-9	**Code #: Other**	21 CFR 182-1033
N. L. Category	Synthetic Allowed	**MSDS**	◉ yes ○ no

Chemistry

Family	Aliphatic Acid
Composition	$C_6H_8O_7$
Properties	Colorless, translucent crystals, (or) white granular to fine crystalline powder, odorless, strong acid taste.
How Made	Traditionally by extraction from citrus juice, no longer commercially available. It is now extracted by fermentation of a carbohydrate substrate (often molasses) by citric acid bacteria, *Aspergillus niger* (a mold) or *Candida guilliermondii* (a yeast). Citric acid is recovered from the fermentation broth by a lime and sulfuric acid process in which the citric acid is first precipitated as a calcium salt and then reacidulated with sulfuric acid.

Use/Action

Type of Use	Processing
Specific Use(s)	Production of fruit products, juices, oils, fats etc. for pH control, flavor enhancer, flavoring agent or adjuvant, leavening agent, sequestrant, antioxidant, solvent, antimicrogial agent, surface-active agent.
Action	Optimizes stability of frozen foods by enhancing the action of antioxidants and inactivating enzymes. Brings out flavor in carbonated beverages. Acts as a synergist for antioxidants employed in inhibiting rancidity in foods containg fats and oils.
Combinations	pure substance

Status

OFPA	
N. L. Restriction	Currently considered synthetic by NOSB.
EPA, FDA, etc	FDA -GRAS
Directions	
Safety Guidelines	Eye irritant, dust may cause mild respiratory irritation.
State Differences	
Historical status	Always been allowed in organic processing and considered natural.
Internationl status	Allowed by IFOAM, EU and Codex.

NOSB Materials Database

5.

OFPA Criteria

2119(m)1: chemical interactions **Not Applicable**

2119(m)2: toxicity & persistence **Not Applicable**

2119(m)3: manufacture & disposal consequences

Microbial fermentation --Clarification --Precipitation --Dissolution --Crystallization --Drying --Sifting --packaging. The NOSB judged that citric acid produced by natural fermentation of carbohydrate substrates and purified by the lime-sulfuric method is synthetic because the citric acid comes into contact with lime and sulfuric acid and because of the chemical change from citric acid to calcium citrate and then back to citric acid during purification.

Biomass residuals are usually recycled as animal feeds and for agriculture.

2119(m)4: effect on human health

Material has been affirmed as GRAS by FDA for use in foods. The amount of citrate added to foods by food processors is about 500 mg per person per day. This amount occurs naturally in 2 ounces of orange juice and does not constitute a significant addition to the total body load.

Long term oral over exposure may cause damage to tooth enamel. Considered an irritatant to eyes and respiratory system during manufacture and handling. Recommended use of eye and respiratory protection during handling. Oral LD50 (rat) 11,700 mg/kg; dermal (acute) tested on skin of rabbit 500mg/24 hr moderate; eye 750 mg/24hr severe. FDA tests show no effect on reproduction, teratogenicity or oncogenicity in rats.

2119(m)5: agroecosystem biology **Not Applicable**

2119(m)6: alternatives to substance

Lactic acid (has some taste problems and not used in infant foods).
Vinegar (strange taste in some foods).
Citrus juices.

2119(m)7: Is it compatible?

Compatible

References

1. FDA. 1977. Evaluation of the health aspects of citric acid, sodium citrate, potassium citrate, calcium citrate, ammonium citrate, triethyl citrate, isopropyl citrate, and stearyl citrate as food ingredients. SCOGS-84. Life Science Research Office, 9650 Rockville Pike, Bethesda, Maryland 20014.

2. Ag Partners of Davis, *Materials Report for Citric Acid*, 1995. Organic Trade Association, Greenfield, MA

6.

MSDS for CITRIC ACID, MONOHYDRATE Page 1

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1 - PRODUCT IDENTIFICATION

PRODUCT NAME: CITRIC ACID, MONOHYDRATE
FORMULA: HOC(COOH)(CH2COOH)2 H2O FORMULA WT: 210.14
CAS NO.: 5949-29-1
COMMON SYNONYMS: 2-HYDROXY-1,2,3,PROPANE-TRICARBOXYLIC ACID, MONOHYDRATE
PRODUCT CODES: 0118,0120,0119,0110
EFFECTIVE: 12/01/86 REVISION #02

PRECAUTIONARY LABELLING
BAKER SAF-T-DATA(TM) SYSTEM
HEALTH - 0 NONE
FLAMMABILITY - 1 SLIGHT
REACTIVITY - 0 NONE
CONTACT - 1 SLIGHT
HAZARD RATINGS ARE 0 TO 4 (0 = NO HAZARD; 4 = EXTREME HAZARD).
LABORATORY PROTECTIVE EQUIPMENT: SAFETY GLASSES; LAB COAT

PRECAUTIONARY LABEL STATEMENTS
CAUTION
MAY CAUSE IRRITATION
DURING USE AVOID CONTACT WITH EYES, SKIN, CLOTHING. WASH THOROUGHLY AFTER HANDLING. WHEN NOT IN USE KEEP IN TIGHTLY CLOSED CONTAINER.
SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)

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2 - HAZARDOUS COMPONENTS

COMPONENT	%	CAS NO.
CITRIC ACID, MONOHYDRATE		05949-29-1

---

3 - PHYSICAL DATA

BOILING POINT: N/A VAPOR PRESSURE(MM HG): N/A
MELTING POINT: N/A VAPOR DENSITY(AIR=1): N/A
SPECIFIC GRAVITY: 1.54 EVAPORATION RATE: N/A
(H2O=1) (BUTYL ACETATE=1)
SOLUBILITY(H2O): APPRECIABLE (MORE THAN 10 %) % VOLATILES BY VOLUME: 0
APPEARANCE & ODOR: WHITE, ODORLESS POWDER.

---

4 - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (CLOSED CUP N/A
FLAMMABLE LIMITS: UPPER - N/A % LOWER - N/A %
FIRE EXTINGUISHING MEDIA
USE WATER SPRAY, CARBON DIOXIDE, DRY CHEMICAL OR ORDINARY FOAM.

SPECIAL FIRE-FIGHTING PROCEDURES
FIREFIGHTERS SHOULD WEAR PROPER PROTECTIVE EQUIPMENT AND SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECE OPERATED IN POSITIVE PRESSURE MODE.

TOXIC GASES PRODUCED: CARBON MONOXIDE, CARBON DIOXIDE

---

5 - HEALTH HAZARD DATA

TOXICITY TEST RESULTS AND SAFETY AND HEALTH EFFECTS ARE LISTED FOR THE ANHYDROUS PRODUCT.
TOXICITY: LD50 (ORAL-RAT)(G/KG) - 11.7
LD50 (IPR-RAT)(MG/KG) - 883
LD50 (SCU-RAT)(MG/KG) - 5500
LD50 (ORAL-MOUSE)(MG/KG) - 5040
CARCINOGENICITY: NTP: NO IARC: NO Z LIST: NO OSHA REG: NO
EFFECTS OF OVEREXPOSURE
DUST MAY IRRITATE NOSE AND THROAT.
DUST MAY CAUSE HEADACHE, COUGHING, DIZZINESS OR DIFFICULT BREATHING.
DUST MAY IRRITATE OR BURN MUCOUS MEMBRANES.
CONTACT WITH SKIN OR EYES MAY CAUSE IRRITATION.

TARGET ORGANS: EYES, SKIN
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: NONE IDENTIFIED
ROUTES OF ENTRY: INHALATION, EYE CONTACT, SKIN CONTACT

EMERGENCY AND FIRST AID PROCEDURES
INGESTION: IF SWALLOWED AND THE PERSON IS CONSCIOUS, IMMEDIATELY GIVE LARGE AMOUNTS OF WATER. GET MEDICAL ATTENTION.
INHALATION: IF A PERSON BREATHES IN LARGE AMOUNTS, MOVE THE EXPOSED PERSON TO FRESH AIR. GET MEDICAL ATTENTION.
EYE CONTACT: IMMEDIATELY FLUSH WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. GET MEDICAL ATTENTION.
SKIN CONTACT: IMMEDIATELY WASH WITH PLENTY OF SOAP AND WATER FOR AT LEAST 15 MINUTES.

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6 - REACTIVITY DATA

STABILITY: STABLE HAZARDOUS POLYMERIZATION: WILL NOT OCCUR
INCOMPATIBLES: STRONG BASES
DECOMPOSITION PRODUCTS: CARBON MONOXIDE, CARBON DIOXIDE

---

7 - SPILL AND DISPOSAL PROCEDURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE
WEAR SUITABLE PROTECTIVE CLOTHING. CAREFULLY SWEEP UP AND REMOVE.
DISPOSAL PROCEDURE
DISPOSE IN ACCORDANCE WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL ENVIRONMENTAL REGULATIONS.

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8 - PROTECTIVE EQUIPMENT

VENTILATION: USE ADEQUATE GENERAL OR LOCAL EXHAUST VENTILATION TO KEEP FUME OR DUST LEVELS AS LOW AS POSSIBLE.
RESPIRATORY PROTECTION: NONE REQUIRED WHERE ADEQUATE VENTILATION CONDITIONS EXIST. IF AIRBORNE CONCENTRATION IS HIGH, USE AN APPROPRIATE RESPIRATOR OR DUST MASK.
EYE/SKIN PROTECTION: SAFETY GLASSES WITH SIDESHIELDS, NITRILE GLOVES RECOMMENDED.

9 - STORAGE AND HANDLING PRECAUTIONS

SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)
SPECIAL PRECAUTIONS
KEEP CONTAINER TIGHTLY CLOSED. SUITABLE FOR ANY GENERAL CHEMICAL STORAGE AREA.

10 - TRANSPORTATION DATA AND ADDITIONAL INFORMATION

DOMESTIC (D.O.T.)
PROPER SHIPPING NAME CHEMICALS, N.O.S. (NON-REGULATED)

INTERNATIONAL (I.M.O.)
PROPER SHIPPING NAME CHEMICALS, N.O.S. (NON-REGULATED)

9.

DOCNUM=1937

U.S. FOOD AND DRUG ADMINISTRATION
FOOD ADDITIVE SAFETY PROFILE

CITRIC ACID

CAS#:	000077929	HUMAN CONSUMPTION:	90.5367	MG/KG BW/DAY/PERSON
FASP#:	1937	MARKET DISAPPEARANCE:	106833333.333	LBS/YR
TYPE:	ASP	MARKET SURVEY:	87	
NAS#:	2306	JECFA:	NL-C	
FEMA#:	2306	JECFA ADI:		MG/KG BW/DAY/PERSON
GRAS#:	3	JECFA ESTABLISHED:	1979	
POTENTIAL BEVERAGE USE		LAST UPDATE:	931115	
FW:	192.12	DENSITY:	LOGP:	

STRUCTURE CATEGORIES: A6

COMPONENTS:

SYNONYMS:
CITRIC ACID, ANHYDROUS
2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID
HYDROXYTRICARBOXYLIC ACID, BETA-
1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-
ACIDE CITRIQUE

CHEMICAL FUNCTION: F

TECHNICAL EFFECT:
PH CONTROL AGENT
FLAVOR ENHANCER
FLAVORING AGENT OR ADJUVANT
LEAVENING AGENT
SEQUESTRANT
ANTIOXIDANT
SOLVENT OR VEHICLE
SURFACE-ACTIVE AGENT
ANTIMICROBIAL AGENT
ENZYME

CFR REG NUMBERS:

173.165	172.755	182.6033
182.1033	PART 133	PART 146
161.190	PART 169	PART 150
155.130	145.145	131.111
131.112	131.136	131.144
131.138	131.146	146.187
150.161	150.141	166.40
169.115	169.140	169.150
173.160	173.280	145.131
166.110	184.1033	

MINIMUM TESTING LEVEL: 3

COMMENTS: STUDY 1-12 FROM SCOGS-84

BOX 4A: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE RAT OR MOUSE STUDIES

STUDY: 4 COMPLETENESS: RANKING FACTOR: 1.938E-2
SPECIES: RAT LEL: 4670 MG/KG BW/DAY
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS
SPLEEN
COMMENTS: MALES ONLY
SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
DATA FROM SCOGS-84

10.

DOCNUM=1937

BOX 4C: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE STUDIES

STUDY: 4 COMPLETENESS: RANKING FACTOR: 1.938E-2
SPECIES: RAT LEL: 4670 MG/KG BW/DAY
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS
SPLEEN
COMMENTS: MALES ONLY
SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
DATA FROM SCOGS-84

BOX 7: ACUTE TOXICITY INFORMATION

STUDY: 2 SOURCE: J TAKEDA RES LAB 30:25-31
SPECIES: RAT YEAR: 1971
LD50: 12000 MG/KG BW
COMMENTS:

STUDY: 1 SOURCE: J TAKEDA RES LAB 30:25-31
SPECIES: MOUSE YEAR: 1971
LD50: 5000 MG/KG BW
COMMENTS:

BOX 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

STUDY: 3 COMPLETENESS: SOURCE: REV PORT FARM 20:41-46
TYPE: SHORT TERM YEAR: 1970
SPECIES: RAT LEL: 200 MG/KG BW/DAY
DURATION: 9 DAYS HNEL:
EFFECTS: BODY WEIGHT DECREASE
SITES:
COMMENTS: INITIAL DECREASE IN WEIGHT DID NOT PERSIST
NOT USED FOR PRIORITY RANKING

STUDY: 4 COMPLETENESS: SOURCE: J TAKEDA RES LAB 30:25-31
TYPE: SHORT TERM YEAR: 1971
SPECIES: RAT LEL: 4670 MG/KG BW/DAY
DURATION: 42 DAYS HNEL: 2260 MG/KG BW/DAY
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS SPLEEN
COMMENTS: SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES

STUDY: 5 COMPLETENESS: SOURCE: J AM PHARM ASSOC SCI ED
34:86-89
TYPE: SUBCHRONIC RODENT YEAR: 1945
SPECIES: RAT LEL: > MG/KG BW/DAY
DURATION: 90 DAYS HNEL: 600 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: BODY WEIGHT, BLOOD, HISTOPATH AND REPRODUCTION OBSERVED

STUDY: 6 COMPLETENESS: SOURCE: J AM PHARM ASSOC SCI ED
34:86-89
TYPE: SUBCHRONIC MAMMAL (NON-RODENT) YEAR: 1945
SPECIES: DOG LEL: > MG/KG BW/DAY
DURATION: 112 DAYS HNEL: 1380 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: NO BEHAVIORAL, BIOCHEMICAL OR HISTOPATHOLOGICAL ABNORMALITIES

STUDY: 10 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: RAT LEL: > MG/KG BW/DAY

11.

DURATION: 10 DAYS HNEL: 295 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION

STUDY: 9 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: MOUSE LEL: > MG/KG BW/DAY
DURATION: 10 DAYS HNEL: 241 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION

STUDY: 11 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: HAMSTER LEL: > MG/KG BW/DAY
DURATION: 5 DAYS HNEL: 272 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-10 OF GESTATION

STUDY: 12 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: RABBIT LEL: > MG/KG BW/DAY
DURATION: 13 DAYS HNEL: 425 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-18 OF GESTATION

STUDY: 8 COMPLETENESS: SOURCE: J AGRIC FOOD CHEM 5:759-760
TYPE: RAT ONCOGENICITY YEAR: 1957
SPECIES: RAT LEL: > MG/KG BW/DAY
DURATION: 728 DAYS HNEL: 2000 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: MALES ONLY

STUDY: 7 COMPLETENESS: SOURCE: VOEDING 17:137-148
TYPE: REPRODUCTION (3-GENERATION) YEAR: 1956
SPECIES: RAT LEL: > MG/KG BW/DAY
DURATION: HNEL: 800 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS:

BOX 3: GENETIC TOXICITY STUDIES

STUDY: 15 COMPLETENESS: SOURCE:
TYPE: YEAR:
SPECIES: LEL: MG/KG BW/DAY
DURATION: HNEL:
EFFECTS:
CELLS:
COMMENTS:

EXHIBIT B

Archived Content
The content on this page is provided for reference purposes only. This content has not been altered or updated since it was archived.

Search Archive

Fresh Express Incorporated 10/6/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda. CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

Via UPS

October 6, 2010

Fernando Aguirre, President and CEO
Chiquita Brands International, Inc. and Fresh Express, Incorporated
250 East Fifth Street
Cincinnati, OR 45202

Dear Mr. Aguirre:

Starting on May 21, 2010 and ending on June 10, 2010, the Food and Drug Administration (FDA) inspected your food manufacturing facility located at 900 E. Blanco Road, Salinas, California. During this inspection, FDA investigators collected labels for your products and reviewed their labeling at http://www.chiquita.com[1]. Based on our review, we have concluded that your Chiquita brand "Pineapple Bites with Coconut" and "Pineapple Bites" products are misbranded in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links at FDA's Internet home page at http://www.fda.gov[2].

Specifically, your "Pineapple Bites with Coconut" product is misbranded within the meaning of Section 403(a) of the Act [21 U.S.C. § 343(a)] in that its statement of identity, "Pineapple Bites with Coconut", is false and misleading. The ingredient statement for this product states that it is made with coconut; however, our investigation determined that this product is made with a coconut flavor spray. The characterizing flavor of your Pineapple with Coconut product must be identified in accordance with 21 CFR 101.22(i)(1)(iii) (for example. "coconut flavor").

Your "Pineapple Bites" and "Pineapple Bites with Coconut" products are misbranded within the meaning of Section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because their labeling bears nutrient content claims but the products do not meet the requirements for the claims.
Specifically, their labeling includes the claim "Plus ... Antioxidants." However, this claim does not include the names of the nutrients that are the subject of the claim or, alternatively, link the term "antioxidants" by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity. 21 CFR 101.54(g)(4). Your use of this antioxidant claim therefore misbrands your products under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

Your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the claim "Plus Phytonutrients." "Phytonutrients" are not nutrients for which a recommended daily intake (RDI) or daily recommended value (DRV) has been established. Therefore, nutrient content claims regarding "phytonutrients" are not authorized and further misbrand your products under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)]. To the extent phytonutrients are intended to be the basis for an antioxidant nutrient content claim, that use would violate FDA regulations for the same reason and because phytonutrients are not recognized as having antioxidant activity. 21 CFR 101.54(g)(1) and (2).

Both your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the statement "Only 40 Calories." This statement implies that the products are "low calorie" foods. A "low calorie" claim may be made if a food with a reference amount customarily consumed (RACC) greater than 30 grams (g) or greater than 2 tablespoons does not provide more than 40 calories per RACC. 21 CFR 101.60(b)(2)(i)(A). The RACC established for pineapple is 140 g. See 21 CFR 101.12(b) (Table 2, Fruits and Fruit Juices, All other fruits fresh, canned, or frozen).
The nutrition information for both products states that there are 40 calories per 1 piece (80 g) of product; this equals about 70 calories per RACC. Therefore, under 21 CFR 101.13(i)(2), the products are required t carry a disclaimer adjacent to the claim, e.g., "Only 40 calories per serving, not a low calorie food". Because your products fail to bear the required disclaimer, they are misbranded within the meaning of section 403(r)(1)(A) of the Act.

The "Pineapple Bites" and "Pineapple Bites with Coconut" products are further misbranded within the meaning of section 403(k) of the Act [21 U.S.C. 343(k)] in that they contain the chemical preservatives ascorbic acid and citric acid but their labels fail to declare these preservatives with a description of their functions. 21 CFR 101.22. Further, the ingredients ascorbic acid and citric acid must be declared by their common or usual names. 21 CFR 101.4(a).

This letter is not intended to be an all-inclusive review of your firm's products and processes. It is your responsibility to ensure that your firm and your products comply with the Act and FDA, regulations. You should take prompt action to correct the violations. Failure to promptly correct these violations may resul in regulatory action without further notice. For instance, we may take further action to seize your product or enjoin your firm from operating.

We also note that, FDA (through its contractor) obtained two samples of Fresh Express Hearts of Romaine the testing of which yielded human pathogens. One sample was found to contain *Salmonella Anatum*; another sample was found to contain *E. coli 0157:H7.* We acknowledge that you issued letters to your customers in an effort to recall affected products. However, FDA recommends that you review your firm's criteria for receipt of raw product, your procedures for ensuring that wash, flume and processing water d not contaminate your products and any other conditions and practices that may relate to the cause of the contamination.

We further acknowledge your June 25, 2010 response to the Good Manufacturing Practices violations cited in the FDA Form 483 regarding this inspection. In your response, you committed to:

- Retrain employees to replace or sanitize their gloves after contacting unsanitized surfaces;
- Include the dryer hoist controls and the equipment control panels that involve direct employee contact in your daily wash and sanitation procedures;
- Create a new storage system for aprons, gloves, and sleeve guards for times during manufacturing when they are not in use; and
- Modify your cutting surface inspection and replacement program so that cutting surfaces will be changed after every **(b)(4)** of use.

However, you did not provide documentation to demonstrate that these corrections have been made. You also did not address the observation that your technician improperly read the free chlorine indicator tests in the flume water. Please provide this information and documentation in your response to this Warning Letter.

In addition to the labeling issues identified above, we note that the available labeling space is at least 6" in height; therefore, the size of the nutrition information declared on these packages is not appropriate and does not meet the formatting requirements under 21 CFR 101.9(d), including hairline and footnote requirements. We note that since some of the nutrients are at insignificant levels, a shortened version of the Nutrition Facts panel may be used, e.g., the statement "Not a significant source of dietary fiber", at the bottom of the table of nutrient values as allowed under 21 CFR 101.9(c).

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. Please include documentation of the corrective actions 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.

Your response should be sent to:

Darlene B. Almogela
Director of Compliance
United States Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

If you have any questions about the content of this letter please contact Sergio Chavez, Compliance Officer, at 510-337-6886.

/s/

Barbara Cassens
District Director

Page Last Updated: 10/08/2010
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Accessibility Contact FDA Careers FDA Basics FOIA No Fear Act Site Map Transparency Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.chiquita.com/
2. http://www.fda.gov

JS 44 (Rev. 11/15)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Michelle Chen and John Does 1-100

(b) County of Residence of First Listed Plaintiff Kings
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
C.K. Lee, Esq., Lee Litigation Group, PLLC
30 East 39th Street, Second Floor, New York, NY 10016
Tel.: (212) 465-1188

DEFENDANTS

Outernational Brands, Inc.

County of Residence of First Listed Defendant Nassau
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☒ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

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- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
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FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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- ☐ 465 Other Immigration Actions

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- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

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- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. 1332(d) - New York General Business Law Section 349

Brief description of cause:
Deceptive and Unfair Trade Practices

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 4-4-16 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

CERTIFICATION OF ARBITRATION ELIGIBILITY

Local Arbitration Rule 83.10 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of $150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

I, C.K. Lee, counsel for Plaintiffs, do hereby certify that the above captioned civil action is ineligible for compulsory arbitration for the following reason(s):

☒ monetary damages sought are in excess of $150,000, exclusive of interest and costs,

☒ the complaint seeks injunctive relief,

☐ the matter is otherwise ineligible for the following reason

DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1

Identify any parent corporation and any publicly held corporation that owns 10% or more or its stocks:

RELATED CASE STATEMENT (Section VIII on the Front of this Form)

Please list all cases that are arguably related pursuant to Division of Business Rule 50.3.1 in Section VIII on the front of this form. Rule 50.3.1 (a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 50.3.1 (b) provides that " A civil case shall not be deemed "related" to another civil case merely because the civil case: (A) involves identical legal issues, or (B) involves the same parties." Rule 50.3.1 (c) further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (d), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

NY-E DIVISION OF BUSINESS RULE 50.1(d)(2)

1.) Is the civil action being filed in the Eastern District removed from a New York State Court located in Nassau or Suffolk County: No

2.) If you answered "no" above:
a) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in Nassau or Suffolk County? No

b) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in the Eastern District? Yes

If your answer to question 2 (b) is "No," does the defendant (or a majority of the defendants, if there is more than one) reside in Nassau or Suffolk County, or, in an interpleader action, does the claimant (or a majority of the claimants, if there is more than one) reside in Nassau or Suffolk County?_____

(Note: A corporation shall be considered a resident of the County in which it has the most significant contacts).

BAR ADMISSION

I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.

☒ Yes ☐ No

Are you currently the subject of any disciplinary action (s) in this or any other state or federal court?

☐ Yes (If yes, please explain) ☒ No

I certify the accuracy of all information provided above.

Signature: _____

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of New York

Michelle Chen and John Does 1-100

Plaintiff(s)

v.

Outernational Brands, Inc.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Outernational Brands, Inc.
234 Birch Drive
Roslyn, NY 11576

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

C.K. Lee, Esq., Lee Litigation Group, PLLC
30 East 39th Street, Second Floor
New York, NY 10016

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

DOUGLAS C. PALMER
CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk