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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

Grace Greenbach, individually and on behalf
of all others similarly situated,

Plaintiff,

v.

Babo Botanicals Inc.

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

1 Plaintiff Grace Greenbach (“Plaintiff”) brings this action on behalf of herself and all others
2 similarly situated against Defendant Babo Botanicals Inc. (“Babo” or “Defendant”). Plaintiff
3 makes the following allegations pursuant to the investigation of her counsel and upon information
4 and belief, except as to allegations specifically pertaining to herself and her counsel, which are
5 based on personal knowledge.

6 INTRODUCTION

7 1. This class action aims to hold Defendant, Babo Botanicals Inc., responsible for
8 failing to truthfully and accurately label and market its bath and cosmetic products

9 2. Defendant manufactures, distributes, advertises and sells a line of bath and cosmetic
10 products (the “Products”¹).

11 3. Through representations made on the front label of the Products, including
12 Products’ plant-theme imagery and the representation that Products are “made with plant-based
13 ingredients” (the “Misrepresentations”), Defendant conveys that the Products are composed
14 exclusively of natural ingredients, free from artificial ingredients. But on the contrary the Products
15 contain a number of artificial ingredients.

16 4. In addition, Defendant reinforces the Misrepresentations through its online listings,
17 which contains further representations regarding the Products’ purported natural and plant-based
18 composition.

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

22 THE PARTIES

23 6. Defendant Babo Botanicals Inc. is a New York Corporation with its principal place
24 of business located in Scarsdale, New York. At all times during the class period, Defendant was
25 the manufacturer, distributor, marketer, and seller of the Products.
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¹ See **Exhibit A**.

1 7. Plaintiff Greenbach purchased Defendant’s Babo Botanicals Moisturizing Oat &
2 Calendula Shampoo² from Amazon.com (the “Product”) while residing in Capitola, California, in
3 or around July 2025. Prior to purchasing the Product, Plaintiff saw Defendant’s flower-themed
4 imagery on the packaging, and Defendant’s representation on the Product that it is “made with
5 Plant-Based ingredients” i.e. the Misrepresentations. Plaintiff also saw Defendant’s representations
6 on the Product’s Amazon.com listing, which stated “Plant-Based & Hypoallergenic formula:
7 Specifically formulated with naturally-derived ingredients including calendula oil soothes scalp
8 with cradle cap or dry patches” and “Made with 23 plant-based ingredients like comforting oat &
9 nourishing calendula.” (the “Additional Representations”). The Misrepresentations and the
10 Additional Representations caused Plaintiff to believe the Product was made exclusively of
11 natural, plant-based ingredients to the exclusion of artificial ingredients. When shopping for the
12 Product, Plaintiff specifically sought out products that were natural. Plaintiff did not expect
13 Defendant’s representations on the front label and in the online listing to be false, and did not
14 expect Defendant to publicly place deceptive statements about the Product on the front label or its
15 online listings.

16 8. Despite Defendant’s representations, the back label revealed that the Product
17 contained a number of artificial ingredients, including citric acid, sodium c14-16 olefin sulfonate,
18 cocamidopropyl betaine, sodium lauroyl methyl isethionate, sodium methyl cocoyl taurate,
19 ethylhexylglycerin.

20 9. Plaintiff saw and relied on the Misrepresentations and Additional Representations
21 on the Product’s Amazon.com listing and on the front label of the Product. Plaintiff would not
22 have purchased the Product, or would have paid less for the Product, had she known that the
23 Product was not exclusively made with plant-based ingredients. As a result, Plaintiff suffered
24 injury in fact when she spent money purchasing the Product she would not have purchased, or
25 would have paid less for, absent Defendant’s misconduct.

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28 ² <https://www.amazon.com/Babo-Botanicals-Moisturizing-Shampoo-Calendula/dp/B00OFXJY50?th=1> (last accessed April 9, 2026)

1 Defendant therefore has sufficient minimum contacts with this state, including within this District
2 and/or intentionally availed itself of the benefits and privileges of the California consumer market
3 through the promotion, marketing, and sale of its products and/or services to residents within this
4 District and throughout California.

5 14. Pursuant to 28 U.S.C. § 1391, this Court is the proper venue for this action because
6 a substantial part of the events, omissions, and acts giving rise to the claims herein occurred in this
7 District. Also, Plaintiff resides in this District and purchased the Product within this District.
8 Moreover, Defendant systematically conducts business in this District and throughout the State of
9 California, and it distributed, advertised, and sold the Products to Plaintiff and Class Members in
10 this State and District.

11 **FACTUAL BACKGROUND**

12 **A. Market and Regulatory Background**

13 15. **Consumer Demand for Natural and Plant-Based Products.** In recent years,
14 consumers have poured billions of dollars into the “plant-based” and “natural” personal care
15 market.³ Consumers value natural, plant-based products for their perceived benefits of avoiding
16 diseases, attaining health and wellness, helping the environment, assisting local farmers, assisting
17 factory workers who would otherwise be exposed to synthetic and hazardous substances, and
18 financially supporting the companies that share these values.⁴ As such, there is a recognized
19 association among consumers and the concept of nature (e.g., “natural” and “plant-based” products)
20 and positive feelings associated with nature. Peer-reviewed published research has found that the
21 perceived naturalness of a product is “very important” to consumers.⁵ In response to consumers’
22 desire for plant-based and natural products, many companies, including Defendant, have scrambled
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24 ³ See generally Plant-Based Personal Care Products, Eternal Spiral Books (Nov. 24, 2018),
25 <https://eternalspiralbooks.com/plant-based-personal-care-products/> (last accessed October 19,
26 2022).

27 ⁴ *Id.*

28 ⁵ S. Roman et al., The importance of food naturalness for consumers: Results of a systematic
review, *Trends in Food Science & Technology* (2017) 67:44-57.

1 to manufacture, market, and sell purportedly “plant-based” and “natural” products in an effort to
2 gain market share. Unfortunately, rather than creating the plant-based and natural products
3 consumers desire, Defendant has instead chosen to “greenwash” the Products and market them
4 through deceptive labeling and advertising (i.e., the Misrepresentations) to convince consumers the
5 Products are natural and plant-based when, in reality, they contain numerous synthetic, artificial,
6 and highly processed ingredients.

7
8 16. FTC Guidelines.

9 a. In response to this consumer fraud, the United States Federal Trade Commission
10 (“FTC”) created the “Green Guides” to help companies avoid making misleading
11 and deceptive claims.⁶ As relevant here, the FTC stated:

12 Marketers, nevertheless, are responsible for substantiating consumers’
13 reasonable understanding of “biobased,” and other similar claims, such
14 as “plant-based,” in the context of their advertisements.

15 16 C.F.R. § 260 – Guides for Use of Environmental Marketing Claims, p. 246.⁷

16 Here, Defendant disregarded FTC guidelines on plant-based claims, opting to
17 manufacture the Products with ingredients that are neither water nor plant, and
18 at times entirely artificial, synthetic, or substantially processed. Thus, Defendant
19 did not fulfill its responsibility to “substantiat[e] consumers’ reasonable
20 understand of... ‘plant-based’” advertising claims as reasonable consumers,
21 such as Plaintiff, reasonably believe that “plant-based” advertising claims as
22 reasonable consumers, such as Plaintiff, reasonably believe that “plant-based”
23 Products only contain water or plant ingredients that have not undergone
24 substantial processing.

25 b. The FTC has also cautioned “[m]arketers that are using terms such as natural must
26 ensure that they can substantiate whatever claims they are conveying to
27 reasonable consumers. If reasonable consumers could interpret a natural claim as

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⁶ See generally 16 C.F.R. § 260 – Guides for the Use of Environmental Marketing Claims.

⁷ Available at <https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-green-guides/greenguidesstatement.pdf> (emphasis added).

1 representation that a product contains nonartificial ingredients, that the marketer
2 must be able to substantiate that fact. Guides for the Use of Environmental
3 Marketing Claims, 75 FR 63552-01, 63586 (Oct. 15, 2010).

4
5 **17. Definitions**

- 6 a. Dictionary: Natural. The Merriam-Webster standard dictionary defines “natural”
7 as “existing in or produced by nature: not artificial,” and “not having any extra
8 substances or chemicals added” not “containing anything artificial.”⁸
- 9 b. Synthetic. “The term ‘synthetic’ means a substance that is formulated or
10 manufactured by a chemical process or by a process that chemically changes a
11 substance extracted from naturally occurring plant, animal, or mineral source[.]”⁷
12 U.S.C. § 6502 (21).
- 13 c. Dictionary: Artificial. The Merriam-Webster standard dictionary defines
14 “artificial” as “humanly contrived” and “MAN-MADE.”⁹

15 **B. Defendant’s background and deception**

16 18. Defendant sells a variety of bath and cosmetic products.

17 19. Below is Defendant’s Moisturizing Oat & Calendula Shampoo & Wash, which is
18 one of Defendants’ Products:

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27 ⁸ Merriam-Webster.com, plant-based, available at [https://www.merriam-](https://www.merriam-webster.com/dictionary/plant-based)
28 [webster.com/dictionary/plant-based](https://www.merriam-webster.com/dictionary/plant-based) (accessed 11/3/2022).

⁹ Merriam-Webster.com, artificial, available at [https://www.merriam-](https://www.merriam-webster.com/dictionary/artificial)
[webster.com/dictionary/artificial](https://www.merriam-webster.com/dictionary/artificial) (accessed 11/3/2022).



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19 20. All of the Products have uniform label representation and marketing.

20 21. The Products' front label say "made with Plant-Based ingredients."

21 22. The Products' front label has images of flowers.

22 23. The Misrepresentations were made at the time of Plaintiff's purchase in July 2025.

23 24. Additionally, Defendant reinforces the Misrepresentations through its Amazon.com

24 product listing, which contains further representations regarding the Product's purported natural
25 and plant-based composition (the "Additional Representations"). Specifically, the Additional
26 Representations include the following statements: "Plant-Based & Hypoallergenic formula:
27 Specifically formulated with naturally-derived ingredients including calendula oil soothes scalp
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1 with cradle cap or dry patches” and is “Made with 23 plant-based ingredients like comforting oat
2 & nourishing calendula.”

3 25. Plaintiff Greenbach saw and relied on the Misrepresentations and the Additional
4 Representations prior to purchasing the Product in or around July 2025.

5 26. Despite the Misrepresentations and Additional Representations, the back label of
6 the Products reveal they contain artificial ingredients, including at least one of the following:

- 7 a. Citric acid
- 8 b. Sodium c14-16 olefin sulfonate – A synthetic surfactant produced through
9 petrochemical processing.¹⁰
- 10 c. Cocamidopropyl betaine - A synthetic surfactant manufactured through chemical
11 reactions involving amines and chloroacetic acid.¹¹
- 12 d. Sodium lauroyl - A chemically synthesized ester surfactant produced through
13 esterification and further chemical modification.¹²
- 14 e. Sodium methyl cocoyl taurate - A synthetic surfactant produced by reacting fatty
15 acids with taurine derivatives.¹³
- 16 f. Ethylhexylglycerin - A synthetic preservative produced through chemical
17 modification of glycerin.¹⁴

18 27. Each of the Products make the Misrepresentations but contain at least one of the
19 artificial ingredients outlined above.

20 **C. The Citric Acid in the Products is Not Natural**

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22 ¹⁰ <https://www.alfa-chemistry.com/product/sodium-c14-olefin-sulfonate-cas-68439-57-6-1480.html?> (last accessed April 12, 2026)

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24 ¹¹ <https://pmc.ncbi.nlm.nih.gov/articles/PMC11187029/?> (last accessed April 12, 2026)

25 ¹² <https://www.specialchem.com/cosmetics/inci-ingredients/sodium-lauroyl-methyl-isethionate?>
(last accessed April 12, 2026)

26 ¹³ <https://www.specialchem.com/cosmetics/inci-ingredients/sodium-methyl-cocoyl-aurate?> (last
27 accessed April 15, 2026)

28 ¹⁴ <https://www.macschem.us/ethylhexylglycerin-in-skin-hair-care-uses-and-side-effects/> (last
accessed April 12, 2026)

1 28. Defendant uses artificial manufactured citric acid in Products.¹⁵ Commercially
 2 produced citric acid is manufactured using a type of black mold called *Aspergillus niger* which is
 3 modified to increase citric acid production.¹⁶ Consumption of manufactured citric acid has been
 4 associated with a adverse health events like joint pain with swelling and stiffness, muscular and
 5 stomach pain, as well as shortness of breath.¹⁷ Defendant does not use natural citric acid extracted
 6 from fruit in the Products. This is because “[a]proximately 99% of the world’s production of [citric
 7 acid] is carried out using the fungus *Aspergillus niger* since 1919.” *Id.* As explained by a study
 8 published in the *Toxicology Reports Journal*:

9
 10 Citric acid naturally exists in fruits and vegetables. However, **it is not the naturally**
 11 **occurring citric acid, but the manufactured citric acid (MCA) that is used**
 12 **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.
Asperiglus niger is a known allergen.¹⁸

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

16 “Traditionally by extraction from citric juice, [is] no longer commercially available.
 17 It is now extract by fermentation of a carbohydrate substance (often molasses) by
 18 citric bacteria, *Asperillus niger* (a mold) or *Candida guilliermondii* (a yeast). Citric
 19 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.”¹⁹

20 ¹⁵ Iliana E. Sweis, et al., Potential role of the common food additive manufactured citric acid in
 21 eliciting significant inflammatory reactions contributing to serious disease states: A series of four
 22 case reports, *TOXICOL REP.* 5:808-812 (2018), available at
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6097542/>

23 ¹⁶ *Id.*; Pau Loke Show, et al., Overview of citric acid production from *Aspergillus niger*, *FRONTIERS*
 24 *IN LIFE SCIENCE*, 8:3, 271-283 (2015), available at
<https://www.tandfonline.com/doi/full/10.1080/21553769.2015.1033653>

25 ¹⁷ Iliana E. Sweis, et al., Potential role of the common food additive manufactured citric acid in
 26 eliciting significant inflammatory reactions contributing to serious disease states: A series of four
 27 case reports, *TOXICOL REP.* 5:808-812 (2018), available at
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6097542/>

28 ¹⁸ *Id.* (emphasis added)

¹⁹ **Exhibit B** at page 6.

1 30. When asked “Is this substance Natural or Synthetic?” USDA AMS reviewers state:
2 “synthetic.”²⁰

3 31. The FDA has determined that manufactured citric acid is not natural; it is artificial.
4 The FDA sent warning letters to Hirzel Canning Company and Oak Tree Farm Dairy, Inc., for similar
5 violations, saying that the FDA’s policy involving the use of the word natural means that nothing
6 artificial or synthetic has been added to the product, and that a product that labels itself “100%
7 Natural” or “All Natural” violates that policy if it contains citric acid, and that the presence of citric
8 acid precludes the use of the term natural to describe the product.²¹

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

19 33. The *Toxicology Reports Journal* study explains that “the potential presence of
20 impurities or fragments from the *Aspergillus niger* in [manufactured citric acid] is a significant
21 difference that may trigger deleterious effects when ingested.”²² The study further explains:
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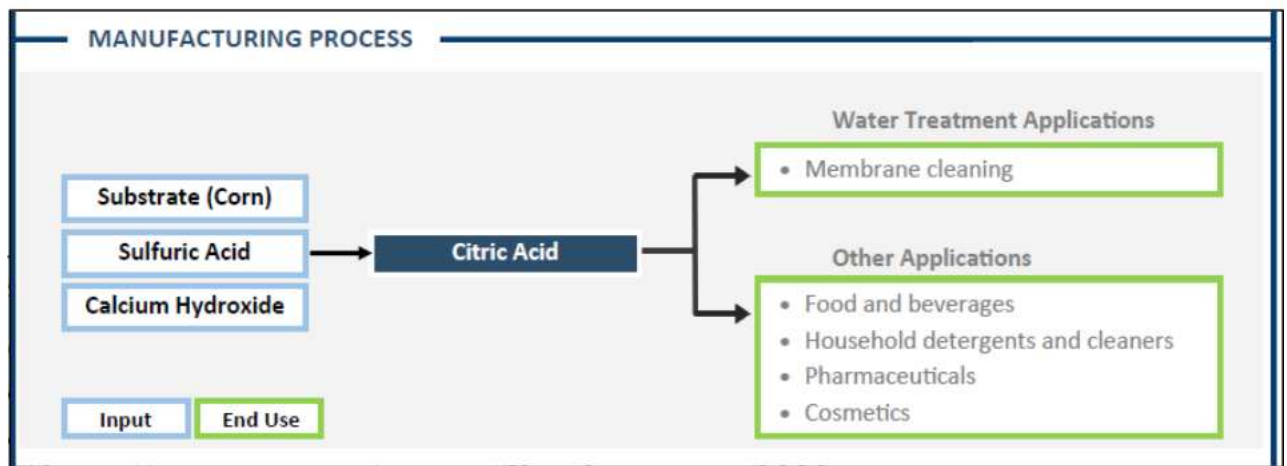
23 _____
24 ²⁰ **Exhibit B** at pages 4-5.

25 ²¹ *See* **Exhibit C** at page 2 and **Exhibit D** at page 2.

26 ²² Iliana E. Sweis, *et al.*, *Potential role of the common food additive manufactured*
27 *citric acid in eliciting significant inflammatory reactions contributing to serious*
28 *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/>

1 “Given the thermotolerance of *A. niger*, there is great potential that
 2 byproduct of *A. niger* remain in the final [manufactured citric acid]
 3 product. Furthermore, given the pro-inflammatory nature of *A. niger*
 4 even when heat-killed, repetitive ingestion of [manufactured citric acid]
 5 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.*

6 34. The EPA provides the following simply schematic of the manufacturing process for
 7 citric acid which includes the use of synthetic solvents like Sulfuric Acid.²³



16 35. Dr. Ryan Monahan, a prominent functional medicine practitioner, notes that the
 17 “[p]resent day process of creating manufactured citric acid involves feeding sugars derived from
 18 GMO corn to black mold, which then ferments to form manufactured citric acid.”²⁴

19 36. Dr. Monahan also notes that “*Aspergillus niger* is associated with systemic
 20 inflammatory issues, including respiratory, gastrointestinal, neurological and musculoskeletal. Due
 21 to the potential for fragments of *Aspergillus niger* to make their way into the finished product of
 22 manufactured citric acid, this toxic inflammatory substance is likely being ingested by consumers of
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26 [https://www.epa.gov/system/files/documents/202303/Citric%20Acid%20Supply%20Chain%20Pro
 file.pdf](https://www.epa.gov/system/files/documents/202303/Citric%20Acid%20Supply%20Chain%20Profile.pdf) (last accessed March 13, 2026)

27 ²⁴ Dr. Ryan Monahan, *Citric Acid: A Common Food Additive With An Uncommon Source* (2024)
 28 available at [https://www.peacefulmountainmedicine.com/post/citric-acid-a-common-food-
 additive-with-an-uncommon-source](https://www.peacefulmountainmedicine.com/post/citric-acid-a-common-food-additive-with-an-uncommon-source) (Last accessed March 12, 2026)

1 Products containing citric acid. Even with high-heat processing to kill it, research has shown
2 *Aspergillus niger* can still elicit an inflammatory response.”²⁵

3 37. Clinical nutritionist Serge Gregoire, notes that [f]ood manufacturers leave out that
4 citric acid is derived from genetically modified black mold grown on GMO corn syrup” and that
5 “[c]ompanies continuously capitalize on an ignorance-based market.”²⁶ Gregoire states, “Citric acid
6 production has become a refined and highly prized industrial process.” Gregoire note that the
7 *Aspergillus niger* used to produce citric acid is engineered to increase production of citric acid which
8 has “resulted in countless generations of genetically modified mutant variants, now specialized for
9 industrial-scale economics.”

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

13 39. “Mutagenesis has been used in recent years to improve the citric-acid producing
14 strains so that they can be used in industrial applications. The most common methods include the
15 use of mutagens to induce mutations on the parental strains. The mutagens utilized for improvements
16 are gamma radiation, ultraviolet radiation and often chemical mutagens. For hyperproducer strains,
17 a hybrid method that combines ultraviolet and chemical mutagens is used (Ratledge & Kristiansen
18 Citation2001).²⁷

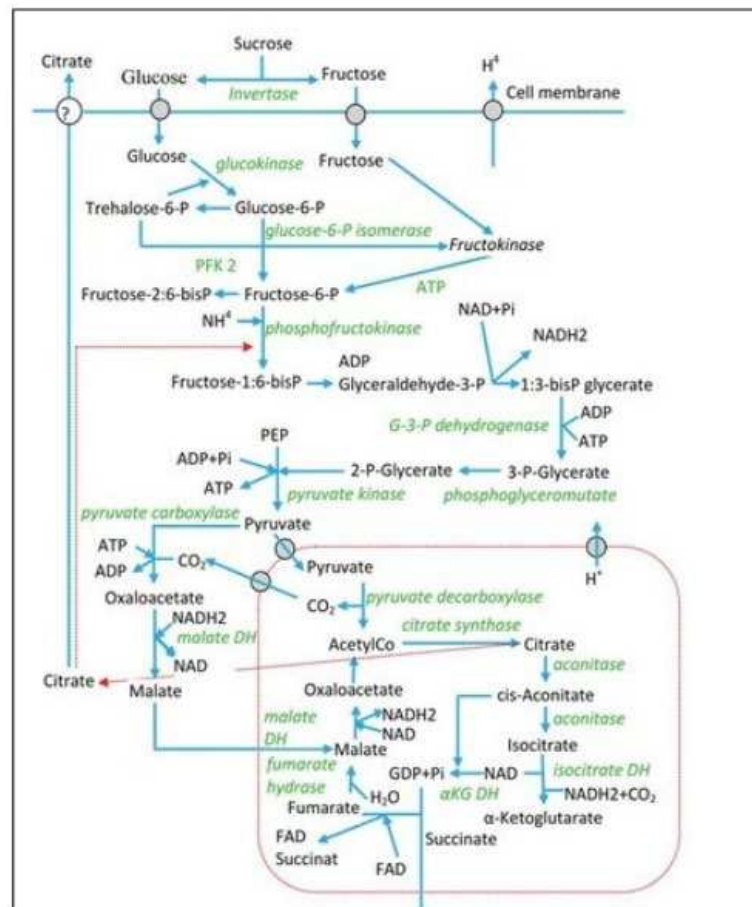
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23 ²⁵ Dr. Ryan Monahan, *Citric Acid: A Common Food Additive With An Uncommon Source* (2024)
24 available at <https://www.peacefulmountainmedicine.com/post/citric-acid-a-common-food-additive-with-an-uncommon-source>.(last accessed March 12, 2026)

25 ²⁶ Serge Gregoire, Avoid citric acid: a mold byproduct! (July 13, 2021) available at
26 <https://www.linkedin.com/pulse/avoid-citric-acid-mold-byproduct-serge-gregoire/>

27 ²⁷ Show, P. L., Oladele, K. O., Siew, Q. Y., Aziz Zakry, F. A., Lan, J. C. W., & Ling, T. C. (2015).
28 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>

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40. 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*.²⁸



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41. Dictionary definitions define “artificial” as something made by man. For example, “artificial” is defined as “made by human skill; produced by humans...”²⁹ Merriam-Webster’s online dictionary states that “artificial” means “humanly contrived...”³⁰ Cambridge Dictionary states that “artificial” means “made by people, often as a copy of something natural.”³¹

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²⁸ *Id.* at Figure 3.

²⁹ *Artificial*, DICTIONARY.COM, available at <https://www.dictionary.com/browse/artificial>

³⁰ *Artificial*, MERRIAM -WEBSTER ’ S DICTIONARY, available at <https://www.merriam-webster.com/dictionary/artificial>

³¹ *Artificial*, CAMBRIDGE DICTIONARY, available at <https://dictionary.cambridge.org/us/dictionary/english/artificial>

1 this time but may be determined through discovery. Class members may be notified of the
2 pendency of this action by mail and/or publication through the distribution records of Defendant.

3 47. **Commonality and Predominance.** Common questions of law and fact exist as to
4 all Class members and predominate over questions affecting only individual Class members.

5 Common legal and factual questions include, but are not limited to:

- 6 (a) Whether Defendant is responsible for the conduct alleged herein which was
7 uniformly directed to all consumers who purchased the Products;
8 (b) Whether Defendant’s misconduct set forth in this Complaint demonstrates that
9 Defendant engaged in unfair, fraudulent, or unlawful business practices with respect
10 to the advertising, marketing, and sale of the Products;
11 (c) Whether Defendant made misrepresentation concerning the Products that were
12 likely to deceive the public;
13 (d) Whether Plaintiff and the Class are entitled to injunctive relief;
14 (e) Whether Plaintiff and the Class are entitled to money damages and/or restitution
15 under the same causes of action as the other Class Members.

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

21 49. **Typicality.** Plaintiff is a member of the Class that Plaintiff seeks to represent.
22 Plaintiff’s claims are typical of the claims of each Class Member in that every member of the Class
23 was susceptible to the same deceptive, misleading conduct and purchased the Products. Plaintiff is
24 entitled to relief under the same causes of action as the other Class Members.

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

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

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

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

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

16 **CAUSES OF ACTION**

17 **Count I:**

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

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

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

24 57. The UCL prohibits any "unlawful," "fraudulent," or "unfair" business act or
25 practice and any false or misleading advertising. Defendant committed unlawful business acts or
26 practices by making the representations and omitted material facts (which constitutes advertising
27 within the meaning of California Business & Professions Code section 17200), as set forth more
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1 fully herein, and by violating California’s Consumers Legal Remedies Act, Cal. Civ. Code
2 §§1750, *et seq.*, California’s False Advertising Law, Cal. Bus. & Prof. § 17500, *et seq.*, 15 U.S.C.
3 § 45, and by breaching express and implied warranties. Plaintiff, individually and on behalf of the
4 other Class members, reserves the right to allege other violations of law, which constitute other
5 unlawful business acts or practices. Such conduct is ongoing and continues to this date.
6

7 58. Defendant committed “unfair” business acts or practices by: (a) engaging in
8 conduct where the utility of such conduct is outweighed by the harm to Plaintiff and the members
9 of the Class; (2) engaging in conduct that is immoral, unethical, oppressive, unscrupulous, or
10 substantially injurious to Plaintiff and the members of the Class; and (3) engaging in conduct that
11 undermines or violates the intent of the consumer protection laws alleged herein. There is no
12 societal benefit from deceptive advertising. Plaintiff and the other Class members paid for
13 Products that are not as advertised by Defendant. Further, Defendant failed to disclose a material
14 fact (that the Products contain artificial ingredients) of which it had exclusive knowledge. While
15 Plaintiff and the other Class members were harmed, Defendant was unjustly enriched by its false
16 misrepresentations and material omissions. As a result, Defendant’s conduct is “unfair,” as it
17 offended an established public policy. There were reasonably available alternatives to further
18 Defendant’s legitimate business interests, other than the conduct described herein.
19

20 59. Defendant committed “fraudulent” business acts or practices by making the
21 Misrepresentations and Additional Representations regarding the Products set forth herein.
22 Defendant’s business practices as alleged are “fraudulent” under the UCL because they are likely
23 to deceive customers into believing the Products are exclusively made of natural ingredients due to
24 the Misrepresentations and Additional Representations.
25

26 60. Plaintiff and the other members of the Class have in fact been deceived as a result of
27 their reliance on Defendant’s material representations and omissions. This reliance has caused harm
28

1 to Plaintiff and the other members of the Class, each of whom purchased Defendant's Products.
2 Plaintiff and the other Class members have suffered injury in fact and lost money as a result
3 purchasing the Products and Defendant's unlawful, unfair, and fraudulent practices.
4

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

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

10 63. Unless restrained and enjoined, Defendant will continue to engage in the above-
11 described conduct. Accordingly, injunctive relief is appropriate. Pursuant to California Business &
12 Professions Code section 17203, Plaintiff, individually and on behalf of the California Class, seeks
13 (1) restitution from Defendant of all money obtained from plaintiff and the other Class members as
14 a result of unfair competition; (2) an injunction prohibiting Defendant from continuing such practices
15 in the State of California that do not comply with California law; and (3) all other relief this Court
16 deems appropriate, consistent with California Business & Professions Code section 17203.
17

18 **Count II**

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

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

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

26 66. California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*,
27 makes it "unlawful for any person to make or disseminate or cause to be made or disseminated
28 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,

1 professional or otherwise, or performance or disposition thereof, which is untrue or misleading and
2 which is known, or which by the exercise of reasonable care should be known, to be untrue or
3 misleading.”

4 67. Defendant committed acts of false advertising, as defined by § 17500, by using
5 statements to promote the sale of its Products by making the Misrepresentations and Additional
6 Representations. In doing so, Defendant communicated that the Products were completely natural
7 and free from artificial ingredients, while omitting that the Products contain artificial ingredients.

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

10 69. Defendant knew or should have known, through the exercise of reasonable care,
11 that its representations were false and misleading and likely to deceive consumers and cause them
12 to purchase Defendant’s Products.

13 70. Defendant wrongful conduct is ongoing and part of a general practice that is still
14 being perpetuated and repeated through the State of California and nationwide.

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

21 **Count III**
22 **Violations of California’s Consumers Legal Remedies Act (“CLRA”),**
23 **Cal. Civ. Code §§ 1750, *et seq.***
24 **(On Behalf of Plaintiff and the California Subclass)**

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

27 73. Civil Code § 1770(a)(5) prohibits “[r]epresenting that goods or services have
28 sponsorships, approval, characteristics, ingredients, uses, benefits, or quantities which they do not

1 have or that a person have a sponsorship, approval, status, affiliation, or connection which he or
2 she does not have.”

3 74. Civil Code § 1770(a)(7) prohibits “[r]epresenting that goods or services are of a
4 particular standard, quality, or grade, or that goods are of a particular style or model, if they are of
5 another.”

6 75. Civil Code § 1770(a)(9) prohibits “advertising goods or services with intent not to
7 sell them as advertised.”

8 76. Defendant’s wrongful business practices constituted, and still constitute, a
9 continuing course of conduct in violation of the CLRA.

10 77. Plaintiff and the Class suffered economic injury as a direct result of Defendant’s
11 misrepresentations and/or omissions because they were induced to purchase the Products they
12 would not have otherwise purchased or would have paid less for had Defendant had not made the
13 Misrepresentations and Additional Representations.

14 78. On December 8, 2025, Plaintiff notified Defendant in writing, by certified mail, of
15 the violations alleged herein and demanded that Defendant remedy those violations pursuant to
16 Cal. Civ. Code 1782. Defendant failed to correct its business practices or provide the requested
17 relief within 30 days.

18 79. Pursuant to §17800(a)(1)-(5) and § 1780(e), Plaintiff and the California Subclass
19 seek, in addition to injunctive relief, monetary damages from Defendant, reasonable attorneys’ fees
20 and litigation costs, and any other relief the Court deems proper under.
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Count IV
Breach of Express Warranty³²
(On behalf of Plaintiff and the Multi-State Warranty Class)

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

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

82. 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 Products.

83. The terms of the contract include the promises and affirmations of fact made by Defendant through the Misrepresentations and Additional Representations.

84. This 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.

85. As set forth above, Defendant purports through its labeling, marketing, and packaging to create an express warranty that the Products were completely natural. However, Defendant breached its express warranties regarding the Products because the Products contain artificial ingredients.

³² 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.

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

1
2
3 105. Plaintiff realleges and incorporates by reference all allegations contained in this
4 complaint, as though fully set forth herein.

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

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

12 108. During the applicable class period, Defendant intentionally misrepresented, omitted,
13 and concealed from consumers material facts regarding the quality and characteristics of the
14 Products, including the fact that the Products contain artificial ingredients despite the
15 Misrepresentations. The Misrepresentations were material and were uniformly made.

16 109. As noted in detail above, the Misrepresentations and Additional Representations
17 were false and misleading, as the Products were not completely natural and contained artificial
18 ingredients. Defendant made the Misrepresentations and Additional Representations with actual
19 knowledge of their falsity and/or made them with fraudulent intent.

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

24 111. Defendant's deceptive or fraudulent intent is evidenced by motive and opportunity.
25 Defendant knew that consumers would pay more for the Products if they believed they were
26 completely natural. For that reason, Defendant misrepresented the Products so that Defendant
27 could realize greater profits. Defendant knew that consumers would place trust and confidence in
28 its Products' claims and rely thereon in their purchases of the Products.

(On Behalf of Plaintiff and the Multi-State Consumer Protection Subclass)

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

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

119. 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 this Complaint, Defendant made the Misrepresentations and Additional Representations, even though the Products were not completely natural but contained artificial ingredients.

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

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

122. 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 Products had they known that the Products were not completely natural but contained artificial ingredients.

123. 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)

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

125. 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.

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

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

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

6 129. Defendant has been unjustly enriched in retaining the revenues derived from
7 Plaintiff's and the Class Members' purchases of the Products, which retention of such revenues
8 under these circumstances is unjust and inequitable because Defendant made the
9 Misrepresentations and Additional Representations. This caused injuries to Plaintiff and Class
10 Members because they would not have purchased the Products or would have paid less for them if
11 the true facts concerning the Products had been known.

12 130. Defendant accepted and retained the benefit in the amount of the gross revenues
13 derived from sales of the Products to Plaintiff and Class Members.

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

16 132. Plaintiff and Class Members are, therefore, entitled to restitution in the form of the
17 revenues derived from Defendant's sale of the Products.

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

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

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

25 136. Legal remedies available to Plaintiff and the Class Members are inadequate because
26 they are not equally prompt, certain, or efficient as equitable relief. Damages are not equally
27 certain as restitution because the standard that governs restitution is different than the standard that
28

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

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

15 **Request for Relief**

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

- 18 a. Declaring that this action is a proper class action, certifying the Class as requested
19 herein, designating Plaintiff as the Class Representative and appointing the
20 undersigned counsel as Class Counsel;
- 21 b. Ordering restitution and disgorgement of all profits and unjust enrichment that
22 Defendant obtained from Plaintiff and the Class members as a result of Defendant's
23 unlawful, unfair, and fraudulent business practices;
- 24 c. Ordering injunctive relief as permitted by law or equity, including enjoining
25 Defendant from continuing the unlawful practices as set forth herein, and ordering
26 Defendant to engage in a corrective advertising campaign;
- 27
- 28

- 1 d. Ordering damages in amount which is different than that calculated for restitution
2 for Plaintiff and the Class;
3
4 e. Ordering Defendant to pay attorneys' fees and litigation costs to Plaintiff and the
5 other members of the Class;
6
7 f. Ordering Defendant to pay both pre- and post-judgment interest on any amounts
8 awarded; and
9
10 g. Ordering other relief as may be just and proper.

11 **Jury Demand**

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

13 Dated: April 16, 2026.

14 Respectfully submitted,

15 **GUCOVSKI LAW FIRM, PLLC**

16 By: /s/ Nathaniel H. Sari
17 Adrian Gucovschi (State Bar No. 360988)
18 Nathaniel Haim Sari (State Bar No. 362634)
19 165 Broadway, Fl. 23
20 New York, NY 10005
21 Telephone: (212) 884-4230
22 Facsimile: (212) 884-4230
23 E-Mail: adrian@gucovschilaw.com
24 nathaniel@gucovschilaw.com

25 *Attorneys for Plaintiff*

| Babo Botancials' Products | Artificial Ingredient(s) |
|---|--|
| 1. Nourishing Shampoo for Dry Hair | Sodium Methyl Cocoyl Taurate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin |
| 2. Purifying Shampoo for Flat, Oily Hair | Sodium Methyl Cocoyl Taurate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin |
| 3. Defining Shampoo for Curly, Frizzy Hair | Sodium Methyl Cocoyl Taurate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin |
| 4. Moisturizing Oat & Calendula Shampoo & Wash – 8oz | Sodium Methyl Cocoyl Taurate, Sodium C14-16 Olefin Sulfonate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin |
| 5. Moisturizing Oat & Calendula Shampoo & Wash – 16oz | Sodium Methyl Cocoyl Taurate, Sodium C14-16 Olefin Sulfonate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin |
| 6. Moisturizing Shampoo & Wash Refill 32oz | Sodium Methyl Cocoyl Taurate, Sodium C14-16 Olefin Sulfonate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin |
| 7. Moisturizing Oat & Calendula Conditioner | Citric Acid |

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| 1 | 8. Smoothing Berry & Primrose Shampoo & Wash – 16oz | Sodium Methyl Cocoyl Taurate, Citric Acid |
| 2 | | |
| 3 | 9. Smoothing Berry & Primrose Shampoo & Wash – 32oz — | Sodium Methyl Cocoyl Taurate, Citric Acid |
| 4 | | |
| 5 | 10. Smoothing Berry & Primrose Conditioner | Citric Acid |
| 6 | | |
| 7 | 11. Smoothing Berry & Primrose Conditioning Spray | Ethylhexylglycerin |
| 8 | | |
| 9 | 12. Swim & Sport Citrus Mint & Passion Fruit Shampoo & Wash – 8oz | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid |
| 10 | | |
| 11 | 13. Swim & Sport Citrus Mint & Passion Fruit Shampoo & Wash – 16oz | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid |
| 12 | | |
| 13 | 14. Swim & Sport Citrus Mint & Passion Fruit Shampoo & Wash – 32oz | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid |
| 14 | | |
| 15 | 15. Eucalyptus Remedy Plant-Based Shampoo & Wash – 16oz | Sodium C14-16 Olefin Sulfonate, Sodium Methyl Cocoyl Taurate, Sodium Lauroyl Methyl Isethionate, |
| 16 | | |
| 17 | 16. Eucalyptus Remedy Plant-Based Conditioner | Citric Acid |
| 18 | | |
| 19 | 17. Eucalyptus Body Wash & Bubble Bath | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid |
| 20 | | |
| 21 | 18. Eucalyptus Remedy Bubble Bath & Wash Refill | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid |
| 22 | | |
| 23 | 19. Calming Lavender Bubble Bath & Wash | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid |
| 24 | | |
| 25 | 20. Calming Lavender Bubble Bath & Wash Refill | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid |
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|----------------------|--|---|
| 1 2 3 4 | 21. Moisturizing Oat & Calendula Shampoo & Wash Duo | Sodium Methyl Cocoyl Taurate, Sodium C14-16 Olefin Sulfonate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin |
| 5 6 7 8 | 22. Nourishing Shampoo & Conditioner Set | Sodium Methyl Cocoyl Taurate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin; Conditioner: none of the six |
| 9 10 11 12 | 23. Defining Shampoo & Conditioner Set | Sodium Methyl Cocoyl Taurate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin; Conditioner: none of the six |
| 13 14 15 16 | 24. Purifying Shampoo & Conditioner Set | Sodium Methyl Cocoyl Taurate, Sodium Lauroyl Methyl Isethionate, Cocamidopropyl Betaine, Citric Acid, Ethylhexylglycerin; Conditioner: none of the six |
| 17 18 19 | 25. Swim & Sport Citrus Mint & Passion Fruit Shampoo & Conditioner Set | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid; Conditioner: none of the six |
| 20 21 | 26. Calming Lavender Bubble Bath & Wash Duo | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid |
| 22 23 24 | 27. Eucalyptus Remedy Plant-Based Bubble Bath & Wash Duo | Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Citric Acid |

Exhibit B

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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
Susan Harper
Bob Durst

 Supplemental Information:

*Microbial form only ...
because of substrate might be
a product*

MISSING INFORMATION: _____

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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 _____

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 ~~any~~ involve use of other substances: substrates: corn syrup, sucrose
Any additional comments or references? ammonium bicarbonate

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

Signature Steve Taylor Date 3-5-95

α.

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:

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 3/10/25

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**USDA / IAF 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:

- Synthetic Allowed,
- Prohibited Natural, or
- This material does not belong on the National List because:

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

Must be listed on the ingredient label if it used used.
Unless it is actually derived from a natural source the labeling must not indicate that it is a natural compound.

Any additional comments or references?

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

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

Signature Robert W. Durst

Date 3/4/95

NOSB Materials Database

4.

Identification

| | | | |
|----------------|--------------------------------|---------------|---|
| Common Name | Citric Acid | Chemical Name | B-hydroxy-tricarboxylic acid C ₆ H ₈ O ₇ |
| Other Names | Citric Acid, Anhydrous USP/FCC | | |
| Code #: CAS | 77-92-9 | Code #: Other | 21 CFR 182-1033 |
| N. L. Category | Synthetic Allowed | MSDS | <input checked="" type="radio"/> yes <input type="radio"/> no |

Chemistry

| | |
|-------------|--|
| Family | Aliphatic Acid |
| Composition | C ₆ H ₈ O 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, <i>Aspergillus niger</i> (a mold) or <i>Candida guilliermondii</i> (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, antimicrobial 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 containing 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 irritant 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).
Vinogar (strange taste in some foods).
Citrus juices.

2119(m)7: Is it compatible?

Compatible

References

1. FDA. 1977. Evaluation of the health aspects of citric acid, sodium citrate, potassium citrate, calcium citrate, ammonium citrate, triethyl citrate, isopropyl citrate, and stearyl citrate as food ingredients. SCOGS-84. Life Science Research Office, 9650 Rockville Pike, Bethesda, Maryland 20014.
2. Ag Partners of Davis, *Materials Report for Citric Acid*, 1995. Organic Trade Association, Greenfield, MA

6.

MSDS for CITRIC ACID, MONOHYDRATE Page 1

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

Table with 2 columns: COMPONENT, % CASNO. Row 1: CITRIC ACID, MONOHYDRATE, (5949-29-1)

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 (H2O=1) (BUTYL ACETATE=1) EVAPORATION RATE: N/A
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.

7.

TOXIC GASES PRODUCED: CARBON MONOXIDE, CARBON DIOXIDE

5 - HEALTH HAZARD DATA

TOXICITY TEST RESULTS AND SAFETY AND HEALTH EFFECTS ARE LISTED FOR THE ANHYDROUS PRODUCT.

TOXICITY: LD50 (ORAL-RAT)(G/KG) - 11.7
LD50 (IPR-RAT)(MG/KG) - 883
LD50 (SCU-RAT)(MG/KG) - 5500
LD50 (ORAL-MOUSE)(MG/KG) - 5040

CARCINOGENICITY: NTP: NO IARC: NO Z LIST: NO OSHA REG: NO

EFFECTS OF OVEREXPOSURE

DUST MAY IRRITATE NOSE AND THROAT.
DUST MAY CAUSE HEADACHE, COUGHING, DIZZINESS OR DIFFICULT BREATHING.
DUST MAY IRRITATE OR BURN MUCOUS MEMBRANES.
CONTACT WITH SKIN OR EYES MAY CAUSE IRRITATION.

TARGET ORGANS: EYES, SKIN

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: NONE IDENTIFIED

ROUTES OF ENTRY: INHALATION, EYE CONTACT, SKIN CONTACT

EMERGENCY AND FIRST AID PROCEDURES

INGESTION: IF SWALLOWED AND THE PERSON IS CONSCIOUS, IMMEDIATELY GIVE LARGE AMOUNTS OF WATER. GET MEDICAL ATTENTION.

INHALATION: IF A PERSON BREATHES IN LARGE AMOUNTS, MOVE THE EXPOSED PERSON TO FRESH AIR. GET MEDICAL ATTENTION.

EYE CONTACT: IMMEDIATELY FLUSH WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. GET MEDICAL ATTENTION.

SKIN CONTACT: IMMEDIATELY WASH WITH PLENTY OF SOAP AND WATER FOR AT LEAST 15 MINUTES.

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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9 - STORAGE AND HANDLING PRECAUTIONS

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

10 - TRANSPORTATION DATA AND ADDITIONAL INFORMATION

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

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

9.

05 MAY 94
 DOCNUM=1937

PAGE 1

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

CITRIC ACID

CAS#: 000077929 HUMAN CONSUMPTION: 90.5387 MG/KG BW/DAY/PERSON
 FASP#: 1937 MARKET DISAPPEARANCE: 10683333.333LBS/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
 SEQUESTANT
 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 |
| | 181.190 | PART 169 | PART 150 |
| | 156.130 | 145.145 | 131.111 |
| | 131.112 | 131.136 | 131.144 |
| | 131.138 | 131.146 | 146.187 |
| | 190.161 | 150.141 | 166.40 |
| | 169.115 | 169.140 | 169.150 |
| | 173.180 | 173.280 | 145.131 |
| | 166.110 | 184.1033 | |

MINIMUM TESTING LEVEL: 3

COMMENTS: STUDY I-12 FROM SCOGS-84

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

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

10.

05 MAY 94

PAGE 2

DDCNUM=1937

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

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

BOX 7: ACUTE TOXICITY INFORMATION

STUDY: 2 SOURCE: J TAKEDA RES LAB 30:25-31
 SPECIES: RAT YEAR: 1971
 LD50: 12000 MG/KG BW
 COMMENTS:
 STUDY: 1 SOURCE: J TAKEDA RES LAB 30:25-31
 SPECIES: MOUSE YEAR: 1971
 LD50: 5000 MG/KG BW
 COMMENTS:

BOX 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

STUDY: 3 COMPLETENESS: SOURCE: REV PORT FARM 20:41-46
 TYPE: SHORT TERM YEAR: 1970
 SPECIES: RAT LEL: 200 MG/KG BW/DAY
 DURATION: 9 DAYS HNEL:
 EFFECTS: BODY WEIGHT DECREASE
 SITES:
 COMMENTS: INITIAL DECREASE IN WEIGHT DID NOT PERSIST
 NOT USED FOR PRIORITY RANKING
 STUDY: 4 COMPLETENESS: SOURCE: J TAKEDA RES LAB 30:25-31
 TYPE: SHORT TERM YEAR: 1971
 SPECIES: RAT LEL: 4670 MG/KG BW/DAY
 DURATION: 42 DAYS HNEL: 2260 MG/KG BW/DAY
 EFFECTS: CHOLESTEROL DECREASE
 GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
 ORGAN WEIGHT DECREASE
 CELLULAR ATROPHY
 SITES: THYMUS SPLEEN
 COMMENTS: SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
 STUDY: 5 COMPLETENESS: SOURCE: J AM PHARM ASSOC SCI ED
 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
 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: GRF 770195 3
 TYPE: TERATOGENICITY YEAR: 1973
 SPECIES: RAT LEL: > MG/KG BW/DAY

Page 12

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11.

05 MAY 94
DOCNUM=1937

PAGE 3

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: 15 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 C



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. 5592.

Sincerely,

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/s/
Robert L. Hart
Acting District Director

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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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1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
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22
23
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28

Exhibit D



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 your 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)(1) of the Act in that its labeling is 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 fresh 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)(1)(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)(1)(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(1)(2) of the Act and 21 CFR 101.4(a)(1). Optional information, such as the term "fresh" is not permitted.

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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 preamble 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 in, 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


Links on this page:

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

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- State & Local Officials
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- Industry
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