GUCOVSCHI LAW FIRM, PLLC
Adrian Gucovschi (State Bar No. 360988)
Nathaniel H. Sari (State Bar No. 362634)
165 Broadway, Fl. 23
New York, New York 10005
Telephone: (212) 884-4230
E-Mail: adrian@gucovschilaw.com
nathaniel@gucovschilaw.com

Attorneys for Plaintiff and the Putative Class

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Sydney Turner, individually and on behalf of all others similarly situated,

Plaintiff,

v.

Costco Wholesale Corporation

Defendant.

Case No.

CLASS ACTION COMPLAINT

(1) UNFAIR COMPETITION
(2) CONSUMER LEGAL REMEDIES ACT
(3) FALSE ADVERTISING
(4) BREACH OF EXPRESS WARRANTY
(5) BREACH OF IMPLIED WARRANTY
(6) NEGLIGENT MISREPRESENTATION
(7) INTENTIONAL MISREPRESENTATION/FRAUD
(8) BREACH OF CONSUMER PROTECTION STATUTES
(9) UNJUST ENRICHMENT

DEMAND FOR JURY TRIAL

Plaintiff Sydney Turner ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendant Costco Wholesale Corporation ("Costco" or "Defendant"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and upon information and belief, except as to allegations specifically pertaining to herself and her counsel, which are based on personal knowledge.

INTRODUCTION

1. This class action aims to hold Defendant, Costco Wholesale Corporation, responsible for failing to truthfully and accurately label and market its food product.

2. Defendant manufactures, distributes, advertises and sells a frozen pasta food product – Kirkland Signature Five Cheese Tortelloni with Parmigiano Reggiano (the "Product").

3. Defendant uniformly makes the representation on the front label of the Product that the Product contains "no preservatives" (the "Misrepresentation") causing reasonable consumers such as Plaintiff to believe that the Product is free from artificial preservatives.

4. But contrary to Defendant's Misrepresentation, the ingredient list on the Product's back panel reveals the presence of manufactured citric acid, an ingredient that functions as a preservative and is produced through industrial fermentation and chemical processing.

5. Like other reasonable consumers, Plaintiff was deceived by Defendant's unlawful conduct and brings this action individually and on behalf of all similarly situated consumers to remedy Defendant's unlawful acts.

THE PARTIES

6. Defendant Costco Wholesale Corporation is a Washington corporation with its principal place of business in Issaquah, Washington. At all times during the class period, Defendant was the manufacturer, distributor, marketer, and seller of the Product.

7. Plaintiff Turner purchased Defendant's Product in person from Costco while residing in Fountain Valley, California, in or around December 2023. Prior to purchasing the Product, Plaintiff saw and believed Defendant's Misrepresentation, which caused her to believe the Product did not contain any preservatives including manufactured citric acid. When purchasing the Product, Plaintiff did not expect Defendant's representation on the front label of Product to be

false. Plaintiff did not expect Defendant to publicly place a deceptive statement about the product on the front label of the product.

8. At the time, Plaintiff saw and relied on the representations on the front label of the Product. Plaintiff would not have purchased the Product, or would have paid less for the Product, had she known that the Product contained the preservative manufactured citric acid. As a result, Plaintiff suffered injury in fact when she spent money purchasing the Product she would not have purchased, or would have paid less for, absent Defendant's misconduct.

9. Plaintiff desires to and would purchase Defendant's Product again if the Product's labels were accurate and if the products truthfully were free from preservatives. However, because of Defendant's ongoing misrepresentations, Plaintiff is unable to rely on the Product's labeling when deciding in the future whether to purchase the Product. Considering that the Defendant continues to sell the Product, she is at an imminent risk of future injury.

10. Plaintiff reserves the right to amend the Complaint to add different or additional defendants, including without limitation any officer, director, employee, supplier, or distributor of Defendant who has knowingly and willfully aided, abetted, and/or conspired in the false and deceptive conduct alleged herein.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(A), as amended by the Class Action Fairness Act of 2005 ("CAFA"), because this case is a class action where the aggregate claims for all members of the proposed class are in excess of $5,000,000.00, exclusive of interests and costs, there are over 100 members of the putative class, and at least one class member is a citizen of a state different from Defendant. The Product is sold at numerous retail stores and Plaintiff is seeking to represent a nationwide class. Thus, there are over 100 members in the proposed class and the proposed class has different citizenships from Defendant. Plaintiff seeks compensatory and statutory damages, disgorgement and restitution. Plaintiff also seeks punitive damages and attorneys' fees and costs. *See Montera v. Premier Nutrition Corp.*, No. 16-CV-06980-RS, 2022 WL 10719057, at *3 (N.D. Cal. Oct. 18, 2022), aff'd, 111 F.4th 1018 (9th Cir. 2024) (noting lodestar after jury trial in consumer protection action was $6,806,031.96). Thus,

upon information and belief, aggregate sales of the Product during the Class Period exceed $5 million.

12. The Court has personal jurisdiction over the parties because Plaintiff resides in this District and because Defendant has, at all times relevant hereto, systematically and continually conducted, and continues to conduct, business in California, including within this District. Defendant therefore has sufficient minimum contacts with this state, including within this District and/or intentionally availed itself of the benefits and privileges of the California consumer market through the promotion, marketing, and sale of its products and/or services to residents within this District and throughout California.

13. 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. Also, Plaintiff resides in this District and purchased the Product within this District. Moreover, Defendant systematically conducts business in this District and throughout the State of California, and it distributed, advertised, and sold the Product to Plaintiff and Class Members in this State and District.

FACTUAL BACKGROUND

A. Defendant's background and deception

14. Defendant sells frozen food products. One such product is Defendant's Kirkland Signature Five Cheese Tortelloni with Parmigiano Reggiano.

15. Defendant represents on the front of the packaging of the Product that the Product contains "no preservatives" as illustrated below:

16. The representation on the front label of the Product gives the impression that the Product contains no artificial preservatives.

17. The Misrepresentation was made on the Product's label at the time of Plaintiff's purchase in December 2023.

18. Defendant uniformly makes the Misrepresentation on the front label of all the Product.

19. Despite the Misrepresentation on the Product, the Product's back panel reveals that the Product contains an artificial preservative – manufactured citric acid.

B. The Citric Acid in the Product is Not Natural

20. Defendant uses artificial manufactured citric acid in Product.[1] Commercial food manufacturers use a synthetic form of citric acid that is derived from heavy chemical processing.[2] Commercially produced citric acid is manufactured using a type of black mold called *Aspergillus niger* which is modified to increase citric acid production.[3] Consumption of manufactured citric acid has been associated with a adverse health events like joint pain with swelling and stiffness, muscular and stomach pain, as well as shortness of breath.[4] Defendant does not use natural citric acid extracted from fruit in the Product. This is because "[a]pproximately 99% of the world's production of [citric acid] is carried out using the fungus *Aspergillus niger* since 1919." *Id*. As explained by a study published in the *Toxicology Reports Journal*:

> Citric acid naturally exists in fruits and vegetables. However**, it is not the naturally occurring citric acid, but the manufactured citric acid (MCA) that is used extensively as a food and beverage additive**. Approximately 99% of the world's production of MCA is carried out using the fungus. *Aspergillus niger* since 1919. *Aspergillus niger is a known allergen.* [5]

21. A technical evaluation report for citric acid compiled by the United States Department of Agriculture Marketing Services ("USDA AMS") further explains that is not commercially feasible to use natural citric acid extracted from fruits:

> "Traditionally by extraction from citric juice, [is] no longer commercially available. It is now extract by fermentation of a carbohydrate substance (often molasses) by citric bacteria, *Asperillus niger* (a mold) or *Candida guilliermondii* (a yeast). Citric

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[1] Iliana E. Sweis, et al., Potential role of the common food additive manufactured citric acid in eliciting significant inflammatory reactions contributing to serious disease states: A series of four case reports, T OXICOL REP. 5:808-812 (2018), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6097542/

[2] A. Hesham, Y. Mostafa & L. Al-Sharqi, Optimization of Citric Acid Production by Immobilized Cells of Novel Yeast Isolates, 48 M YCOBIOLOGY 122, 123 (2020), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7178817/

[3] *Id*; Pau Loke Show, et al., Overview of citric acid production from Aspergillus niger, FRONTIERS IN L IFE SCIENCE, 8:3, 271-283 (2015), available at https://www.tandfonline.com/doi/full/10.1080/21553769.2015.1033653

[4] Iliana E. Sweis, et al., Potential role of the common food additive manufactured citric acid in eliciting significant inflammatory reactions contributing to serious disease states: A series of four case reports, T OXICOL REP. 5:808-812 (2018), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6097542/

[5] *Id*. (emphasis added)

> 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."[6]

22. When asked "Is this substance Natural or Synthetic?" USDA AMS reviewers state: "synthetic."[7]

23. The FDA has determined that manufactured citric acid is not natural; it is artificial. The FDA sent warning letters to Hirzel Canning Company and Oak Tree Farm Dairy, Inc., for similar violations, saying that the FDA's policy involving the use of the word natural means that nothing artificial or synthetic has been added to the product, and that a product that labels itself "100% Natural" or "All Natural" violates that policy if it contains citric acid, and that the presence of citric acid precludes the use of the term natural to describe the product.[8]

24. The FDA explains that "Solvent extraction process for citric acid" is accomplished via "recovery of citric acid from conventional *Aspergillus niger* fermentation liquor may be safely used to produce food-grade citric acid in accordance with the following conditions: (a) The solvent used in the process consists of mixture of n-octyl alcohol meeting the requirements of § 172.864 of this chapter, ***synthetic*** isoparaffinic petroleum hydrocarbons meeting the requirements of § 172.882 of this chapter, and tridodecyl amine. 21 C.F.R. § 173.280 (emphasis added). Chemical solvents such as n-octyl alcohol and synthetic isoparaffinic petroleum hydrocarbons are used to extract the citric acid that Defendant uses in the Product from *aspergillus niger* fermentation liquor. *See* 21 C.F.R § 173.280. The citric acid that Defendant uses in the Product is produced through chemical solvent extraction and contains residues of those chemical solvents.

25. The *Toxicology Reports Journal* study explains that "the potential presence of impurities or fragments from the *Aspergillus niger* in [manufactured citric acid] is a significant difference that may trigger deleterious effects when ingested."[9] The study further explains:

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[6] **Exhibit A** at page 6.

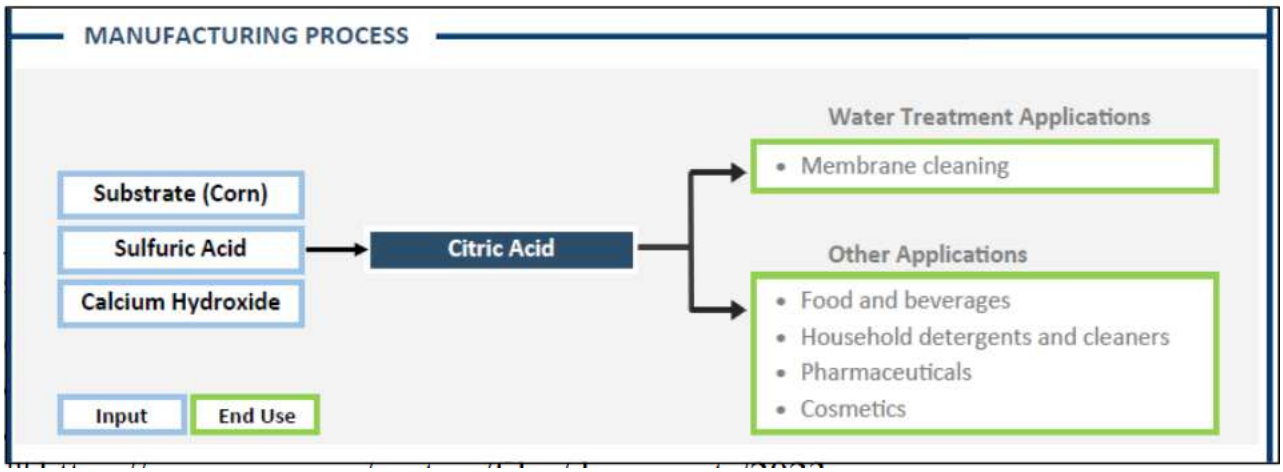
[7] **Exhibit A** at pages 4-5.

[8] *See* **Exhibit B** at page 2 and **Exhibit C** at page 2.

[9] Iliana E. Sweis, *et al., Potential role of the common food additive manufactured*

> "Given the thermotolerance of A. niger, there is great potential that byproduct of A. niger remain in the final [manufactured citric acid] product. Furthermore, given the pro-inflammatory nature of A. niger even when heat-killed, repetitive ingestion of [manufactured citric acid] may trigger sensitivity or allergic reactions in susceptible individuals. Over the last two decades, there has been a significant rise in the incidence of food allergies" *Id*.

26. The EPA provides the following simple schematic of the manufacturing process for citric acid which includes the use of synthetic solvents like Sulfuric Acid.[10]



27. Dr. Ryan Monahan, a prominent functional medicine practitioner, notes that the "[p]resent day process of creating manufactured citric acid involves feeding sugars derived from GMO corn to black mold, which then ferments to form manufactured citric acid."[11].

28. Dr. Monahan also notes that "*Aspergillus niger* is associated with systemic inflammatory issues, including respiratory, gastrointestinal, neurological and musculoskeletal. Due

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citric acid in eliciting significant inflammatory reactions contributing to serious disease states: A series of four case reports, TOXICOL REP. 5:808-812 (2018), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6097542/

[10] https://www.epa.gov/system/files/documents/202303/Citric%20Acid%20Supply%20Chain%20Profile.pdf (last accessed March 13, 2026)

[11] Dr. Ryan Monahan, *Citric Acid: A Common Food Additive With An Uncommon Source* (2024) *available at* https://www.peacefulmountainmedicine.com/post/citric-acid-a-common-food-additive-with-an-uncommon-source (Last accessed March 12, 2026)

to the potential for fragments of *Aspergillus niger* to make their way into the finished product of manufactured citric acid, this toxic inflammatory substance is likely being ingested by consumers of Product containing citric acid. Even with high-heat processing to kill it, research has shown *Aspergillus niger* can still elicit an inflammatory response."[12]

29. Clinical nutritionist Serge Gregoire, notes that [f]ood manufacturers leave out that citric acid is derived from genetically modified black mold grown on GMO corn syrup" and that "[c]ompanies continuously capitalize on an ignorance-based market."[13] Gregoire states, "Citric acid production has become a refined and highly prized industrial process." Gregoire notes that the *Aspergillus niger* used to produce citric acid is engineered to increase production of citric acid which has "resulted in countless generations of genetically modified mutant variants, now specialized for industrial-scale economics."

30. "Further genetic modification in the lab has taken place through the engineering of the glycolytic pathway, resulting in a metabolic-streamlining that facilitates greater citric acid production from sugar while shutting off side avenues of glycolysis." *Id*.

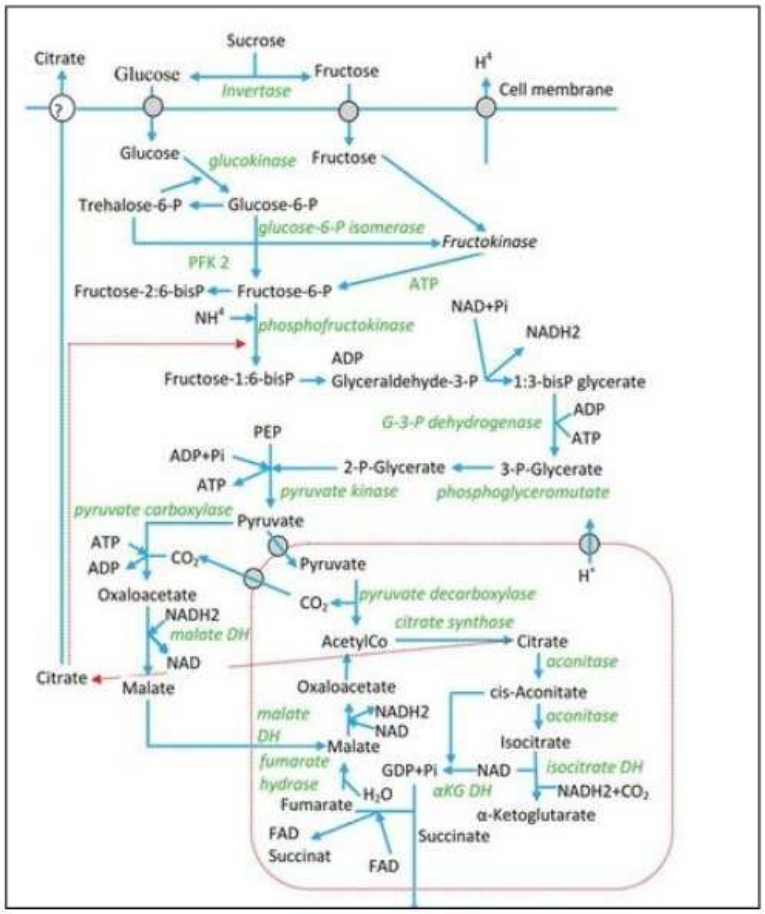
31. "Mutagenesis has been used in recent years to improve the citric-acid producing strains so that they can be used in industrial applications. The most common methods include the use of mutagens to induce mutations on the parental strains. The mutagens utilized for improvements are gamma radiation, ultraviolet radiation and often chemical mutagens. For hyperproducer strains, a hybrid method that combines ultraviolet and chemical mutagens is used (Ratledge & Kristiansen Citation2001).[14]

[12] Dr. Ryan Monahan, *Citric Acid: A Common Food Additive With An Uncommon Source* (2024) *available* at https://www.peacefulmountainmedicine.com/post/citric-acid-a-common-food-additive-with-an-uncommon-source.(last accessed March 12, 2026)

[13] Serge Gregoire, Avoid citric acid: a mold byproduct! (July 13, 2021) *available at* https://www.linkedin.com/pulse/avoid-citric-acid-mold-byproduct-serge-gregoire/

[14] Show, P. L., Oladele, K. O., Siew, Q. Y., Aziz Zakry, F. A., Lan, J. C. W., & Ling, T. C. (2015). Overview of citric acid production from Aspergillus niger. F RONTIERS IN LIFE S CIENCE , 8(3), 271–283, *available* at https://doi.org/10.1080/21553769.2015.1033653

32. Below is a schematic representation of the metabolic reactions involved in citric acid production, the enzymes (italics), the known feedback loops (dashed lines) and their locations with the cellular structure of *Aspergillus niger*.[15]



33. Dictionary definitions define "artificial" as something made by man. For example, "artificial" is defined as "made by human skill; produced by humans…"[16] Merriam-Webster's online

[15] *Id*. at Figure 3.

[16] *Artificial*, DICTIONARY.COM , *available at* https://www.dictionary.com/browse/artificial

dictionary states that "artificial" means "humanly contrived …"[17] Cambridge Dictionary states that "artificial" means "made by people, often as a copy of something natural."[18]

34. Below are images of the chemical process used to create citric acid for use in food – a process that is visibly artificial:

[17] *Artificial*, MERRIAM -WEBSTER ' S DICTIONARY, *available at* https://www.merriam-webster.com/dictionary/artificial

[18] *Artificial*, CAMBRIDGE DICTIONARY, *available at* https://dictionary.cambridge.org/us/dictionary/english/artificial

35. Citric acid acts as an artificial flavoring and preserving agent when added to food products, including the Product at issue.[19] Citric acid has a sour acidic, and slightly tart flavor. *Id*.

36. The Food and Drug Administration ("FDA") defines a preservative as "any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties." 21C.F.R. §101.22(a)(5). The FDA has listed citric acid as a preservative in its "Overview of Food Ingredients, Additives and Colors" as shown below:[20]

Types of Ingredients	What They Do	Examples of Uses	Names Found on Product Labels
Preservatives	Prevent food spoilage from bacteria, molds, fungi, or yeast (antimicrobials); slow or prevent changes in color, flavor, or texture and delay rancidity (antioxidants); maintain freshness	Fruit sauces and jellies, beverages, baked goods, cured meats, oils and margarines, cereals, dressings, snack foods, fruits and vegetables	Ascorbic acid, citric acid, sodium benzoate, calcium propionate, sodium erythorbate, sodium nitrite, calcium sorbate, potassium sorbate, BHA, BHT, EDTA, tocopherols (Vitamin E)

37. In a warning letter sent to Chiquita Brands International, Inc. and Fresh Express, Inc., the FDA warned that certain products were misbranded under the Federal Food Drug and Cosmetics Act because 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 C.F.R. [§] 101.22" (emphasis added).[21]

[19] https://www.webstaurantstore.com/blog/3350/what-is-citric-acid.html#:~:text=What%20Is%20Sour%20Salt?,salt%20tastes%20sour%20and%20acidic. (last accessed March 12, 2026)

[20] *Overview of Food Ingredients Additives & Colors, Food and Drug Administration*, *available at* https://web.archive.org/web/20220901032454/http://www.fda.gov/food/foodingredients-packaging/overview-food-ingredients-additives-colors.

[21] *See* **Exhibit D** at page 2 (highlighted)

38. The USDA's Food Safety Inspection Service's "Guideline for Label Approval" states that "common ***chemical*** preservatives include BHA, BHT, calcium propionate, citric acid, natamycin and sodium propionate.[22]

CLASS ACTION ALLEGATIONS

39. Plaintiff brings the action on behalf of herself and all others similarly situated pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), (b)(2), and (b)(3). The proposed classes are defined below as ("collectively, the "Classes"):

The Nationwide Class

All persons in the United States who, within the applicable statute of limitations period, up to and including the date of final judgment in this action, who purchased Defendant's Product

Multi-State Consumer Protection Subclass:

All persons who, during the maximum period of time permitted by law, purchased Defendant's Product in Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

Multi-State Warranty Subclass:

All persons who, during the maximum period of time permitted by law, purchased Defendant's Product in Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wyoming.

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[22] FSIS Guideline for Label Approval, UNITED S TATES DEPARTMENT OF AGRICULTURE , *available at* https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-GD-2023-0001.pdf (emphasis added)

California Subclass:

All persons in California who, during the maximum period of time permitted by the law, purchased Defendant's Product for their personal use.

40. The Classes do not include (1) Defendant, its officers, and/or directors; (2) the Judge and/or Magistrate to whom this cause is assigned; (3) the Judge or Magistrate's staff and family; and (4) Plaintiff's counsel and Defendant's counsel.

41. Plaintiff reserves the right to amend the above class definitions and add additional classes and subclasses as appropriate based on investigation, discovery, and the specific theories of liability.

42. ***Numerosity.*** Members of the Class are so numerous that their individual joinder herein is impracticable. On information and belief, the Class comprises at least millions of consumers. The precise number of Class members and their identities are unknown to Plaintiff at this time but may be determined through discovery. Class members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant.

43. ***Commonality and Predominance***. Common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members. Common legal and factual questions include, but are not limited to:

(a) Whether Defendant is responsible for the conduct alleged herein which was uniformly directed to all consumers who purchased the Product;

(b) Whether Defendant's misconduct set forth in this Complaint demonstrates that Defendant engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of the Product;

(c) Whether Defendant made misrepresentations concerning the Product that were likely to deceive the public;

(d) Whether Plaintiff and the Class are entitled to injunctive relief;

(e) Whether Plaintiff and the Class are entitled to money damages and/or restitution under the same causes of action as the other Class Members.

44. With respect to the California Subclass, additional questions of law and fact common to the members include whether Defendant violated California's Consumers Legal Remedies Act, ("CLRA"), Cal. Civ. Code §§ 1750, *et seq*., California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code § 17500, *et seq.*, and California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200, *et seq*.

45. ***Typicality.*** Plaintiff is a member of the Class that Plaintiff seeks to represent. Plaintiff's claims are typical of the claims of each Class Member in that every member of the Class was susceptible to the same deceptive, misleading conduct and purchased the Product. Plaintiff is entitled to relief under the same causes of action as the other Class Members.

46. ***Adequacy***. Plaintiff will fairly and adequately protect Class members' interests. Plaintiff has no interests antagonistic to Class members' interests, and Plaintiff has retained counsel that have considerable experience and success in prosecuting complex class-actions and consumer-protection cases.

47. ***Superiority***. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy for, *inter alia*, the following reasons: prosecutions of individual actions are economically impractical for members of the Class; the Class is readily definable; prosecution as a class action avoids repetitious litigation and duplicative litigation costs, conserves judicial resources, and ensures uniformity of decisions; and prosecution as a class action permits claims to be handled in an orderly and expeditious manner.

48. Defendant has acted or failed to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief with respect to the Class as a whole.

49. Without a class action, Defendant will continue a course of action that will result in further damages to Plaintiff and members of the Class and will likely retain the benefits of its wrongdoing.

50. Based on the foregoing allegations, Plaintiff's claims for relief include those set forth below.

CAUSES OF ACTION

Count I:
Violations of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq*.
(On behalf of Plaintiff and the California Subclass)

51. Plaintiff re-alleges and incorporates by reference every allegation set forth in the preceding paragraphs as though alleged in this Count.

52. Plaintiff brings this claim under the UCL individually and on behalf of the California Class against Defendant.

53. The UCL prohibits any "unlawful," "fraudulent," or "unfair" business act or practice and any false or misleading advertising. Defendant committed unlawful business acts or practices by making the representations and omitted material facts (which constitutes advertising within the meaning of California Business & Professions Code section 17200), as set forth more fully herein, and by violating California's Consumers Legal Remedies Act, Cal. Civ. Code §§1750, *et seq.*, California's False Advertising Law, Cal. Bus. & Prof. § 17500, *et seq.*, 15 U.S.C. § 45, and by breaching express and implied warranties. Plaintiff, individually and on behalf of the other Class members, reserves the right to allege other violations of law, which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

54. Defendant committed "unfair" business acts or practices by: (a) engaging in conduct where the utility of such conduct is outweighed by the harm to Plaintiff and the members of the Class; (2) engaging in conduct that is immoral, unethical, oppressive, unscrupulous, or substantially injurious to Plaintiff and the members of the Class; and (3) engaging in conduct that undermines or violates the intent of the consumer protection laws alleged herein. There is no societal benefit from deceptive advertising. Plaintiff and the other Class members paid for Product that is not as advertised by Defendant. Further, Defendant failed to disclose a material fact (that the Product contains manufactured citric acid) of which it had exclusive knowledge. While Plaintiff

and the other Class members were harmed, Defendant was unjustly enriched by its false misrepresentations and material omissions. As a result, Defendant's conduct is "unfair," as it offended an established public policy. There were reasonably available alternatives to further Defendant's legitimate business interests, other than the conduct described herein.

55. Defendant committed "fraudulent" business acts or practices by making the Misrepresentation regarding the Product set forth herein. Defendant's business practices as alleged are "fraudulent" under the UCL because they are likely to deceive customers into believing the Product is free from artificial preservatives such as citric acid.

56. Plaintiff and the other members of the Class have in fact been deceived as a result of their reliance on Defendant's material representations and omissions. This reliance has caused harm to Plaintiff and the other members of the Class, each of whom purchased Defendant's Product. Plaintiff and the other Class members have suffered injury in fact and lost money as a result purchasing the Product and Defendant's unlawful, unfair, and fraudulent practices.

57. Defendant's wrongful business practices and violations of the UCL are ongoing.

58. Plaintiff and the Class seek pre-judgment interest as a direct and proximate result of Defendant's unfair and fraudulent business conduct. The amount of which is to be calculated is a sum certain and capable of calculation, and Plaintiff and the Class seek interest in an amount according to proof.

59. Unless restrained and enjoined, Defendant will continue to engage in the above-described conduct. Accordingly, injunctive relief is appropriate. Pursuant to California Business & Professions Code section 17203, Plaintiff, individually and on behalf of the California Class, seeks (1) restitution from Defendant of all money obtained from plaintiff and the other Class members as a result of unfair competition; (2) an injunction prohibiting Defendant from continuing such practices

in the State of California that do not comply with California law; and (3) all other relief this Court deems appropriate, consistent with California Business& Professions Code section 17203.

Count II
Violations of California's False Advertising Law ("FAL"),
Cal. Bus. & Prof. Code §§ 17500, *et seq*.
(On Behalf of Plaintiff and the California Subclass)

60. Plaintiff re-alleges and incorporates by reference every allegation set forth in the preceding paragraphs as though alleged in this Count.

61. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and Subclass against Defendant.

62. California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*, makes it "unlawful for any person to make or disseminate or cause to be made or disseminated before the public in this state, …in any advertising device … or in any other manner or means whatever, including over the Internet, any statement, concerning … personal property or services, professional or otherwise, or performance or disposition thereof, which is untrue or misleading and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

63. Defendant committed acts of false advertising, as defined by § 17500, by using statements to promote the sale of its Product by making the Misrepresentation. In doing so, Defendant communicated that the Product did not contain preservatives, while omitting that the Product contained manufactured citric acid.

64. Defendant knew or should have known that its advertising claims have not been substantiated and are misleading and/or false.

65. Defendant knew or should have known, through the exercise of reasonable care, that its representations were false and misleading and likely to deceive consumers and cause them to purchase Defendant's Product.

66. Defendant's wrongful conduct is ongoing and part of a general practice that is still being perpetuated and repeated through the State of California and nationwide.

67. Plaintiff, individually and on behalf of all similarly situated California consumers, seeks individual, representative, and public injunctive relief and any other necessary orders or judgments that will prevent Defendant from continuing with its false and deceptive advertisements and omissions; restitution that will restore the full amount of their money or property; disgorgement of Defendant's relevant profits and proceeds; and an award of costs and reasonable attorneys' fees.

Count III
Violations of California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750, *et seq.*
(On Behalf of Plaintiff and the California Subclass)

68. Plaintiff re-alleges and incorporates by reference every allegation set forth in the preceding paragraphs as though alleged in this Count.

69. Civil Code § 1770(a)(5) prohibits "[r]epresenting that goods or services have sponsorships, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person have a sponsorship, approval, status, affiliation, or connection which he or she does not have."

70. Civil Code § 1770(a)(7) prohibits "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another."

71. Civil Code § 1770(a)(9) prohibits "advertising goods or services with intent not to sell them as advertised."

72. Defendant's wrongful business practices constituted, and still constitute, a continuing course of conduct in violation of the CLRA.

73. Because Plaintiff has not yet provided Defendant with the notice required by California Civil Code § 1782(a), Plaintiff and the California Subclass currently seek injunctive relief only under the CLRA. Pursuant to California Civil Code § 1782(d), Plaintiff reserves the right to amend the Complaint to seek actual, punitive, and any other damages available under the CLRA after providing the statutorily required notice and the expiration of the applicable thirty (30)

day period, should Defendant fail to rectify its unlawful, unfair, false, and/or deceptive practices alleged herein.

Count IV
Breach of Express Warranty[23]
(On behalf of Plaintiff and the Multi-State Warranty Class)

74. Plaintiff realleges and incorporates by reference all allegations contained in this complaint, as though fully set forth herein.

75. Plaintiff brings this claim individually and on behalf of the Multi-State Warranty Class against Defendant.

76. Plaintiff and the Multi-State Warranty Class Members formed a contract with Defendant at the time Plaintiff and the Multi-State Warranty Class Members purchased the Product.

77. The terms of the contract include the promises and affirmations of fact made by Defendant through the Misrepresentation.

78. The labeling and advertising constitute express warranties and became part of the basis of the bargain and part of the standardized contract between Plaintiff and the Multi-State Warranty Class and Defendant.

79. As set forth above, Defendant purports through its labeling, marketing, and packaging to create an express warranty that the Product does not contain preservatives. However,

[23] While discovery may alter the following, Plaintiff asserts that the states with similar express warranty laws under the facts of this case include, but are not limited to: Alaska Stat. § 45.02.313; A.R.S. § 47-2313; Ark. Code § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. § 42a-2-313; 6 Del. C. § 2-313; D.C. Code § 28:2 313; Ga. Code § 11-2-313; HRS § 490:2- 313; Idaho Code § 28-2-313; 810 ILCS 5/2-313; Ind. Code § 26-1-2-313; K.S.A. § 84-2-313; KRS § 355.2-313; 11 M.R.S. § 2-313; Mass. Gen. Laws Ann. ch. 106 § 2-313; Minn. Stat. § 336.2-313; Miss. Code Ann. § 75-2-313; R.S. Mo. § 400.2-313; Mont. Code Anno. § 30-2 313; Neb. Rev. Stat. § 2- 313; Nev. Rev. Stat. Ann. § 104.2313; RSA 382-A:2 313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. § 25-2-313; N.D. Cent. Code § 41-02-30; ORC Ann. § 1302.26; 12A Okl. St. § 2-313; Or. Rev. Stat. § 72-3130; 13 Pa. C.S. § 2313; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Codified Laws, § 57A 2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code § 2.313; Utah Code Ann. § 70A-2-313; 9A V.S.A. § 2-313; Va. Code Ann. § 59.1-504.2; Wash. Rev. Code Ann. § 62A.2-313; W. Va. Code § 46- 2-313; and Wyo. Stat. § 34.1-2-31.

Defendant breached its express warranties regarding the Product because the Product contains the preservative manufactured citric acid.

80. Plaintiff and the Multi-State Warranty Class performed all conditions precedent to Defendant's liability under this contract when they purchased the Product.

81. Plaintiff and the members of the Multi-State Warranty Class would not have purchased the Product had they known the true nature of the Product.

82. As a result, Defendant violated the express warranties of the Multi-State Warranty Class. Plaintiff and each members of the Nationwide Class suffered financial damage and injury as a result and are entitled to all damages, in addition to costs, interest, and fees, including attorney's fees, as allowed by law.

Count V
Breach of Implied Warranty,
Cal. Com. Code. § 2314
(On Behalf of Plaintiff and the California Subclass)

83. Plaintiff realleges and incorporates by reference all allegations contained in the complaint, as though fully set forth herein.

84. Plaintiff brings this claim for breach of implied warranty individually and on behalf of the California Subclass against Defendant.

85. Plaintiff and the Class purchased the Product manufactured, advertised, and sold by Defendant, as described herein.

86. Defendant, through its act and omissions set forth herein, in the sale, marketing, and promotion of the Product, misrepresented the characteristics of the Product to Plaintiff and the Class.

87. Defendant is a merchant with respect to the goods of this kind of which were sold to Plaintiff and the Class, and there was, in the sale to Plaintiff and other consumers, an implied warranty that those were merchantable.

88. However, Defendant breached that implied warranty in that the Product contained a preservative, despite the Misrepresentation.

89. As an actual and proximate result of Defendant's conduct, Plaintiff and the Class did not receive goods as impliedly warranted by Defendant to be merchantable in that the Product did not conform to promises and affirmations made on the label of the Product.

90. Plaintiff and the Class have sustained damages as a proximate result of the foregoing breach of implied warranties in the amount of the Product's price premium.

Count VI
Negligent Misrepresentation
(On Behalf of Plaintiff and the California Subclass)

91. Plaintiff realleges and incorporates by reference all allegations contained in this complaint, as though fully set forth herein.

92. Plaintiff brings this claim for negligent misrepresentation individually and on behalf of the California Subclass against Defendant.

93. Defendant had a duty to disclose to Plaintiff and Class Members correct information as to the quality and characteristics of the Product because Defendant was in a superior position to Plaintiff and Class Members such that reliance by Plaintiff and Class Members was justified. Defendant possessed the skills and expertise to know the type of information that would influence a consumer's purchasing decision.

94. During the applicable class period, Defendant negligently or carelessly misrepresented, omitted, and concealed from consumers material facts regarding the quality and characteristics of the Product, including the fact that the Product contains a preservative, despite the Misrepresentation.

95. Defendant made such false and misleading statements and omissions with intent to induce Plaintiff and Class Members to purchase the Product at premium price.

96. Defendant was careless in ascertaining the truth of its representations in that it knew or should have known that Plaintiff and Class Members would be overpaying for the Product.

97. Plaintiff and Class Members were unaware of falsity in Defendant's misrepresentations and omissions and, as a result, justifiably relied on them when making the decision to purchase the Product.

98. Plaintiff and Class Members would not have purchased the Product or paid as much for the Product if the true facts had been known.

Count VII
Intentional Misrepresentation/Fraud
(On Behalf of Plaintiff and the California Subclass)

99. Plaintiff realleges and incorporates by reference all allegations contained in this complaint, as though fully set forth herein.

100. Plaintiff brings this claim for intentional misrepresentation/fraud individually and on behalf of the California Subclass against Defendant.

101. Defendant had a duty to disclose to Plaintiff and Class Members correct information as to the quality and characteristics of the Product because Defendant was in a superior position to Plaintiff and Class Members such that reliance by Plaintiff and Class Members was justified. Defendant possessed the skills and expertise to know the type of information that would influence a consumer's purchasing decision.

102. During the applicable class period, Defendant intentionally misrepresented, omitted, and concealed from consumers a material fact regarding the quality and characteristics of the Product, that the Product contains a preservative despite the Misrepresentation. The Misrepresentation was material and was uniformly made.

103. As noted in detail above, the Misrepresentation was false and misleading, as the Product was not free from preservatives. Defendant made the Misrepresentation with actual knowledge of its falsity and/or made it with fraudulent intent.

104. Defendant made such false and misleading statements and omissions with the intent to induce Plaintiff and Class Members to purchase the Product at a premium price, deprive Plaintiff and Class Members of property or otherwise causing injury, and thus, Defendant has committed fraud.

105. Defendant's deceptive or fraudulent intent is evidenced by motive and opportunity. Defendant knew that consumers would pay more for the Product if they believed it did not contain

preservatives. For that reason, Defendant misrepresented the Product so that Defendant could realize greater profits. Defendant knew that consumers would place trust and confidence in its Product's claims and rely thereon in their purchases of the Product.

106. Plaintiff and the Class Members were unaware of the falsity in Defendant's misrepresentations and omissions and, as a result, justifiably relied on them when making the decision to purchase the Product.

107. As a proximate result of Defendant's intentional misrepresentations, Plaintiff and the Class were induced to purchase the Product at a premium.

108. Plaintiff and the Class Members would not have purchased the Product or paid as much for the Product if the true facts had been known.

109. As a result of their reliance, Plaintiff and the Class Members were injured in an amount to be proven at trial, including, but not limited to, their lost benefit of the bargain and overpayment at the time of purchase.

110. Defendant's conduct was knowing, intentional, with malice, demonstrated a complete lack of care, and was in reckless disregard for the rights of Plaintiff and Class Members Plaintiff and Class Members are therefore entitled to an award of punitive damages.

COUNT VIII
Breach of Consumer Protection Statutes[24]
(On Behalf of Plaintiff and the Multi-State Consumer Protection Subclass)

111. Plaintiff hereby incorporates the foregoing paragraphs as if fully stated herein.

112. Plaintiff brings this claim individually and on behalf of the Multi-State Consumer Protection Subclass against Defendant.

113. Defendant's acts and practices, as described herein, have deceived and/or are likely to continue to deceive members of the Multi-State Consumer Protection Subclass and the public. As described throughout the Complaint, Defendant made the Misrepresentation, even though the Product was not free from preservatives.

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

115. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the nature and value of the Product.

[24] While discovery may alter the following, Plaintiff asserts that the states with similar consumer fraud laws under the facts of this case include but are not limited to: Alaska Stat. § 45.50.471, et seq.; Ariz. Rev. Stat. §§ 44-1521, et seq.; Ark. Code § 4-88-101, et seq.; Cal. Bus. & Prof. Code § 17200, et seq.; Cal. Civ. Code §1750, et seq.; Colo. Rev. Stat. Ann. § 6-1-101, et seq.; Colo. Rev. Stat. Ann. § 6-1-101, et seq.; Conn. Gen Stat. Ann. § 42- 110, et seq.; 6 Del. Code § 2513, et seq.; D.C. Code § 28-3901, et seq.; Fla. Stat. Ann.§ 501.201, et seq.; Ga. Code Ann. § 10-1-390, et seq.; Haw. Rev. Stat. § 480-2, et seq.; Idaho Code. Ann. § 48-601, et seq.; 815 ILCS 501/1, et seq.; Ind. Code § 24-5-0.5-2, et seq.; Kan. Stat. Ann. § 50-623, et seq.; Ky. Rev. Stat. Ann. § 367.110, et seq.; LSA-R.S. 51:1401, et seq.; Me. Rev. Stat. Ann. Tit. 5, § 207, et seq.; Md. Code Ann. Com. Law, § 13-301, et seq.; Mass. Gen Laws Ann. Ch. 93A, et seq.; Mich. Comp. Laws Ann. § 445.901, et seq.; Minn. Stat. § 325F, et seq.; Mo. Rev. Stat. § 407, et seq.; Neb. Rev. St. §§ 59-1601, et seq.; Nev. Rev. Stat. § 41.600, et seq.; N.H. Rev. Stat. § 358-A:1, et seq.; N.J. Stat. Ann. § 56:8, et seq.; N.M. Stat. Ann. § 57-12-1, et seq.; N.Y. Gen. Bus. Law § 349, et seq.; N.C. Gen Stat. § 75-1.1, et seq.; N.D. Cent. Code § 51-15, et seq.; Ohio Rev. Code Ann. § 1345.01, et seq.; Okla. Stat. tit. 15 § 751, et seq.; Or. Rev. Stat. § 646.605, et seq.; 73 P.S. § 201-1, et seq.; R.I. Gen. Laws § 6-13.1- 5.2(B), et seq.; S.C. Code Ann. §§ 39-5- 10, et seq.; S.D. Codified Laws § 37-24-1, et seq.; Tenn. Code Ann. § 47-18-101, et seq.; Tex. Code Ann., Bus. & Con. § 17.41, et seq.; Utah Code. Ann. § 13-11-175, et seq.; 9 V.S.A. § 2451, et seq.; Va. Code Ann. § 59.1-199, et seq.; Wash. Rev. Code § 19.86.010, et seq.; W. Va. Code § 46A, et seq.; Wis. Stat. § 100.18, et seq.; and Wyo. Stat. Ann. § 40-12-101, et seq.

116. As a result of Defendant's deceptive practices, Plaintiff and the Multi-State Consumer Protection Subclass suffered an economic injury because they would not have purchased (or paid a premium for) the Product had they known that the Product was not preservative free.

117. Plaintiff and the Multi-State Consumer Protection Subclass seek to recover their actual damages, statutory damages, punitive damages, and reasonable attorneys' fees and costs.

COUNT IX
Unjust Enrichment
(On Behalf of Plaintiff and the Nationwide Class)

118. Plaintiff hereby incorporates the foregoing paragraphs as if fully stated herein.

119. Plaintiff brings this claim individually and on behalf of the Nationwide Class against Defendant under California law, or, in the alternative, on behalf of the respective state laws of the Nationwide Class, which are substantially similar to the law of unjust enrichment. California law requires: (1) receipt of a benefit; (2) unjust or wrongful retention of the benefit; and (3) at the expense of another.

120. To the extent required, Plaintiff asserts this cause of action in the alternative to legal claims, as permitted by Rule 8.

121. Plaintiff and the Class Members conferred a benefit on Defendant in the form of the gross revenues Defendant derived from the money they paid to Defendant.

122. Defendant knew of the benefit conferred on it by Plaintiff and the Class Members.

123. Defendant has been unjustly enriched in retaining the revenues derived from Plaintiff's and the Class Members' purchases of the Product, which retention of such revenues under these circumstances is unjust and inequitable because Defendant made the Misrepresentation. This caused injuries to Plaintiff and Class Members because they would not have purchased the Product or would have paid less for it if the true facts concerning the Product had been known.

124. Defendant accepted and retained the benefit in the amount of the gross revenues derived from sales of the Product to Plaintiff and Class Members.

125. Defendant has thereby profited by retaining the benefit under circumstances which would make it unjust for Defendant to retain the benefit.

126. Plaintiff and Class Members are, therefore, entitled to restitution in the form of the revenues derived from Defendant's sale of the Product.

127. As a direct and proximate result of Defendant's actions, Plaintiff and the Class Members have suffered in an amount to be proven at trial.

128. Plaintiff and the Class Members have suffered an injury in fact and have lost money as a result of Defendant's unjust conduct.

129. Plaintiff and the Class Members lack an adequate remedy at law with respect to the claim and are entitled to non-restitutionary disgorgement of the financial profits that Defendant obtained as a result of its unjust conduct.

130. Legal remedies available to Plaintiff and the Class Members are inadequate because they are not equally prompt, certain, or efficient as equitable relief. Damages are not equally certain as restitution because the standard that governs restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines Plaintiff fails to sufficiently adduce evidence to support an award of damages. Damages and restitution are not the same amount. Unlike damages, restitution is not limited to the amount of money a defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles a plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Legal claims for damages are not equally certain as restitution because such claims require different elements. In short, significant differences in proof and certainty establish that any potential legal claim cannot serve as an adequate remedy at law.

131. Equitable relief is appropriate because Plaintiff may lack an adequate remedy at law if, for instance, damages resulting from their purchase of the Product are determined to be an amount less than the premium price of the Product. Without compensation for the full premium price of the Product, Plaintiff and the Class Members would be left without the parity in purchasing power to which they are entitled.

Request for Relief

132. Plaintiff, individually, and on behalf of all others similarly situated, requests for relief pursuant to each claim as follows:

a. Declaring that this action is a proper class action, certifying the Class as requested herein, designating Plaintiff as the Class Representative and appointing the undersigned counsel as Class Counsel;

b. Ordering restitution and disgorgement of all profits and unjust enrichment that Defendant obtained from Plaintiff and the Class members as a result of Defendant's unlawful, unfair, and fraudulent business practices;

c. Ordering injunctive relief as permitted by law or equity, including enjoining Defendant from continuing the unlawful practices as set forth herein, and ordering Defendant to engage in a corrective advertising campaign;

d. Ordering damages in amount which is different than that calculated for restitution for Plaintiff and the Class;

e. Ordering Defendant to pay attorneys' fees and litigation costs to Plaintiff and the other members of the Class;

f. Ordering Defendant to pay both pre- and post-judgment interest on any amounts awarded; and

g. Ordering other relief as may be just and proper.

Jury Demand

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

Dated: April 29, 2026.

Respectfully submitted,

GUCOVSCHI LAW FIRM, PLLC

By: */s/ Nathaniel H. Sari*

Adrian Gucovschi (State Bar No. 360988)
Nathaniel Haim Sari (State Bar No. 362634)
165 Broadway, Fl. 23
New York, NY 10005
Telephone: (212) 884-4230
E-Mail: adrian@gucovschilaw.com

nathaniel@gucovschilaw.com
Attorneys for Plaintiff

CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)

I, Nathaniel Sari, declare as follows:

1. I am an attorney at law licensed to practice in the State of California and a member of the bar of this Court. I am of counsel at Gucovschi Law Firm, PLLC, counsel of record for Plaintiff Sydney Turner in this action. Sydney Turner alleges that she is a citizen of California who resides in Fountain Valley, California. I have personal knowledge of the facts set forth in this declaration and, if called as a witness, I could and would competently testify thereto under oath.

2. The Complaint filed in this action is filed in the proper place for trial under Civil Code Section 1780(d) in that Defendant Costco Wholesale Corporation, regularly does business in the California Central District of California, and a substantial portion of the events alleged in the Complaint, including the same misrepresentations, omissions, and injuries as alleged herein, have occurred in this District.

I declare under the penalty of perjury under the laws of the State of California and the United States that the foregoing is true and correct, and that this declaration was executed at Miami, Florida, on Wednesday, April 29, 2026.

/s/ Nathaniel H. Sari
Nathaniel H. Sari

Exhibit A

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 as product

MISSING INFORMATION: _____

Page 1

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** _____

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1.

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 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

Page 3

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

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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 _____ Date 3/4/95

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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.
International status	Allowed by IFOAM, EU and Codex.

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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

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6.

MSDS for CITRIC ACID, MONOHYDRATE Page 1

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)

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.

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7.

TOXIC GASES PRODUCED: CARBON MONOXIDE, CARBON DIOXIDE

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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.

---

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.

---

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.

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8.

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)

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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:	106833333.333LBS/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

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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

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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:

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Exhibit B

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Home Inspections, Compliance, Enforcement, and Criminal Investigations Enforcement Actions Warning Letters

Hirzel Canning Company 29-Aug-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

August 29, 2001
WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Karl A. Hirzel, President
Hirzel Canning Company
411 Lemoyne Road
Northwood, Ohio 43619

Dear Mr. Hirzel:

During an inspection of you firm on June 13, 2001 our Investigator collected labels for canned tomato products manufactured by your firm. We have limited our review to three of your products, which we have determined to be sufficiently representative of the labeling efficiencies of your products. Our review of the labels collected for the products listed below show that they cause the products to be in violation of Section 403 of the Federal Food Drug , and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling as follows:

Dei Fratelli CONCENTRATED/ITALIAN STYLE TOMATO PUREE No Salt Added (28 OZ. Cm)

The above product is misbranded within the meaning of Section 403 (a)(l) of the Act in that its labeling 1s false or misleading. The term "FRESH-PACKED" used on the principal display panel, which falsely implies that the finished product in the package is ?fresh," when in fact it has been thermally processed. The Food and drug Administration (FDA) would not object to the use of the term "fresh" in the context of a statement such as "packed from lies tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

Dei Fratelli Fresh & Read CHOPPED TOMATOES ONION & GARLIC (14.5 oz. cans) and Dei ratelli Fresh & Ready CHOPPED MEXICAN TOMATOES & JALAPENOS (14.5 oz. cans)

The above products are misbranded within the meaning of Section 403 a)(1) of the Act in that their labeling is false or misleading. The statements "FRESH- PACKED" on the principal display panel and "Fresh & Ready" in the brand name of the products falsely imply that the finished products in the package are "fresh," when in fact the have been thermally processed. In addition, according to the ingredient statements, the products contain at east two preservatives. Products that have been thermally processed or that contain preservatives do not meet the definition of "fresh." As stated above, FDA does not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

The Dei Fratelli ® ***. CHOPPED MEXICAN TOMATOES & JALAPENOS product is also misbranded under section 403 (r)((l)(A) of the Act because the label bears the nutrient content claim "HEALTHY," but does not meet the requirements for the claim, as defined in 21 CFR 101.65 (d). Based on the information m the nutrition label, the CHOPPED MEXICAN TOMATOES & JALAPENOS product contains 590 mg of sodium. A "healthy" claim may be used where, among other thing, the product contains no more than 360 mg of sodium.

Furthermore, the Dei Fratelli ® *** CONCENTRATED/ITALIAN STYLE TOMATO PUREE, CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS products are misbranded under section 403(r)(l)(A) of the Act because the labels bear nutrient content claims that are not authorize by regulation for the Act or are not consistent with an authorizing regulation. The claims include "** *a great source of Vitamins A and C, and the nutrient Lycopene." In the context used on these labels, the term "great source" is considered to be an unauthorized synonym for "high." FDA has define the nutrient content claim "high" in 21 CFR 101.54(b). ?High" can be used on a food label provided the food contains 20 percent or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed.

There is no established reference value for Lycopene; therefore, the claim "*** great source of *** Lycopene" is not authorized. In addition, the Dei Fratelli ® *** CONCENTRATE/ITALIAN STYLE TOMATO PUREE does not contain 20% or more of the RDI of vitamin A and the CHOPPED MEXICAN TOMATOES & JALAPENOS does not contain 20% or more of the RDIs for Vitamin A or C.

Some of the labels for your tomato products have a "NO SALT ADDED" statement on products that are not sodium free. However, the required statement, "not a sodium free food" or "not for control of sodium in the diet" does not appear on the information panel of the labels.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result m enforcement action such as seizure and/or injunction being initiated by FDA without further notice.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject your food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should also be aware that the term "fresh" in the ingredient name "FRESH TOMATOES" should not appear in the ingredient statement as part of the common or usual name of an ingredient. Ingredients must be declared b their common or usual & name, as stated in section 403(I)(2) of the Act and 21 CFR 101.4(a)(l). Optional information, such as the term "fresh? is not permitted.

Also, the Dei Fratelli ® *** CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS labels bear the term "All NATURAL," but according to the ingredient statements, calcium chloride and citric acid are added to the products. We have not established a regulatory definition for the term "natural," however; we discussed its use in the ream le to the food labeling final regulations (58 Federal Register 2407, January 6, 1993). FDA?s policy regarding the use "natural", means that nothing artificial or synthetic as been included m, or as been added to, a food that would not normally be expected to be in the food. Therefore, the addition of calcium chloride and citric acid to these products preclude use of the term "natural" to describe this product.

Please advise us in writing within fifteen(15) working days of receipt of this letter of the specific actions you have taken to correct the violations along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,
Henry Fielden
District Director
Cincinnati District

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

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Exhibit C

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Home Inspections, Compliance, Enforcement, and Criminal Investigations Enforcement Actions Warning Letters

Oak Tree Farm Dairy, Inc. 16-Aug-01
DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food & Drug Administration
New York District
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED
August 16, 2001
Ref: NYK-2001-113

Richard Classey
Vice President and General Manager
Oak Tree Farm Dairy, Inc.
544 Elwood Road
East Northport, NY 11731

Dear Mr. Classey:

On May 17 and June 5 and 7,2001, we inspected your beverage manufacturing facility located at the above address. During the inspection, we collected a sample of your "OAKTREE REAL BREWED ICED TEA" product and labels for your "OAKTREE FRUIT PUNCH" and "OAKTREE ALL NATURAL LEMONADE" products. Our analysis of the iced tea and review of the labels found serious violations of the Federal Food, Drug, and Cosmetic Act ("the Act") and Title 21, Code of Federal Regulations, Part 101 - ,Food Labeling(21 CFR 101).

The "OAKTREE REAL BREWED ICED TEA" is misbranded under Section 403(i)(2) of the Act in that it contains the color additive "FD&C Red No. 40", but the certified color additive fails to be declared on the product label in the statement of ingredients by its specific name, as required (21 CFR 101.22(k)(1)). The product is also misbranded under Section 403(k) of the Act because it contains an artificial coloring that is not declared on the label.

The "OAKTREE FRUIT PUNCH" is misbranded under Section 403(k) of the Act because it contains sodium benzoate and potassium sorbate, which are not declared on the product label. A food to which a chemical preservative is added must declare the common or usual name of that ingredient and a description of its function, e.g., "preservative", as required by 21 CFR 101.226).

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your product labels. Other label violations can subject the foods to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration ("FDA").

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

As you know, during the inspection, our investigator also reviewed the labels and formulations for your "OAKTREE ALL NATURAL LEMONADE" and "OAKTREE FRUIT PUNCH". Your lemonade label fails to declare the ingredient, citric acid, which is declared as an ingredient on the label of the lemonade concentrate used to make your lemonade. Further, your fruit punch label fails to declare the ingredients, grape juice, artificial fruit punch flavor, propylene glycol, sodium benzoate, and potassium sorbate, which are declared as ingredients on the label of the fruit punch concentrate used to make your fruit punch. Also, your fruit punch label declares the ingredients, concentrated pineapple juice, gum arabic, glycerol ester of wood resin, and blue 1.

However, these ingredients are not found in the fruit punch concentrate used to make your fruit punch and are not listed as ingredients in your fruit punch formulation. The investigator discussed these labeling discrepancies with you at the conclusion of the inspection.

The term "all natural" on the "OAKTREE ALL NATURAL LEMONADE" label is inappropriate because the product contains potassium sorbate. Although FDA has not established a regulatory definition for "natural," we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6, 1993, copy enclosed). FDA?s policy regarding the use of "natural," means nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. The same comment applies to use of the terms" 100 % NATURAL" and "ALL NATURAL" on the "OAKTREE REAL BREWED ICED TEA" label because it contains citric acid.

Further, the declaration of potassium sorbate in the ingredient statement on the "OAKTREE ALL NATURAL LEMONADE" label must be followed by a description of its function, e.g., "preservative", as required by 21 CFR 101.22(j).

You should notify this office in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be directed to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions concerning the violations noted, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

/s/
Robert L. Hart
Acting District Director

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Exhibit D

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Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters

Inspections, Compliance, Enforcement, and Criminal Investigations

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 b 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 dc 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

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