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# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

DENISE MASON, individually and on behalf of other similarly situated individuals,

Case No.

Plaintiff,

CLASS ACTION COMPLAINT

v.

REED'S INC. d/b/a VIRGIL'S SODAS,

DEMAND FOR JURY TRIAL

Defendant.

Denise Mason, a New York Resident ("Plaintiff"), individually and on behalf of other similarly situated individuals, allege the following Class Action Complaint against Defendant, Reed's Inc. d/b/a Virgil's Sodas ("Virgil's" or "Defendant"), upon personal knowledge as to herself and her own acts and upon information and belief as to all other matters, based upon, inter alia, the investigation made by her attorneys – as to all other matters, as follows:

#### INTRODUCTION

- This is a consumer protection action seeking redress for, and a stop to, Defendant's unfair and deceptive practice of advertising and marketing its line of soda products (the "Products") as "Made Naturally,"
   "Made with Natural Ingredients," "Brewed with 100% Natural Ingredients" and having "No Preservatives."
  - Specifically, the Products include, but are not limited to:
    - · Virgil's Root Beer
    - Virgil's Orange Cream Soda<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Discovery may demonstrate that additional Virgil's' products are within the scope of this Complaint.

- 3. Defendant's "No Preservatives" representations are false, deceptive and misleading because the Products contain the preservative, citric acid. This labeling deceives consumers into believing that they are receiving healthier preservative-free soda even though these products cannot live up to these claims.
- 4. Similarly, Defendant's "Made Naturally," "Made with Natural Ingredients," and "Brewed with 100% Natural Ingredients" representations are false, deceptive, and misleading because the preservative, citric acid, is a synthetic compound and thus not natural. Citric acid is usually produced from certain strains of the mold *Aspergillus niger*, which is mass produced, and the application of chemical solvents such as sulfuric acid.
- 5. These misrepresentations deceive consumers into thinking they are receiving healthier and "natural" soda, when they are not. Conscious of consumers' increased interest in more nutritious foods free of additives, and their willingness to pay more for products perceived to meet these preferences, Defendant misleadingly, illegally and deceptively seek to capitalize on these consumer health trends.
- 6. Plaintiff and those similarly situated ("Class Members") relied on Defendant's misrepresentations that the Products are natural and contain no preservatives when purchasing the Products. Plaintiff and Class Members paid a premium for the Products over comparable products that did not purport to be natural or preservative-free. Given that Plaintiff and Class Members paid a premium for the Products based on Defendant's misrepresentations that they are natural and contain no preservatives, Plaintiff and Class Members suffered an injury in the amount of the premium paid.
- 7. Defendant's conduct violated and continues to violate New York General Business Law §§ 349 and 350. Defendant breached and continues to breach their express warranties regarding the Products. Accordingly, Plaintiff brings this action against Defendant on behalf of herself and Class Members who purchased the Products during the applicable statute of limitations period (the "Class Period").

#### JURISDICTION AND VENUE

- 8. This Court has original jurisdiction over the claims asserted herein individually and on behalf of the Class pursuant to 28 U.S.C. §1332, as amended in 2005 by the Class Action Fairness Act Subject matter jurisdiction is proper because: (1) the amount in controversy in this class action exceeds \$5,000,000, exclusive of interest and costs; and (2) a substantial number of the members of the proposed class are citizens of a state different from that of Defendant, a corporate entity each having a principal place of business in Los Angeles, California.
- 9. This Court has personal jurisdiction over Defendant because it regularly conducts business in this District and purposefully avails itself of the laws of New York to market, promote, distribute,

and sell the Products to consumers in New York and this District. Defendant engages in the wrongdoing alleged in this Complaint throughout the United States, including New York State. Defendant is authorized to do business in New York State, and Defendant has sufficient contacts with New York and/or otherwise has intentionally availed itself of the markets in New York State, rendering the exercise of jurisdiction by the Court permissible under traditional notions of fair play and substantial justice. Moreover, Defendant engages in substantial and not isolated activity within New York State.

10. Venue is proper in this District under 28 U.S.C. § 1391(a). Substantial acts in furtherance of the alleged improper conduct, including the dissemination of false and misleading information regarding the nature, quality, and/or ingredients of the Products, occurred within this District.

#### **PARTIES**

- 11. This is a nationwide consumer class action brought by Plaintiff on behalf of all individuals who purchased the Products for personal use and not for resale.
- 12. During the relevant period, Class Members in New York and throughout the United States purchased the Products through numerous brick-and-mortar retail locations. Plaintiff and Class Members suffered an injury in fact caused by the false, fraudulent, unfair, deceptive, and misleading practices set forth in this Complaint.
- 13. Plaintiff is a resident of Bronx County, New York. She purchased the Defendant's Products at a Whole Foods Market in New York, New York, during the three years preceding the filing of this Complaint.
- 14. Plaintiff purchased Defendant's Products because she saw the labeling, advertising, and read the packaging, which represented that the products were "Made Naturally," "Made with Natural Ingredients," "Brewed with 100% Natural Ingredients" and contained "No preservatives." She relied on Defendant's false, misleading, and deceptive representations that the products were natural and contained no preservatives. Had she known the truth—that the representations she relied upon in making her purchases were false, misleading, and deceptive—she would not have purchased the products at a premium price.
- 15. Defendant's statements are false and misleading to a reasonable consumer because, as set forth more fully herein, the Products contain a synthetic chemical and preservative, citric acid.
- 16. Defendant is a corporation organized and existing under the laws of the State of California with its principal place of business in Los Angeles, California. Defendant manufactures, markets, advertises and distributes the Products throughout New York and the United States. Defendant created and/or authorized

the false, misleading and deceptive advertisements, packaging and labeling for the Products.

#### SUBSTANTIVE ALLEGATIONS

# Defendant's "No Preservatives" Representation Is False and Misleading To A Reasonable Consumer

- 17. Defendant misleads consumers into thinking that the Products contain no preservatives with its false labeling claims to this effect. However, the Products actually contain citric acid, whose functions as a preservative have been well-documented.
- 18. Citric acid is a preservative as the term is defined by the FDA in 21 C.F.R. § 101.22(a)(5): "The term chemical preservative means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties."
- 19. The scientific evidence and FDA statements cited below establish that citric acid tends to prevent or retard the deterioration of food products. This remains the case regardless of the subjective purpose for which this substance is added to the Product.
- Citric acid does not fall into any of the regulatory exemptions from the definition of a preservative.
- 21. The FDA expressly classifies citric acid as a preservative in its "Overview of Food Ingredients, Additives, and Colors" on the FDA's website<sup>2</sup>:

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	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,
	(antioxidants); maintain freshness		EDTA, tocopherols (Vitamin E)

22. The FDA's classification of citric acid as a preservative is further confirmed by its Warning

<sup>&</sup>lt;sup>2</sup> http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm094211.htm

Letter, dated October 6, 2010, to the manufacturer of the Chiquita brand "Pineapple Bites with Coconut" and "Pineapple Bites," which states, in pertinent part:

"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 preservative ascorbic acid and citric acid but their labels fail to declare these preservatives with a description of their functions. 21 CFR 101.22." See, **EXHIBIT A**, FDA Warning Letter dated October 6, 2010.

- 23. As described above, a preservative as defined by the FDA is a substance that "tends" to prevent or retard the deterioration of food products. Thus, it is not necessary that it function as a preservative in every single instance for it to qualify as a preservative according to the FDA's definition, so long as this is its general tendency.
- 24. Citric acid's nature as a preservative is also acknowledged by insiders in the preservative manufacturing and distribution industries. FBC Industries, Inc. a manufacturer and supplier of FCC grade Citric Acid additives, acidulants, buffering agents and preservatives for the food and beverage industry, describes citric acid's function: "Citric acid is the most commonly used acidulant in the industry. As a food additive or food grade product, citric acid is used as a flavoring and preservative."
- 25. Citric acid functions as a preservative by serving as an acidulant. Citric acid kills microbes by reducing the pH of the product that it is added to. Microorganisms contaminating food generally multiply more slowly or not at all at lower PH levels.<sup>4</sup>
- 26. Citric acid likewise functions as a preservative by serving as a sequestrant, i.e., it prevents oxidation and impedes microbial growth, thereby slowing degradation of food and beverages.<sup>5</sup>
- 27. Citric acid further functions as a preservative by infiltrating and then weakening or killing microorganisms through direct antimicrobial effect.<sup>6</sup>

<sup>4</sup> "Acids as food additives serve a dual purpose, as acidulants and preservatives." DeMan, John M., Principles of Food Chemistry. AVI Publishing Co, Inc., 1999, p. 438; see also, Doores, S., 1993. Organic Acids. In: Davidson, P.M., Branen, A.L. (Eds.), Antimicrobials in Foods. Marcel Dekker, Inc., New York, pp. 95-136; see also, Nazer, A.I., et al. Combinations of Food Antimicrobials at Low Levels to Inhibit the Growth of Salmonella sv. Typhimurium: a Synergistic Effect? Food Microbiology 22.5 (2005) pp. 391-398.

http://www.fbcindustries.com/Citric Acid.aspx

<sup>&</sup>lt;sup>5</sup> Igoe, Robert S., *Dictionary of Food Ingredients*. Springer Science & Business Media, 2001, p. 167; see also, DeMan, John M., Principles of Food Chemistry. AVI Publishing Co, Inc., 1999, p. 438.

<sup>&</sup>lt;sup>6</sup> Juvonen, Riikka, et al. Microbiological Spoliage and Safety Risks in Non-Beer Beverages. VTT Research Notes 2599 (2011), p. 73.

28. In sum, with the use of citric acid, various effects such as (i) spoilage from bacteria, mold, fungi and yeast, (ii) changes in flavor, color and texture, (iii) browning and (iv) rancidity, can be prevented over the shelf-life of the food product.<sup>7</sup>

#### Plaintiffs' Claims Are Not Preempted by the FDCA

- 29. Defendant's deceptive misrepresentations violate the FDCA, which provides that "[a] food shall be deemed misbranded if its labeling is false or misleading in any particular." 21 U.S.C. § 343 (a)(1).
- 30. Plaintiff's claims are not preempted by the FDCA because the definition of "preservative" as used herein is identical with that of the FDA (see above). Moreover, FDA regulations specifically note that claims like "No Preservatives" are non-nutritive claims that are not governed by 21 C.F.R. §101.13. See, 21 C.F.R. § 101.65(b)(2). Since the FDA has not issued specific standards governing when "No Preservative" claims are either true or false, such representations fall outside the ambit of FDA regulations. Accordingly, Plaintiff's claim cannot possibly be preempted. See, Bimont v. Unilever U.S., Inc., No. 14-CV-7749 (JPO), 2015 U.S. Dist. LEXIS 119908, at \*6 (S.D.N.Y. Sep. 9, 2015) ("[P]reemption does not preclude a state-law claim if the state requirement is outside the scope of the relevant federal requirements").

#### Defendant's Misrepresentations Are Material to a Reasonable Consumer and Were Relied Upon by Plaintiff and the Class

- 31. Plaintiff and Class members reasonably relied on Defendant's representations that the Products are free of preservatives.
- 32. Defendant's misrepresentations are misleading and deceive reasonable consumers. At the point of sale, Plaintiff and Class members did not know, and had no reason to know, that the Products were misbranded as set forth herein. A representation that a product has "No Preservatives" is material to a reasonable consumer when deciding to purchase it. Plaintiff did, and a reasonable consumer would, attach importance to whether Defendant's Products have "No Preservatives" because it is common knowledge that consumers prefer to avoid foods with potentially unhealthy additives.

#### Defendant Has an Intent to Mislead

33. Defendant would not include the representations on the labels of the Products if these

<sup>&</sup>lt;sup>7</sup> Doores, S., 1993. Organic Acids. In: Davidson, P.M., Branen, A.L. (Eds.), Antimicrobials in Foods. Marcel Dekker, Inc., New York, pp. 95-136.

representations would not influence consumer behavior.

- 34. By representing that the Products have "No Preservatives," Defendant seeks to capitalize on consumers' preference for less processed foods with fewer additives and the association between such products and a wholesome way of life. Consumers are willing to pay more for less processed products with no additives because of this association, as well as the perceived higher quality, health, and safety benefits associated with products labeled as being free of preservatives.
- 35. The marketing research firm Mintel reports that more and more Americans are concerned about avoiding food products that contain preservatives:

Foods bearing "free-from" claims are increasingly relevant to Americans, as they perceive the products as closely tied to health. New research from Mintel reveals that 84 percent of American free-from consumers buy free-from foods because they are seeking out more natural or less processed foods. In fact, 43 percent of consumers agree that free-from foods are healthier than foods without a free-from claim, while another three in five believe the fewer ingredients a product has, the healthier it is (59 percent).

Among the top claims free-from consumers deem most important are trans-fat-free (78 percent) and **preservative-free** (71 percent).<sup>8</sup>

36. Alternet.org reports on research that shows that most Americans are willing to pay a premium price for healthier food options:

Not only are consumers increasingly seeking out wholesome foods, they are willing to pay a premium for them. According to Nielsen's 2015 Global Health & Wellness Survey that polled over 30,000 people online, 88 percent of Americans are willing to pay more for healthier foods. Global sales of healthy food products are estimated to reach \$1 trillion by 2017, according to Euromonitor. When it comes to what consumers will be seeking out more of over the coming year, it may amount to single word. "Just think of the word no," Seifer said. "No preservatives, no additives, no growth hormones."

- 37. Defendant has a natural interest in misrepresenting its Products as free of preservatives given these trends addressed above, despite the presence of citric acid. The Products' misrepresentations provide a clear marketing advantage over competitors that do not engage in such deceptive conduct.
- 38. Defendant knows that their "No Preservatives" representations on the Products are false and intend that they be relied upon by Plaintiff and the Class.

<sup>8</sup> http://www.mintel.com/press-centre/food-and-drink/84-of-americans-buy-free-from-foods-becausethey-believe-them-to-be-more-natural-or-less-processed

<sup>9</sup> http://www.alternet.org/food/8-food-trends-watch-2016

#### Plaintiff and the Class Were Injured as The Result of Defendants' Deceptive Practices

39. Plaintiff and the Class were injured when Defendant denied them the full benefit of their bargain. They paid money for Products that were represented to them as preservative-free, and then received Products that were preservative-laden, which have significantly less value. Plaintiff and the Class were thus deprived of the benefit of their bargain. They would not have purchased the Products, or would only have been willing to pay less for them, had they known the truth. Plaintiff and the Class were injured in an amount up to the purchase price, the difference between the actual value of the Products and the value of the Products as misrepresented to them by Defendant, to be determined by expert testimony at trial. Defendant's very inclusion of "No Preservatives" on the Products' labels is an acknowledgment that this increases the Products' perceived value. See, Orlander v. Staples, Inc., 802 F.3d 289, 302 (2d Cir. 2015) ("the issue of 'price premium' was relevant because it showed that plaintiffs paid more than they would have for the good but for the deceptive practices of the defendant-sellers"); Kacocha v. Nestle Purina Petcare Co., No. 15-CV-5489 (KMK), 2016 U.S. Dist. LEXIS 107097, at \*51-52 (S.D.N.Y. Aug. 11, 2016) ("[I]n his Complaint, Plaintiff seeks monetary damages on the grounds that he 'would not have paid the premium price he paid' to buy the Products had he 'known the truth.'...Case law makes clear that this is sufficient at the motion-to-dismiss phase for a \ 349 claim to survive."); Koenig v. Boulder Brands, Inc., 995 F.Supp. 2d 274, 288-89 (S.D.N.Y. 2014) ("Plaintiffs claim that, but for Defendants' 'unfair and deceptive practices,' they-and the putative class-would not have purchased, or paid a price premium for, Smart Balance, Compl. ¶¶ 7, 81, Indeed, Plaintiffs claim that they paid price premiums specifically 'based on Defendants' misrepresentations,' and allege that they deserve damages in the amount of either the purchase prices, or the price premiums that they paid for Smart Balance. Id. ¶ 81. Accordingly, the Court finds that Plaintiffs have adequately alleged injury under GBL § 349...").

#### Defendant Cultivates a "Natural" Brand Image for the Products

- 40. Defendant knows that consumers seek out and wish to purchase whole, natural foods that do not contain artificial chemicals and are preservative-free, and that consumers will pay more for foods that they believe to be natural and preservative-free than they will pay for foods that they do not believe to be natural or preservative-free.
- 41. A recent nationally representative Consumer Reports survey of 1,005 adults found that more than half of consumers usually seek out products with a "natural" food label, often in the false belief that they're produced without genetically modified organisms, hormones, pesticides, or artificial ingredients. *See*, Consumer Reports National Research Center, *Natural Food Labels Survey* (2015).<sup>10</sup>

Available at http://www.consumerreports.org/content/dam/cro/magazine-articles/2016/March/Consumer Reports Natural Food Labels Survey 2015.pdf.

- 42. To capture this market, Defendant has prominently made claims on their product labels that their Products are "natural" or statements of similar import, cultivating a wholesome and healthful image in an effort to promote the sale of these products.
- 43. In particular, the Defendant's labels assert that the Products are "Made Naturally," "Made with Natural Ingredients," and "Brewed with 100% Natural Ingredients." See, Exhibit B, annexed hereto.
- 44. Upon information and belief, Defendant has profited enormously from its falsely marketed Products and its carefully orchestrated label and image.
  - 45. Representing that a product is "natural" is a false statement of fact.
- 46. Consumers reasonably believe that a product or ingredient represented as "natural" does not contain synthetic chemicals.

#### Citric Acid Is Not a Natural Ingredient

- 47. Defendant's representations that the Products are "Made Naturally," "Made with Natural Ingredients," and "Brewed with 100% Natural Ingredients" "are false.
- 48. Citric acid (2-hydroxy-propane-1,2,3-tricarboxylic acid) is a synthetic, non-natural ingredient. While the chemical's name has the word "citric" in it, citric acid is no longer extracted from the citrus fruit but industrially manufactured by fermenting certain genetically mutant strains of the black mold fungus, *Aspergillus niger*. <sup>11</sup>
- 49. A technical evaluation report for the substance, citric acid, compiled by the United States Department of Agriculture, Agriculture Marketing Service ("USDA AMS") for the National Organic Program, classified citric acid as "Synthetic Allowed." *See*, Exhibit C, annexed hereto.
  - 50. As one of the USDA AMS reviewers commented:

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

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

<sup>&</sup>lt;sup>11</sup> See, e.g., Belen Max, et al. Biotechnological production of citric acid, BRAZILIAN JOURNAL OF MICROBIOLOGY, 41.4 Sao Paolo (Oct./Dec. 2010)

"Traditionally by extraction from citrus juice, no longer commercially available. It is now extracted by fermentation of a carbohydrate substance (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.

52. Because citric acid is a synthetic acid and cannot be reasonably considered a natural ingredient, Defendant's claims that the Products are "Made Naturally," "Made with Natural Ingredients," and "Brewed with 100% Natural Ingredients" are false, deceptive, and misleading.

#### Defendant's Labels Are Misleading and Omit Material Facts

- 53. Virgil's' conduct in labeling or representing the Products as "Made Naturally," "Made with Natural Ingredients," and "Brewed with 100% Natural Ingredients" deceived and/or was likely to deceive the public.
- 54. Consumers were deceived into believing that the Products are natural and that nothing in the Products was not natural.
  - 55. Instead, the Products contain citric acid, a synthetic ingredient.
  - Consumers cannot discover the true nature of the Products from reading the label.
- 57. Discovery of the true nature of the content of the Products requires knowledge of chemistry that is not available to the average reasonable consumer.
- 58. Defendant deceptively and misleadingly conceals material facts about the Products, namely, that the Products are not "natural" because in fact the Products contain citric acid; and the Products are not what a reasonable consumer would consider "natural" because in fact they contain citric acid.
  - 59. Defendant's concealment tolls the applicable statute of limitations.

#### Defendant Knew That its Representations Were False

- 60. Consumers frequently rely on label representations and information in making purchase decisions, especially in purchasing food.
- 61. Defendant made the false, misleading, and deceptive representations and omissions intending for consumers to rely upon these representations and omissions in purchasing the Products.

- 62. In making the false, misleading, and deceptive representations and omissions at issue, Defendant knew and intended that consumers would purchase the Products when consumers would otherwise purchase a competing product.
- 63. Consumers are not only willing to pay more for a product with ingredients that purport to be "natural" they also expect that product to be free of synthetic ingredients.
- 64. In making the false, misleading, and deceptive representations and omissions at issue, Defendant also knew and intended that consumers would pay more for "natural" products that are free of unnatural agents than they would pay for products that are not "natural," furthering Defendant's private interest of increasing sales of their products and decreasing the sales of the natural products that are truthfully marketed by their competitors.
- 65. Defendant knows that consumers prefer "natural" ingredients, and foods that do not contain unnatural chemicals. Defendant knows that consumers will pay more for "natural" foods or would not purchase the foods at all unless they were "natural" and free from unnatural chemicals.
- 66. Similarly, independent surveys confirm that consumers will purchase more "natural" products than conventional products, and will pay more for "natural" products.
- 67. On or about June 25, 2018, Plaintiff's counsel first provided Defendant with all the material allegations included in this Complaint. Defendant was thus specifically notified that their Products labeled as "Made Naturally," "Made with Natural Ingredients," "Brewed with 100% Natural Ingredients" and containing "No preservatives" were misbranded. Defendant thus knew all the facts demonstrating that their Products were falsely advertised. Defendant made the false, deceptive, and misleading representations and omissions, intending for Plaintiff and the Class members to rely upon these representations and omissions in purchasing the falsely labeled Products.
- 68. Upon information and belief, Defendant has failed to remedy the problem with the Products, thus causing future harm to consumers.
- 69. Defendant has failed to provide adequate relief to members of the proposed classes as of the date of the filing of this Complaint.
- 70. Plaintiff contends that the Products were sold pursuant to unfair and unconscionable trade practices because the sale of Defendant's Products offends public policy and is immoral, unethical, oppressive, unscrupulous, and caused substantial economic injuries to consumers.

- 71. Reasonable consumers do not expect the Products, represented and advertised as "natural," to contain unnatural chemicals or ingredients such as citric acid. Defendant's statements and other representations convey a series of express and implied claims and/or omissions which Defendant knows are material to the reasonable consumer in making a purchasing decision, and which Defendant intended for consumers to rely upon when choosing to purchase the Products.
- 72. Based on Defendant's misleading and deceptive representations, Defendant was able to, and did, charge a premium price for the Products over the cost of competitive products not bearing a "natural" label.

#### CLASS ALLEGATIONS

- 73. Plaintiff re-alleges and incorporates by reference the allegations set forth in each of the preceding paragraphs of this Complaint.
- 74. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of herself and all others similarly situated individuals within the United States (the "Class" or the "Nationwide Class"), defined as follows:

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

75. Additionally, Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of herself and all others similarly situated New York Citizens (the "New York Subclass"), defined as follows:

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

- 76. Upon information and belief, the scope of the Class and Subclass definitions, including temporal scope, may be further refined after discovery of Defendant's and/or third party records.
- 77. The Class and the New York Subclass will be referred to collectively throughout the Complaint as the "Class."
- 78. Excluded from the Class are (1) Defendant, any entity or division in which Defendant has a controlling interest, and their legal representatives, officers, directors, assigns, and successors; and (2) the judge to whom this case is assigned and the judge's staff.

- 79. All members of the Class were and are similarly affected by the deceptive advertising of the Defendant, and the relief sought herein is for the benefit of Plaintiff and members of the Class.
- 80. Certification of Plaintiff's claims for class-wide treatment is appropriate because Plaintiff can prove the elements of her claims on a class-wide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.
- 81. Numerosity Federal Rule of Civil Procedure 23(a)(l). At this time, Plaintiff does not know the exact number of the Class and Subclass members. Based on the annual sales and popularity of the Products, it is readily apparent that the number of consumers in the Class is so large as to make joinder impracticable, if not impossible. Class Members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. Mail, electronic mail, Internet postings, and/or published notice.
- 82. Commonality and Predominance -Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3). There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions that may affect individual Class members include:
  - (a) whether Defendant misrepresented and/or failed to disclose material facts concerning the falsely labeled Products;
  - (b) whether Defendant's conduct was unfair, misleading and/or deceptive; and
  - (c) whether Defendant breached an express warranty created through the labeling and marketing of its falsely labeled Products;
  - (d) whether, as a result of Defendant's misconduct as alleged herein, Plaintiff and the Class suffered an ascertainable loss; and
  - (e) Whether Defendant was unjustly enriched at the expense of the Plaintiff and Class Members.
- 83. With respect to the New York Subclass, additional questions of law and fact common to the members that predominate over questions that may affect individual members include:
  - (a) whether, in violation of § 349 of the New York General Business Law ("GBL"), Defendant engaged in deceptive acts or practices; and
  - (b) whether, in violation of GBL § 350, Defendant engaged in false advertising.
- 84. Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiff, on behalf of herself, and the other Class members. Similar or identical statutory and

common law violations, business practices, and injuries are involved. Individual questions, if any, pale by comparison, in both quality and quantity, to the numerous common questions that dominate this action.

- 85. Plaintiff's claims are typical of the claims of the Nationwide Class. Plaintiff is a member of a well-defined class of similarly situated persons and the members of the Nationwide Class were similarly affected by Defendant's conduct and are owed the same relief, as alleged in this Complaint. Members of the Nationwide Class are ascertainable from Plaintiff's description of the class, Defendant's records, and records of third parties accessible through discovery.
- 86. Plaintiff's claims are typical of the claims of the New York Subclass. Plaintiff is a member of a well-defined class of similarly situated persons and the members of the New York Subclass were similarly affected by Defendant's conduct and are owed the same relief, as alleged in this Complaint. Members of the New York Subclass are ascertainable from Plaintiff's description of the class, Defendant's records, and records of third parties accessible through discovery.
- 87. Adequacy of Representation Federal Rule of Civil Procedure 23(a)(4). Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff is an adequate representative of the Class because her interests do not conflict with the interests of the Class members she seeks to represent, and she has retained counsel competent and experienced in both consumer protection and class action litigation. Plaintiff and her counsel will fairly and adequately protect the interests of the members of the Class. Undersigned counsel has represented consumers in a variety of actions where they have sought to protect consumers from fraudulent and deceptive practices.
- 88. Insufficiency of Separate Actions Federal Rule of Civil Procedure 23(b)(l). Absent a representative class action, members of the Class would continue to suffer the harm described herein, for which they would have no remedy. Even if separate actions could be brought by individual consumers, the resulting multiplicity of lawsuits would cause undue burden and expense for both the Court and the litigants, as well as create a risk of inconsistent rulings and adjudications that might be dispositive of the interests of similarly situated purchasers, substantially impeding their ability to protect their interests, while establishing incompatible standards of conduct for Defendant. The proposed Class thus satisfies the requirements of Fed. R. Civ. P. 23(b)(l).
- 89. **Predominance and Superiority of Class Action.** The prerequisites to maintaining a class action pursuant to Federal Rule of Civil Procedure 23(b)(3) are met because questions of law and fact common to each Class member predominates over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

- 90. Individual joinder of the Class members is not practicable, and questions of law and fact common to the Class predominate over any questions affecting only individual Class members. Each Class member has been damaged and is entitled to recovery as a result of the violations alleged herein.
- 91. Moreover, because the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation would make it difficult or impossible for individual Class members to redress the wrongs done to them, while an important public interest will be served by addressing the matter as a class action. Class action treatment will allow those persons similarly situated to litigate their claims in the manner that is most efficient and economical for the parties and the judicial system.
- 92. Defendant's conduct is generally applicable to the Class and the New York Subclass as a whole and Plaintiff seeks, inter alia, equitable remedies with respect to the Class and the New York Subclass as a whole. As such, Defendant's systematic policies and practices make declaratory relief with respect to the Class and the New York Subclass as a whole appropriate.
  - 93. Plaintiff is unaware of any difficulties in managing this case that should preclude class action.

# CAUSES OF ACTION COUNT I

#### Violation of New York General Business Law § 349 (On Behalf of the New York Sub-Class)

- 94. Plaintiff incorporates by reference all the allegations of the preceding paragraphs of this Complaint.
- 95. New York General Business Law Section 349 ("GBL § 349") declares unlawful "[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state . . ."
- 96. The conduct of Defendant alleged herein constitutes recurring, "unlawful" deceptive acts and practices in violation of GBL § 349, and as such, Plaintiff and the New York Subclass Members seek monetary damages, compensatory damages, injunctive relief, restitution and disgorgement of all moneys obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.
  - 97. There is no adequate remedy at law.
  - 98. Defendant misleadingly, inaccurately, and deceptively presented its Products to consumers.

- 99. Defendant's improper consumer-oriented conduct—including labeling and advertising the Products as being "Made Naturally," "Made with Natural Ingredients," "Brewed with 100% Natural Ingredients" and containing "No preservatives"—is misleading in a material way in that it, *inter alia*, induced Plaintiff and the New York Subclass Members to purchase and pay a premium for Defendant's Products and to use the Products when they otherwise would not have. Defendant made its untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.
- 100. Plaintiff and the New York Subclass Members have been injured inasmuch as they paid a premium for Products that were—contrary to Defendant's representations—not preservative-free and not "Made Naturally," "Made with Natural Ingredients," or "Brewed with 100% Natural Ingredients." Accordingly, Plaintiff and the New York Subclass Members received less than what they bargained and/or paid for.
- 101. Defendant's advertising, including online advertising, and the Products' packaging and labeling induced the Plaintiff and the New York Subclass Members to buy Defendant's Products and to pay a premium price for them.
- 102. Defendant's deceptive and misleading practices constitute a deceptive act and practice in the conduct of business in violation of New York General Business Law §349(a) and Plaintiff and the New York Sub-Class Members have been damaged thereby.
- 103. As a result of Defendant's recurring, unlawful deceptive acts and practices, Plaintiff and the New York Sub-Class Members are entitled to monetary, compensatory, injunctive relief, restitution and disgorgement of all moneys obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.

THEREFORE, Plaintiff prays for relief as set forth below.

#### COUNT II

# Violation of the New York General Business Law § 350 (On Behalf of the New York Sub-Class)

- 104. Plaintiff incorporates by reference all the allegations of the preceding paragraphs of this Complaint.
- 105. The acts of Defendant, as described above, and each of them, constitute unlawful, deceptive and fraudulent business acts and practices.

- 106. New York General Business Law § 350 provides: "False advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful."
- 107. GBL § 350-a defines "false advertising," in relevant part, as "advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect."
- 108. Plaintiff and the members of the New York Subclass are consumers who purchased the Products in New York.
- 109. As sellers of goods to the consuming public, Defendant is engaged in the conduct of business, trade, or commerce within the intended ambit of GBL § 350.
- 110. Defendant's representations made by statement, word, design, device, sound, or any combination thereof, and also the extent to which Defendant's advertising fails to reveal material facts with respect to the Products, as described above, constitute false advertising in violation of the New York General Business Law.
  - 111. Defendant's false advertising was knowing and intentional.
- 112. Defendant's actions led to direct, foreseeable and proximate injury to Plaintiff and the New York Subclass.
- 113. As a consequence of Defendant's deceptive marketing scheme, Plaintiff and the other members of the New York Subclass suffered an ascertainable loss, insofar as they would not have purchased the Products had the truth been known, or would have purchased the Products on different terms, or would otherwise purchase a competing product, and as a result of Defendant's conduct, they received products of less value than what they paid for.
- 114. By reason of the foregoing, Defendant is liable to Plaintiff and the other members of the New York Subclass for actual damages, injunctive relief, attorneys' fees, and the costs of this suit.

THEREFORE, Plaintiff prays for relief as set forth below.

#### COUNT III

#### Breach of Express Warranty (On Behalf of the Class)

115. Plaintiff incorporates by reference all the allegations of the preceding paragraphs of this Complaint.

- 116. Defendant provided Plaintiff and other members of the Class with written express warranties including, but not limited to, warranties that its falsely labeled Products were "Made Naturally," "Made with Natural Ingredients," "Brewed with 100% Natural Ingredients" and contained "No preservatives."
- 117. These affirmations of fact or promises by Defendant relate to the goods and became part of the basis of the bargain.
- 118. Plaintiff and members of the Class purchased the falsely labeled Products believing them to conform to the express warranties.
- 119. Defendant breached these warranties. This breach resulted in damages to Plaintiff and other members of the Class, who bought the falsely labeled Products but did not receive the goods as warranted.
- 120. Plaintiff and the members of the Class performed all conditions precedent to Defendant's liability under this contract when they purchased the Products.
- 121. Plaintiff, on behalf of herself and the Class, provided Defendant with pre-suit notice of its breach of the express warranties provided on the label of the Products.
- 122. By providing pre-suit notice, Plaintiff has effectively notified the Defendant of the troublesome nature of its transactions within a reasonable time of discovering the breach.
- 123. Despite providing the above notice to the Defendant that the Products do not meet Defendant's warranties and in fact fail in many respects to perform consistent with the Products' representations, Defendant continues to hide the facts from consumers and fails to correct the material misrepresentations regarding the Products.
- 124. Actual and/or constructive notice was duly given to Defendant of the breaches of these warranties, and Defendant has yet failed to cure.
- 125. As a proximate result of the breach of warranties by Defendant, Plaintiff and the other members of the Class did not receive goods as warranted. Plaintiff and the members of the Class therefore have been injured and have suffered damages in an amount to be proven at trial. Among other things, Plaintiff and members of the Class did not receive the benefit of the bargain and have suffered other injuries as detailed above. Moreover, had Plaintiff and the Class members known the true facts, they would not have purchased the products, would have purchased fewer products, or would not have been willing to pay the premium price Defendant charged for the products.

THEREFORE, Plaintiff prays for relief as set forth below.

#### **COUNT IV**

#### Unjust Enrichment (On Behalf of the Class)

- 126. Plaintiff brings this claim individually and on behalf of members of the Class as an alternative to her Express Warranty Claim.
  - 127. Plaintiff and the Class conferred a benefit on Defendant by purchasing the Products.
- 128. As set forth above, Defendant engaged in fraudulent conduct that misrepresented the Products as "Made Naturally," "Made with Natural Ingredients," "Brewed with 100% Natural Ingredients" and containing "No preservatives."
- 129. As a result of Defendant's deceptive, fraudulent, and misleading labeling, advertising, marketing, and sales of its Products, Defendant was enriched, at the expense of Plaintiff and the Class members, through the payment of the purchase price for Defendant's Products.
- 130. Under the circumstances, it would be against equity and good conscience to permit Defendant to retain the ill-gotten benefits that they received from Plaintiff and the Class members in light of the fact that the Products purchased by Plaintiff and the Class members were not what Defendant purported them to be. Thus, it would be unjust or inequitable for Defendant to retain the benefit without restitution to Plaintiff and the Class members for the monies paid to Defendant for the Products.
- 131. By reason of the foregoing, Plaintiff and Class members are entitled to their actual damages in an amount to be determined at trial, with interest thereon, and disgorgement of all amounts by which Defendant has been unjustly enriched.

#### **COUNT V**

#### Common Law Fraud (On Behalf of the Class)

- 132. Plaintiff incorporates by reference all the allegations of the preceding paragraphs of this Complaint.
- 133. Defendant intentionally makes materially false and misleading representations regarding the nature of the Products.
- 134. Plaintiff and Class members reasonably relied on Defendant's false and misleading representations. They did not know, and had no reason to know, that the Products contain preservatives and synthetic ingredients. They would not have purchased the Products had they known the truth.

- 135. Defendant knew and intended that Plaintiff and the Class members would rely on their misrepresentations.
  - 136. Plaintiff and Class members have been injured as a result of Defendant's fraudulent conduct.
- 137. Defendant is liable to Plaintiffs and Class members for damages sustained as a result of Defendant's fraud.

#### PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff demands judgment on behalf of herself, the Nationwide Class and the New York Subclass, providing such relief as follows:

- A. An order certifying the proposed Nationwide Class and the New York Subclass; appointing Plaintiff as representative of the Nationwide Class; appointing Plaintiff as representative of the New York Subclass; and appointing Plaintiff's undersigned counsel as Class counsel for the Class and Subclass;
- B. A declaration that Defendant is financially responsible for notifying Class and Subclass members of the pendency of this suit;
  - C. An order requiring proper, complete, and accurate labeling of the Products;
- D. An order declaring that Defendant's conduct violates the statutes and common law referenced herein;
- E. An order finding in favor of the Plaintiff, the Class, and the New York Subclass on all counts asserted herein;
- F. An order awarding compensatory, treble, and punitive damages in amounts to be determined by the Court and/or jury;
  - G. An order disgorging all amounts by which Defendant has been unjustly enriched;
  - An order awarding pre-judgment and post-judgment interest on all amounts awarded;
  - An order of restitution and all other forms of equitable monetary relief;
  - Declaratory and injunctive relief as pleaded or as the Court may deem proper;
- K. An order awarding Plaintiff, the Class, and New York Subclass their reasonable attorneys' fees and expenses and costs of suit; and

L. An order awarding such other and further relief as the Court deems just and proper.

#### JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury. Plaintiff also respectfully requests leave to amend this Complaint to conform to the evidence, if such amendment is needed for trial.

DATED: November 19, 2018

GABRIELLI LEVITT LLP

Michael J. Gabrielli (MG-2421)

michael@gabriellilaw.com

2426 Eastchester Rd., Ste. 103

Bronx, New York 10469 Telephone: (718) 708-5322 Facsimile: (718) 708-5966

Counsel for Plaintiff and the Proposed Class

# EXHIBIT A

Warning Letters > Fresh Express Incorporated 10/8/10

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#### 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<sup>1</sup>. 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<sup>2</sup>.

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  $[21 \text{ U.S.C. } \S 343(r)(2)(A)(i)]$ .

1/23/2015

Warning Letters > Fresh Express Incorporated 10/6/10

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 to 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 result 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 do 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

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

Your response should be sent to:

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

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

/s/

Barbara Cassens District Director

Page Last Updated: 10/08/2010

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



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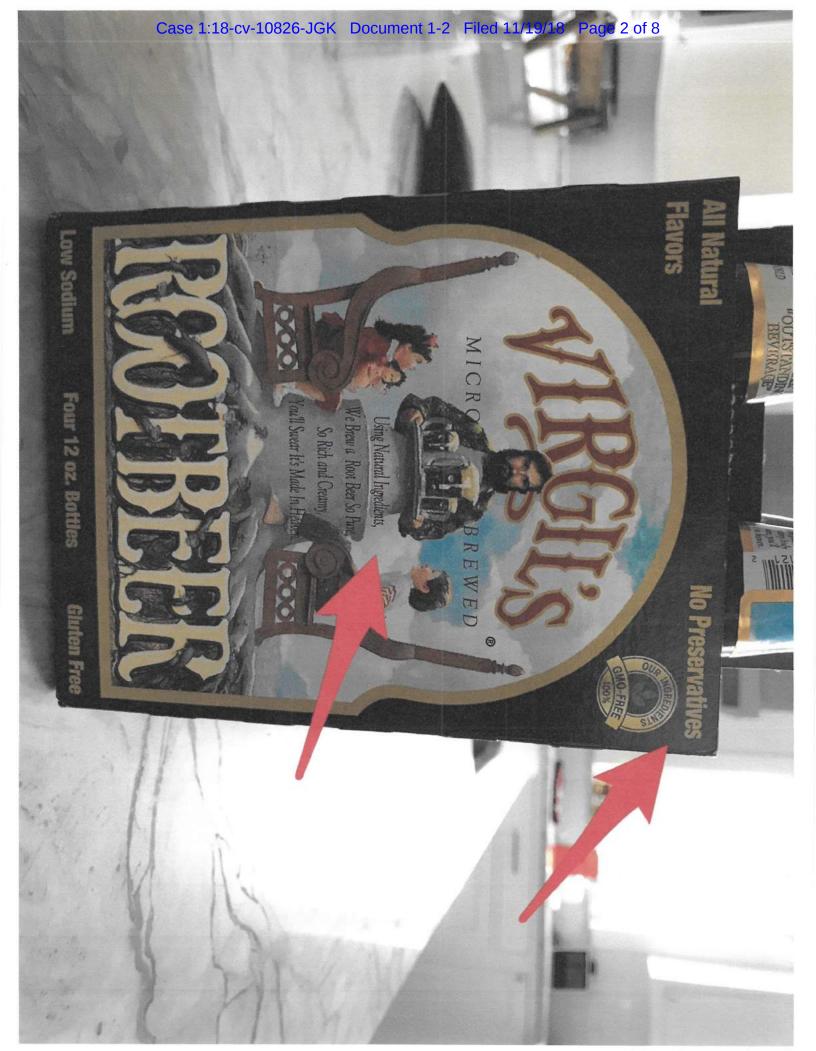


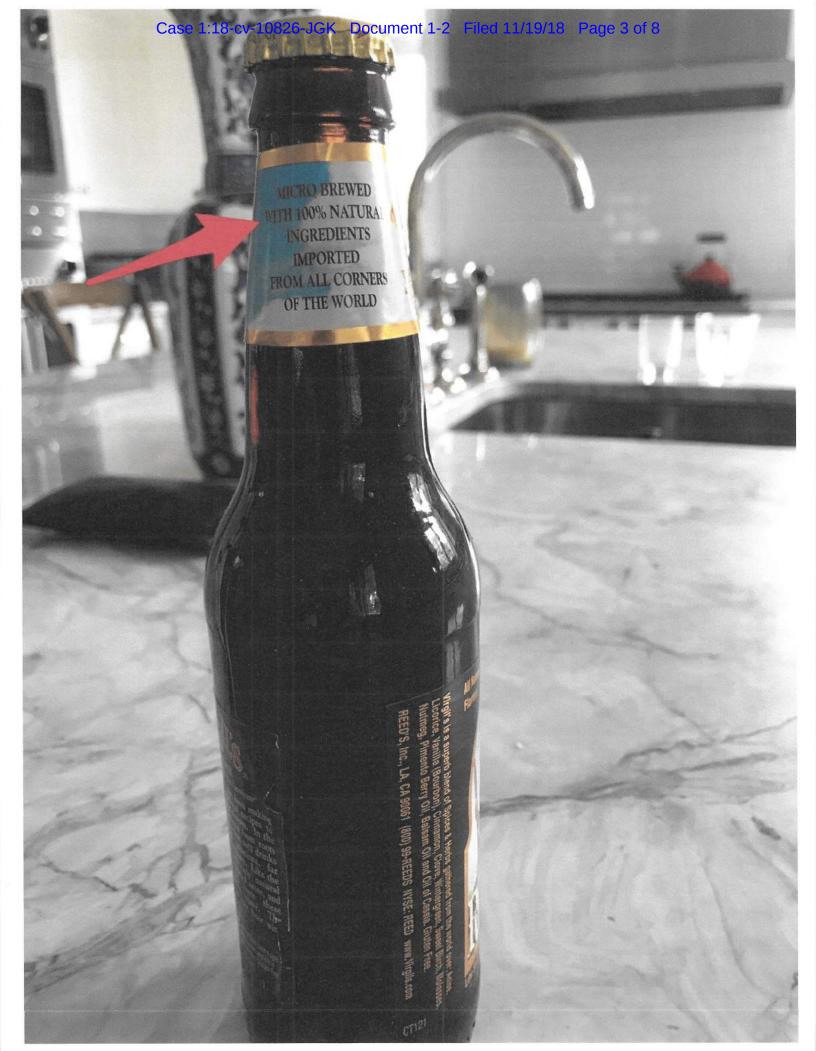
U.S. Department of Health & Human Services

#### Links on this page:

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

# EXHIBIT B















# EXHIBIT C

Case 1:18-cv-10826-1GK Document 1-3 Filed 11/19/18 Page 2 of 14

# NOSB NATIONAL LIST FILE CHECKLIST

# **PROCESSING**

MATERIAL NAME	: Citric Acid
CATEGORY: Synthe	3/*
	NOSB Database Form
	References
	MSDS (or equivalent)
	FASP (FDA)
	Date file mailed out:1/8/95
	TAP Reviews from: Strue Tay lor
	Bob Durst
***	Supplemental Information:
hierobial	Som, only
becous	of Substrate might be
az p	volue
MISSING INFORMATI	ON:

# 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;	V	Processing
TAP Review by:  1. <u>Stave</u> 2. <u>Stave</u>	Taylor n Hasper		***	
3. Bab 1	Durst			
Comments/Question	s:			
My Opinion/Vote is	<b>5</b> :			
Signature		Date	<u>und nijema avimonijeke</u>	

# 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: 1207
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 any involve use of other substances: Substrates: corn syrup, sucre Any additional comments or references? ammonium bicarbonate
Need to find out more about process and processing aids to make determination.
Signature Swe Taylor Date 3-5-95

# 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 bac	k to us within	30 days of:	Jen 7
Name of Material: Reviewer Name:	Citric Ac Steven t	id	
Is this substance Na	atural or Synth	etic? Explain	(If appropriate)
Please comment on the	accuracy of the	information in t	he file:
This material should Synthetic or, This rules because:	Allowed	Prohibit	ted Natural
Are there any restriplaced on this mate National List?	ictions or limit rial by use or	ations that sh application o	ould be n the
Any additional com	ments or refer	ences?	
CH	sey Hack or	Date 3/10	e/as

# 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 Maleuth. Dun Date 3/4/95

### **NOSB Materials Database**

# Identification

Citric Acid Common Name

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

ves Ono

# Chemistry

Family

Aliphatic Acid

Composition

C6H8O7

**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.

Internation status

Allowed by IFOAM, EU and Codex.

#### NOSB Materials Database

### 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 time 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

MSDS for CITRIC ACID, MONOHYDRATE Page 1 1 - PRODUCT IDENTIFICATION PRODUCT NAME: CITRIC ACID, MONOHYDRATE FORMULA: HOC(COOH)(CH2COOH)2 H2O FORMULA WT: 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

MELTING POINT: N/A

SPECIFIC GRAVITY: 1.54

(H2O=1)

VAPOR PRESSURE(MM HG): N/A

VAPOR DENSITY(AIR=1): N/A

EVAPORATION RATE: N/A

(BUTYL ACETATE=1) SOLUBILITY(H2O): APPRECIABLE (MORE THAN 10 %) % VOLATILES BY VOLUME: 0 APPEARANCE & ODOR: WHITE, ODORLESS POWDER. 4 - FIRE AND EXPLOSION HAZARD DATA FLASH POINT (CLOSED CUP N/A FLAMMABLE LIMITS: UPPER - N/A % LOWER - N/A % FIRE EXTINGUISHING MEDIA USE WATER SPRAY, CARBON DIOXIDE, DRY CHEMICAL OR ORDINARY FOAM. SPECIAL FIRE-FIGHTING PROCEDURES FIREFIGHTERS SHOULD WEAR PROPER PROTECTIVE EQUIPMENT AND SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECE OPERATED IN POSITIVE PRESSURE MODE.

TOXIC GASES PRODUCED: CARBON MONOXIDE, CARBON DIOXIDE 5 - HEALTH HAZARD DATA TOXICITY TEST RESULTS AND SAFETY AND HEALTH EFFECTS ARE LISTED FOR THE ANHYDROUS PRODUCT. TOXICITY: LD50 (ORAL-RAT)(G/KG) 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.

#### 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

	FOOD ADDITIVE SAFETY PROFILE						
	CITRIC AC						
	FASP#: ITYPE: ANAS#: 2	1937 ASP 2306 2306	HUMAN CONSUMPTI MARKET DISAPPEA MARKET SURVEY: JECFA: JECFA ADI:	RANCE:	106833333 87 NL-C	3.333LBS/YR	BW/DAY/PERSON
		BEVERAGE USE	JECFA ESTABLISH LAST UPDATE:	EU:	931115		
	FW: 1	192.12	DENSITY:		LOGP:		
	STRUCTURE	CATEGORIES:	A6				
	COMPONENT	rs:					
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				
			PH CONTROL AGENT FLAVOR ENHANCER FLAVORING AGENT OR ADJUVANT LEAVENING AGENT SEQUESTRANT ANTIOXIDANT SOLVENT OR VEHICLE SURFACE - ACTIVE AGENT ANTIMICROBIAL AGENT ENZYME				
	CFR REG N	UMBERS:	173.165 182.1033 161.190 155.130 131.112 131.138 150.161 169.115 173.160 166.110	172.755 PART 16 145.145 131.136 131.146 150.141 169.140 173.280 184.103	3	182.6033 PART 146 PART 150 131.111 131.144 146.187 166.40 169.150 145.131	
	MINIMUM T	ESTING LEVEL:					
		STUDY 1-12 F	ROM SCOGS-84				
	BOX 4A:	LOWEST EFFECT	LEVEL OBSERVED	IN ALL	AVAILABLE	RAT OR MOU	ISE STUDIES
	STUDY: SPECIES: EFFECTS:	CHOLESTEROL D GLUTAMIC-OXAL ORGAN WEIGHT CELLULAR ATRO	OACETIC TRANSAMI DECREASE	LEL:	4670	MG/KG BW/DA	¥
		DATA FROM SCO	Y OF THYMUS AND GS-84		FOLLICLES	S	

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              LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE STUDIES
BOX 4C:
                                                           RANKING FACTOR: 1.938E-2
LEL: 4670 MG/KG BW/DAY
STUDY:
SPECIES:
                                  COMPLETENESS:
               CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
               THYMUS
SITES:
SPLEEN
COMMENTS: MALES ONLY
SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
               DATA FROM SCOGS-84
               ACUTE TOXICITY INFORMATION
BOX 7:
                                                            SOURCE: J TAKEDA RES LAB 30:25-31
YEAR: 1971
LD50: 12000 MG/KG BW
STUDY: 2
SPECIES: RAT
COMMENTS:
                                                            SOURCE: J TAKEDA RES LAB 30:25-31
YEAR: 1971
LD50: 5000 MG/KG BW
STUDY: 1
SPECIES: MOUSE
 COMMENTS:
               ORAL TOXICITY STUDIES (OTHER THAN ACUTE)
                                                            SOURCE: REV PORT FARM 20:41-46
YEAR: 1970
LEL: 200 MG/KG BW/DAY
 STUDY:
                                   COMPLETENESS:
 TYPE:
SPECIES:
                SHORT TERM
 SPECIES: RAT
DURATION: 9 DAYS
 EFFECTS: BODY WEIGHT DECREASE SITES:
 COMMENTS: INITIAL DECREASE IN WEIGHT DID NOT PERSIST NOT USED FOR PRIORITY RANKING
                                                             SOURCE: J TAKEDA RES LAB 30:25-31
YEAR: 1971
LEL: 4670 MG/KG BM/DAY
                                   COMPLETENESS:
 STUDY:
                4
SHORT TERM
 TYPE:
SPECIES:
                                                                                   MG/KG BW/DAY
              RAT
 SPECIES: RAT
DURATION: 42 DAYS
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS
COMMENTS: SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
                                                             SOURCE: J AM PHARM ASSOC SCI ED
                                   COMPLETENESS:
  STUDY:
                                                                         34:86-89
                                                             YEAR: 1945
                SUBCHRONIC RODENT
                                                                                   MG/KG BW/DAY
  SPECIES: RAT
DURATION: 90 DAYS
EFFECTS: NO EFFECTS
                                                             LEL: >
HNEL: 600
  COMMENTS: BODY WEIGHT, BLOOD, HISTOPATH AND REPRODUCTION OBSERVED
                                                             SOURCE: J AM PHARM ASSOC SCI ED
34:86-89
                                    COMPLETENESS:
  STUDY:
                 SUBCHRONIC MAMMAL (NON-RODENT) YEAR: 1945
  TYPE: SUBCHRONIC SPECIES: DOG DURATION: 112 DAYS EFFECTS: NO EFFECTS
                                                                                   MG/KG BW/DAY
                                                             LEL: >
HNEL: 1380
   COMMENTS: NO BEHAVIORAL, BIOCHEMICAL OR HISTOPATHOLOGICAL ABNORMALITIES
                                                             SOURCE: GRP 7T0195 3
YEAR: 1973
LEL: > MG/KG
                                    COMPLETENESS:
   STUDY:
                 TERATOGENICITY
   TYPE: TER
                                                                                    MG/KG BW/DAY
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DOCNUM=1937 DURATION: 10 DAYS EFFECTS: NO EFFECTS SITES: HNEL: 295 MG/KG BW/DAY COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION COMPLETENESS: SOURCE: GRP 7T0195 3 TYPE: TERATOGENIC SPECIES: MOUSE DURATION: 10 DAYS EFFECTS: NO EFFECTS TERATOGENICITY YEAR: 1973 LEL: > MG/KG BW/DAY LEL: > HNEL: 241 COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION STUDY: 11 CONTROL OF TERATOGENICITY SPECIES: HAMSTER DURATION: 5 DAYS EFFECTS: NO EFFECTS SITES: SOURCE: GRP 7T0195 3 YEAR: 1973 LEL: > MG/KG HNEL: 272 MG/KG COMPLETENESS: MG/KG BW/DAY COMMENTS: ADMINISTERED DAY 6-10 OF GESTATION STUDY: 12 CONTROL OF TERATOGENICITY SPECIES: RABBIT DURATION: 13 DAYS EFFECTS: NO EFFECTS SITES: SOURCE: GRP 7T0195 3 YEAR: 1973 LEL: > MG/KG COMPLETENESS: LEL: > HNEL: 425 MG/KG BW/DAY COMMENTS: ADMINISTERED DAY 6-18 OF GESTATION SOURCE: J AGRIC FOOD CHEM 5:759-760 YEAR: 1957 LEL: > MG/KG BW/DAY STUDY: COMPLETENESS: TYPE: RAT ONCOGES
SPECIES: RAT
DURATION: 728 DAYS
EFFECTS: NO EFFECTS
SITES: RAT ONCOGENICITY MG/KG BW/DAY LEL: > HNEL: 2000 COMMENTS: MALES ONLY STUDY: 7
TYPE: REPRODUCTION
SPECIES: RAT
DURATION:
EFFECTS: NO EFFECTS
SITES:
COMMENTS: SOURCE: VOEDING 17:137-148
YEAR: 1956
LEL: > MG/KG BH/DA'
HNEL: 800 MG/KG BH/DA' 7
REPRODUCTION (3-GENERATION) MG/KG BW/DAY MG/KG BW/DAY BOX 3: GENETIC TOXICITY STUDIES STUDY: COMPLETENESS: SOURCE: TYPE: SPECIES: DURATION: EFFECTS: CELLS: YEAR: LEL: MG/KG BW/DAY HNEL:

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COMMENTS: