UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

CHRISTOPHER SILVA, individually on behalf of himself and all others similarly situated,

Plaintiff,

v.

SMUCKER NATURAL FOODS, INC., J.M SMUCKER CO.

Defendants.

Case No. CV 14 6154

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

GLEESON, J.
LEVY, M.J.

Plaintiff, individually and on behalf of all others similarly situated, by his attorneys, alleges the following upon information and belief, except for those allegations pertaining to Plaintiff, which are based on personal knowledge:

NATURE OF ACTION

1. Plaintiff Christopher Silva ("Plaintiff") brings this action against SMUCKER NATURAL FOODS, Inc. and J.M. SMUCKER CO. ("Smucker or "Defendants") on behalf of himself and a class consisting of all consumers nationwide who purchased "Natural Brew Draft Root Beer" ("the product") at any time during the applicable statute of limitations period (the "Class Period");
2. Smucker is a major international food company that owns ubiquitous food brands such as Jif and Crisco. In the interest of appealing to more health conscious consumers interested in purchasing beverages that are not artificially and/or chemically flavored, colored, and/or preserved, Smucker began selling Draft Root Beer under the "Natural Brew" label.

3. Smucker claims on its website and elsewhere that the product: a) is "made from all natural ingredients;" b) has "no artificial colors, flavors, or additives, ever;" and c) is "brewed in small batches with the finest natural ingredients." **(Exhibit A).**

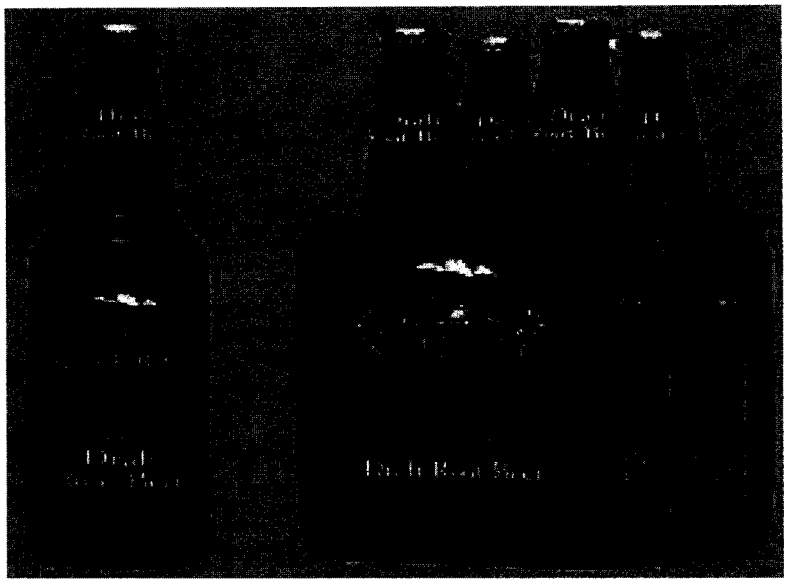
4. Smucker also claims on its website and elsewhere that:

> "Natural Brew was specially formulated to meet the consumer's need for a quality-crafted, natural carbonated beverage. We make Natural Brew using old-fashioned micro-brewing techniques to bring out the robust flavor of all key ingredients. Unlike most other soft drink companies, Natural Brew is brewed in small batches allowing the ingredients to blend together forming a full, rich flavor, free from any artificial additives or preservatives." **(Exhibit B).**

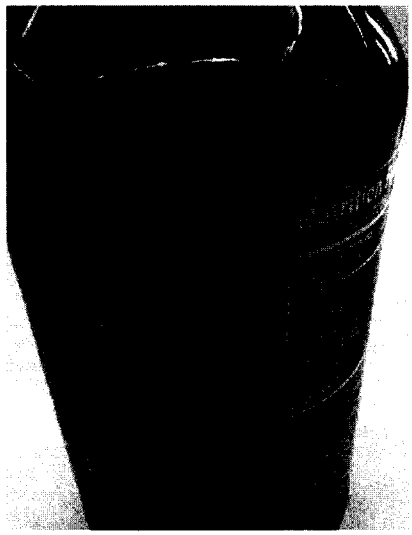
5. Smucker also claims on its website and elsewhere that: "we chose the name 'Natural Brew' to reflect the hand-crafted, premium nature of our products. Far from the typical options, our sodas are lovingly brewed in small batches from high-quality natural and organic ingredients, using time-honored traditional methods." **(Exhibit C).**

6. Smucker also claims on its website and elsewhere that: "we utilize traditional brewing methods that have been perfected over centuries. These simple processes allow the true essences of the ingredients to stand out, creating an honest and bold flavor experience unlike any other. The flavor essences are then carefully blended with other natural ingredients to give our handcrafted brews a complex flavor profile." **(Exhibit D).**

7. Moreover, as shown below, the product prominently displays that it is "Natural."



8. As shown below, the product prominently displays that the brew "blends tradition and quality, *naturally*." (emphasis added)



9. The product also prominently provides: "to give our root beer a subtly rich, creamy flavor we add vanilla extract and other natural flavors to our recipe."

10. Smucker uses its "Natural Brew" product line to fool consumers into believing that its root beer is not artificially flavored, colored, or chemically preserved. In so doing,

Smucker has misled and deceived consumers, and it has violated consumer protection laws.

11. United States regulatory organizations have clearly delineated between natural ingredients and synthetic ingredients. They have not, however, adopted a formal definition of the term "natural."

12. The FDA declared in 2012: "From a food science perspective, it is difficult to define a food product that is 'natural' because the food has probably been processed and is no longer the product of the earth. That said, the FDA has not developed a definition for use of the term natural or its derivatives. ***However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances."*** (emphasis added). **(Exhibit E).** This declaration reiterated and reaffirmed the policy that the FDA had previously articulated in 1993. 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

13. On January 6, 2014, the FDA issued a letter to Judges Yvonne G. Rogers and Jeffrey S. White of the United States District Court, Northern District of California and to Judge Kevin McNulty of the District of New Jersey. In essence, the FDA declined the courts' invitation to comment on whether food containing substances derived from genetically modified seeds could be labeled "natural." Notably, the FDA declared: "The agency has, however, stated that its policy regarding the use of the term 'natural' on food labeling means that 'nothing artificial or synthetic (***including color additives regardless of source***) has been included in, or has been added to, a food that would not normally be expected to be in food." (emphasis added) (**Exhibit F**).

14. Moreover, as described in 21 C.F.R 101.22(k)(2) and the 1986 FDA Compliance Guide, any color added to food means the food becomes "artificially colored."

15. In its Compliance Policy Guide 7127.01, the FDA made it clear that use of the word "natural" may be erroneously interpreted to mean the color is a naturally occurring constituent in the food. And, "since all added colors result in an artificially colored food, [the FDA] would object to the declaration of any added color as 'natural'."

16. Smucker claims its product is natural and is: a) "made from all natural ingredients;" b) free from artificial flavors or preservatives and free from any artificial additives or colors; and, c) "brewed in small batches with the finest natural ingredients."

17. These claims—which Smucker has made uniformly to consumers nationwide during the class period—are false and misleading.

18. Contrary to Smucker's representations, the product contains caramel color and phosphoric acid.

19. Caramel color is an artificial color additive.

20. Phosphoric acid (also known as orthophosphoric acid) is an artificial flavor and artificial, chemical preservative. It is also used as an acidifying agent in industrial settings and it is used in industrial processes such as the coagulation of rubber latex. **(Exhibit G).**

Caramel Color is an Artificial Color

21. 21 C.F.R. § 73.85 dictates that caramel coloring is a "color additive."

22. 21 C.F.R. § 101.22 dictates that the term "color additive" is synonymous with "artificial color" or "artificial coloring."

23. Accordingly, the product is artificially colored, has added color, and has color additives. The product is not, therefore, natural or free from artificial additives or colors.

24. Smucker's conduct is particularly egregious given the peer-reviewed studies demonstrating a link between 4-MEI contained in certain classes of caramel coloring and increased incidence of tumors in those who consume it.

25. 4-MEI forms during the manufacturing of certain types of caramel coloring (known as Class III and Class IV caramel coloring) that are used to color cola-type beverages and other foods. In 2007, the National Toxicology Program (NTP) issued a report in which it concluded that 4-MEI caused lung cancer in male and female mice and may have been associated with development of leukemia in female rats. **(Exhibit H)**.

Phosphoric Acid is an Artificial Flavor

26. 21 C.F.R. § 101.22(a) (1) provides that, "The term 'artificial flavor' or 'artificial flavoring' means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat fish, poultry, eggs dairy products, or fermentation products, thereof."

27. The function of phosphoric acid is, *inter alia*, to impart flavor.

28. Phosphoric acid is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat fish, poultry, eggs dairy products, or fermentation products, thereof.

29. Phosphoric acid is, therefore, an artificial flavoring under 21 C.F.R. § 101.22(a) (1).

30. Phosphoric acid does not meet the criteria to be a natural flavoring.

31. 21 C.F.R. § 101.22(a)(3) provides that, "The terms 'natural flavor' or 'natural flavoring' means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring

constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional."

32. Phosphoric acid is not an essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof.

33. Therefore, phosphoric acid is not a natural flavor as defined by 21 C.F.R. § 101.22(a)(3).

34. Accordingly, the product is artificially flavored. The product is not, therefore, natural or free from artificial flavors.

Phosphoric Acid is a Chemical Preservative

35. 21 C.F.R. § 101.22(a)(5) provides that, "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, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties." (emphasis added).

36. Phosphoric acid is not a "common salt, sugar, vinegar, spice, or oil extracted from spices, nor is it a substance added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties."

37. As used in the product, phosphoric acid prevents or retards deterioration of the product.

38. Therefore, phosphoric acid is a "chemical preservative" as defined in 21 C.F.R. § 101.22(a)(5).

39. Accordingly, the product is chemically preserved. The product is not, therefore, natural or free from artificial preservatives.

Smucker's Product is Misbranded and Violative of Consumer Protection Laws

40. Because the product contains artificial flavoring, artificial coloring, and chemical preservatives, Smucker product labels are required to state the presence of such artificial flavoring and chemical preservatives on the product's label and must specifically identify the function of phosphoric acid.

41. 21 C.F.R. § 101.22(c) provides that "[a] statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food or on its container or wrapper, or on any two or all three of these, as may be necessary to render such statement likely to be read by the ordinary person under customary conditions of purchase and use of such food."

42. 21 C.F.R. § 101.22(j) further provides that "[a] food to which a chemical preservative(s) is added shall …bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., 'preservative', 'to retard spoilage', 'a mold inhibitor', 'to help protect flavor' or 'to promote color retention.'"

43. The product does not include a statement that it contains artificial flavoring.

44. The product does not include a statement that it contains artificial coloring.

45. The product does not include a statement that it contains chemical preservatives.

46. The product does not include a statement specifying the function of phosphoric acid. Accordingly, the product is misbranded under, *inter alia*, the FDCA and New York law.

47. Smucker knowingly and intentionally failed to include statements on the product containers regarding the presence of artificial flavoring, artificial colors, artificial additives, and chemical preservatives.

48. Smucker has violated, *inter alia*, NY General Business Law § 392-b by: a) putting upon an article of merchandise, bottle, wrapper, package, label or other thing, containing or covering such an article, or with which such an article is intended to be sold, or is sold, a false description or other indication of or respecting the kind of such article or any part thereof; and b) selling or offering for sale an article, which to their knowledge is falsely described or indicated upon any such package, or vessel containing the same, or label thereupon, in any of the particulars specified.

49. Smucker has violated, *inter alia*, NY General Business Law § 349 and § 350 by misleadingly, inaccurately, and deceptively advertising its product and representing that its product is, *inter alia*, "natural" and is: a) "made from all natural ingredients;" b) free from artificial flavors or preservatives and free from any artificial additives or colors; and, c) "brewed in small batches with the finest natural ingredients."

50. Had Plaintiff and Class Members known that the product was misbranded and contained false and misleading representations, Plaintiff and Class Members would not have purchased the product at an unwarranted premium above alternative products that were not illegal and misbranded.

JURISDICTION AND VENUE

51. Jurisdiction is proper pursuant to 28 U.S.C. 1332(d) (2). Plaintiff is a citizen of the State of New York; Defendant, SMUCKER NATURAL FOODS is a company organized and existing under the laws of California with its principal place of business in

California; and Defendant, J.M Smucker Co. is an Ohio Corporation with its principal place of business in Ohio. Upon information and belief, the aggregate amount in controversy is in excess of $5,000,000, exclusive of interests and costs.

52. This Court has personal jurisdiction over Defendants because Defendants conduct and transact business in the State of New York, contract to supply goods within the State of New York, and supply goods within the State of New York.

53. Venue is proper because Plaintiff and many Class Members reside in the Eastern District of New York and Defendants have, at all relevant times, been doing business in the Eastern District of New York, and throughout the state.

54. A substantial part of the events or omissions which give rise to the claims occurred in Queens County.

55. Smucker has made these false and misleading statements in order to exploit the preference of health-conscious consumers for beverages devoid of, *inter alia*, artificial ingredients.

56. The false and misleading statements induced consumers nationwide to a pay a premium for the product as opposed to purchasing less expensive sodas that are not purported to be, *inter alia*, natural, made with all natural ingredients, free from artificial flavors, preservatives, and additives, and brewed in small batches with the finest natural ingredients.

57. Smucker's conduct is unacceptable. Smucker misleads and deceives consumers by mislabeling its product and falsely advertising to consumers that its product contains natural and/or all natural ingredients when, in fact, they are artificially colored, artificially flavored, chemically preserved, and are unnatural.

THE PARTIES

58. Plaintiff is a citizen of the State of New York in the County of Queens. In October 2014, Plaintiff purchased the product in New York and paid a premium for the product because he saw and relied upon the product labeling, product advertising, and read the packaging which stated, *inter alia*, that the product is "Natural," and a) "made from all natural ingredients;" b) free from artificial flavors or preservatives and free from any artificial additives or colors; and, c) "brewed in small batches with the finest natural ingredients." These representations were material to Plaintiff's decision to make the purchase and buy the product at a premium.

59. Plaintiff paid a premium for the product and opted against buying less expensive sodas not purported to be, *inter alia*, made from all natural ingredients; and/or all natural. As a result of purchasing the product at a premium price in reliance on advertising and representations that are false, Plaintiff and Class Members suffered an injury in fact.

60. The members of the proposed class consist of men and women across the country who purchased the product.

61. Defendant Smucker Natural Foods, Inc. is a California corporation that manufactures, sells, markets, distributes, advertises, and promotes the product in New York and throughout the United States.

62. Defendant J.M Smucker Co. is an Ohio Corporation that manufactures, sells, markets, distributes, advertises, and promotes the product in New York and throughout the United States.

SUBSTANTIVE ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

63. Smucker falsely advertises and misrepresents to its consumers, including Plaintiff and Class Members, that its product is "Natural," and is: a) "made from all natural ingredients," b) free from artificial flavors or preservatives and free from any artificial additives or colors; and c) "brewed in small batches with the finest natural ingredients."

64. The material misrepresentations and mislabeling induced Smucker's consumers, including Plaintiff and Class Members, to purchase the product at a premium price. To their detriment, Plaintiff and Class Members relied on Smucker's false and misleading misrepresentations and mislabeling.

65. Smucker's statements are false and its practices are deceptive and misleading because, *inter alia*, the product is artificially colored, artificially flavored, chemically preserved, and contains artificial ingredients. The product is not, therefore, natural or free from artificial flavors, preservatives, or additives.

CLASS ALLEGATIONS

66. Plaintiff brings this matter on behalf of himself and those similarly situated. As detailed at length in this complaint, Smucker orchestrated deceptive marketing and labeling practices. Smucker customers were uniformly impacted by and exposed to this misconduct. Accordingly, this Complaint is uniquely situated for class-wide resolution, including injunctive relief.

67. The class is defined as all consumers who purchased the product at any time during the period within the applicable statute of limitations.

68. The Class is properly brought and should be maintained as a class action under

Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

69. Numerosity: Class Members are so numerous that joinder of all members is impracticable. Plaintiff believes that there are thousands of consumers who are Class Members as described above who have been damaged by, *inter alia*, Smucker's deceptive and misleading practices.

70. Common Questions of Fact and Law: The questions of law and fact common to the Class Members which predominate over any questions which may affect individual Class Members include, but are not limited to:

    a) Whether Smucker is responsible for the conduct alleged herein which was uniformly directed at all consumers who purchased its product;

    b) Whether Smucker's misconduct set forth in this complaint demonstrates whether Smucker has engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of its product.

    c) Whether Smucker's false and misleading statements concerning its product and its concealment of material facts regarding the product were likely to deceive reasonable consumers.

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

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

71. Typicality: Plaintiff is a member of the Class. Plaintiff's claims are typical of the claims of each Class Member, in that, every member of the Class was susceptible to the same

deceptive, misleading conduct and purchased Smucker's product. Plaintiff is entitled to relief under the same causes of action as the other Class Members.

72. Adequacy: Plaintiff is an adequate Class representative because his interests do not conflict with the interests of the Class Members he seeks to represent; his claims are common to all members of the Class and he has a strong interest in vindicating his rights; he has retained counsel competent and experienced in complex class action litigation and they intend to vigorously prosecute this action. Plaintiff has no interests which conflict with those of the Class. The Class Members' interests will be fairly and adequately protected by Plaintiff and his counsel. Smucker has acted in a manner generally applicable to the Class, making relief appropriate with respect to Plaintiff and the Class Members. The prosecution of separate actions by individual Class Members would create a risk of inconsistent and varying adjudications.

73. The Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action is superior. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any other questions affecting only individual members of the class. The Class issues fully predominate over any individual issue because no inquiry into individual conduct is necessary, just a narrow focus on Smucker's deceptive and misleading product marketing and labeling practices. In addition, this class is superior to other methods for fair and efficient adjudication of this controversy because, *inter alia*:

74. Superiority: A class action is superior to the other available methods for the fair and efficient adjudication of this controversy because:

a) The joinder of thousands of individual Class Members is impracticable, cumbersome, unduly burdensome, and a waste of judicial and/or litigation resources;

b) The individual claims of the Class Members may be relatively modest compared with the expense of litigating the claim, thereby making it impracticable, unduly burdensome, and expensive—if not totally impossible—to justify individual actions;

c) When Defendant's liability has been adjudicated, all Class Members' claims can be determined by the Court and administered efficiently in a manner far less burdensome and expensive than if it were attempted through filing, discovery, and trial of all individual cases;

d) This class action will promote orderly, efficient, expeditious, and appropriate adjudication and administration of class claims;

e) Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action;

f) This class action will assure uniformity of decisions among Class Members; and

g) The Class is readily definable and prosecution of this action as a class action will eliminate the possibility of repetitious litigation.

INJUNCTIVE CLASS RELIEF

75. Rules 23(b) (1), (2), and (3) contemplate a class action for purposes of seeking class-wide injunctive relief. Here, Smucker has engaged in conduct resulting in misleading consumers about ingredients in its product. Since Smucker's conduct

has been uniformly directed at all consumers nationwide, and the conduct continues presently, injunctive relief on a class-wide basis is a viable and suitable solution to remedy Smucker's continuing misconduct.

76. The injunctive class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

a) Numerosity: Individual joinder of the injunctive class members would be wholly impracticable. Smucker's product has been purchased by thousands of persons nationwide.

b) Commonality: Questions of law and fact are common to members of the class. Smucker's misconduct was uniformly directed at all consumers. Thus, all members of the class have a common cause against Smucker to stop its misleading conduct through an injunction. Since the issues presented by this injunctive class deal exclusively with Smucker's misconduct, resolution of these questions would be necessarily common to the entire class. Moreover, there are common questions of law and fact inherent in the resolution of an injunctive class, including, *inter alia*:

i. Resolution of the issues presented in the 23(b)(3) class;

ii. Whether members of the class will continue to suffer harm by virtue of Smucker's deceptive product marketing and labeling; and

iii. Whether, on equitable grounds, Smucker should be prevented from continuing to omit material information from its labeling.

c) Typicality: Plaintiff's claims are typical of the claims of the injunctive class because his claims arise from the same course of conduct (i.e. Smucker's deceptive and misleading product marketing, labeling, and practices). Plaintiff is a typical class representative, because, like all member of the injunctive class, he purchased Smucker's product which was sold unfairly and deceptively to consumers nationwide.

d) Adequacy: Plaintiff will fairly and adequately represent and protect the interests of the injunctive class. His consumer protection claims are common to all members of the injunctive class and he has a strong interest in vindicating his rights. In addition, Plaintiff and the Class are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

77. The injunctive class is properly brought and should be maintained as a class action under Rule 23(b) (2) because Plaintiff seeks injunctive relief on behalf of the Class Members on grounds generally applicable to the entire injunctive class. Certification under Rule 23(b)(2) is appropriate because Smucker has acted or refused to act in a manner that applies generally to the injunctive class (i.e., Smucker has marketed its product using the same misleading and deceptive product labeling to all of the Class Members). Any final injunctive relief or declaratory relief would benefit the entire injunctive class as Smucker would be prevented from continuing its misleading and deceptive product marketing practices and would be required to honestly disclose to consumers the true ingredients in its product.

FIRST CAUSE OF ACTION
VIOLATION OF NEW YORK GBL §349
(On Behalf of Plaintiff and All Class Members)

78. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

79. 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…"

80. GBL § 349(h) directs that "any person who has been injured by reason of any violation of [GBL § 349] may bring an action in his own name to enjoin such unlawful act or practice…"

81. The conduct of Smucker alleged herein constitutes recurring, "unlawful" deceptive acts and practices in violation of GBL § 349, and as such, Plaintiff and the Class Members seek monetary damages and the entry of preliminary and permanent injunctive relief against Smucker, enjoining it from inaccurately describing, labeling, marketing, and promoting its product.

82. There is no adequate remedy at law.

83. Smucker misleadingly, inaccurately, and deceptively presents its product.

84. Smucker's improper consumer-oriented conduct—including labeling and advertising that its product is natural and is, inter alia, a) "made from all natural ingredients," b) free from artificial flavors or preservatives and free from any artificial additives or colors; and c) "brewed in small batches with the finest natural ingredients"—is misleading in a material way in that it, *inter alia*, induced Plaintiff and Class Members to purchase and pay a premium for Smucker's product.

85. Plaintiff and the Class Members have been injured inasmuch as they paid a premium for product that was—contrary to Smucker's representations—not natural and not free from artificial flavors, preservatives, additives, and colors. Accordingly, Plaintiff and the Class Members received less than what they bargained and/or paid for.

86. Smucker's advertising and product labeling induced the Plaintiff and Class Members to buy Smucker's product.

87. Smucker's deceptive and misleading practices constitute a deceptive act and practice in the conduct of its business in violation of New York General Business Law § 349(a) and Plaintiff and the Class have been damaged thereby.

88. As a result of Smucker's recurring "unlawful" deceptive acts and practices, Plaintiff and Class Members are entitled to monetary damages, injunctive relief, restitution, disgorgement of all monies obtained by means of Smucker's unlawful conduct, interest, and attorneys' fees and costs.

SECOND CAUSE OF ACTION
VIOLATION OF NEW YORK GBL §350
(On Behalf of Plaintiff and All Class Members)

89. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

90. N.Y. Gen. Bus. Law § 350, provides, in part, as follows:

> 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.

91. N.Y. Gen. Bus. Law § 350-a(1) provides , in part, as follows:

> The term 'false advertising' means advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any employment opportunity if such

> advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual…

92. Smucker's labeling and advertisements contain untrue and materially misleading statements concerning Smucker's product inasmuch as they misrepresent that the product is, inter alia: a) "made with all natural ingredients;" b) free from artificial flavors or preservatives and free from any artificial additives or colors; and c) "brewed in small batches with the finest natural ingredients."

93. Plaintiff and the Class Members have been injured inasmuch as they relied upon the labeling and advertising and paid a premium for a product that was did not conform to Smucker's representations. Accordingly, Plaintiff and the Class Members received less than what they bargained and/or paid a premium for.

94. Smucker's advertising and product labeling induced the Plaintiff and Class Members to buy Smucker's product.

95. Smucker knew, or by exercising reasonable care should have known, that its statements and representations as described in this Complaint were untrue and/or misleading.

96. Smucker's conduct constitutes multiple, separate violations of N.Y. Gen. Bus. Law § 350.

97. Smucker made the material misrepresentations described in this Complaint in

Smucker's advertising and on its product's labels.

98. Smucker's material misrepresentations were substantially uniform in content, presentation, and impact upon consumers at large. Moreover, all consumers purchasing the product were and continue to be exposed to Smucker's material misrepresentations.

99. As a result of Smucker's false or misleading labeling and advertising, Plaintiff and Class Members are entitled to monetary damages, injunctive relief, restitution, disgorgement of all monies obtained by means of Smucker's unlawful conduct, interest, and attorneys' fees and costs.

THIRD CLAIM FOR RELIEF
VIOLATION OF NEW YORK GBL LAW § 350-a(1) BY OMISSION
(On Behalf of Plaintiff and All Class Members)

100. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

101. N.Y. Gen. Bus. Law § 350-a(1) expressly covers material omissions:

> In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual…

102. Smucker's product labeling and advertising contains misleading and/or unfair material omissions concerning Smucker's product, including: that the product is not natural and not free from artificial flavors, preservatives, and additives.

103. Plaintiff and the Class Members have been injured inasmuch as they relied upon the labels and advertising and paid a premium for product that, contrary to Smucker's labels and advertising, are not natural and/or a) "made from all natural ingredients," b) free from artificial flavors or preservatives and free from any artificial additives or colors; and c) "brewed in small batches with the finest natural ingredients."

104. Smucker knew, or in the exercise of reasonable care should have known, that the statements and representations made about the product as described in this Complaint omitted material facts.

105. Smucker's dissemination of advertising and labeling containing material omissions of fact constitutes multiple, separate violations of N.Y. Gen. Bus. Law § 350.

106. Smucker's material misrepresentations by way of omissions, as described in this Complaint, were substantially uniform in content, presentation, and impact upon consumers at large. Moreover, all consumers purchasing the product were and continue to be exposed to Smucker's material misrepresentations by way of omissions.

107. Smucker's advertising and product labeling induced the Plaintiff and Class Members to buy the product.

108. Plaintiff and Class Members relied on Smucker's advertising, which was deceptive, false and contained material omissions.

109. As a result of Smucker's false or misleading advertising and labeling, the Plaintiff and Class Members are entitled to monetary damages, injunctive relief, restitution,

disgorgement of all monies obtained by means of Smucker's unlawful conduct, interest, and attorneys' fees and costs.

FOURTH CLAIM FOR RELIEF
BREACH OF EXPRESS WARRANTY
(On Behalf of Plaintiff and All Class Members)

110. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

111. Smucker provided the Plaintiff and Class Members an express warranty in the form of written and oral affirmations of fact promising and representing that its product is natural and a) "made from all natural ingredients," b) free from artificial flavors or preservatives and free from any artificial additives or colors; and, c) "brewed in small batches with the finest natural ingredients."

112. The above affirmations of fact were not couched as "belief" or "opinion," and were not "generalized statements of quality not capable of proof or disproof."

113. These affirmations of fact became part of the basis for the bargain and were material to the transaction for the Plaintiff's and Class Members' transactions.

114. Plaintiff and Class Members reasonably relied upon the Smucker's affirmations of fact and justifiably acted in ignorance of the material facts omitted or concealed when they decided to buy Smucker's product.

115. Smucker was given opportunities to cure its default but refused to do so.

116. Contrary to Smucker's affirmations of fact, Smucker breached the express warranty because the product is not natural, and not a) "made from all natural ingredients," b) free from artificial flavors or preservatives and free from any artificial additives or colors; and c) "brewed in small batches with the finest natural ingredients."

FIFTH CLAIM FOR RELIEF
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(On Behalf of Plaintiff and All Class Members)

117. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

118. Smucker is in the business of manufacturing, producing, distributing, and selling soda.

119. Under the Uniform Commercial Code's implied warranty of merchantability, Smucker warranted to the Plaintiff and the Class Members that the product is natural and a) "made from all natural ingredients;" b) free from artificial flavors or preservatives and free from any artificial additives or colors; and, c) "brewed in small batches with the finest natural ingredients."

120. Smucker breached the implied warranty of merchantability in that the product's ingredients deviate from the label and product description, and reasonable consumers expecting a product that conforms to its label would not accept the product if they knew that it is not natural, and not a) "made from all natural ingredients;" b) free from artificial flavors or preservatives and free from any artificial additives or colors and c) "brewed in small batches with the finest natural ingredients.

121. Smucker breached the implied warranty of merchantability in that Smucker's product does not conform to the promises or affirmations of fact made on the product containers or labels or literature. Any reasonable consumer would not accept the product if they knew that the product is not natural, and not a) "made from all natural ingredients," b) free from artificial flavors or preservatives and free from any artificial additives or colors; and c) "brewed in small batches with the finest natural ingredients."

122. Within a reasonable time after the Plaintiff discovered that the product is not natural, and not a) "made from all natural ingredients;" b) free from artificial flavors or preservatives and free from any artificial additives or colors; and, c) "brewed in small batches with the finest natural ingredients, Plaintiff notified Smucker of such breach.

123. The inability of the product to meet the label description was wholly due to the Smucker's fault and without Plaintiff's fault or neglect, and was solely due to the Smucker's manufacture and distribution of the product to the public.

124. As a result of the foregoing, Plaintiff and the Class Members have been damaged in the amount paid for the Smucker's product, together with interest thereon from the date of purchase.

SIXTH CLAIM FOR RELIEF
COMMON LAW UNJUST ENRICHMENT
(On Behalf of Plaintiff and All Class Members)

125. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

126. Plaintiff, on behalf of himself and consumers nationwide, brings a common law claim for unjust enrichment.

127. Smucker's conduct violated, inter alia, New York General Business Law 392-b by: a) putting upon an article of merchandise, bottle, wrapper, package, label or other thing, containing or covering such an article, or with which such an article is intended to be sold, or is sold, a false description or other indication of or respecting the kind of such article or any part thereof; and b) selling or offering for sale an article, which to their knowledge is falsely described or indicated upon any such package, or vessel containing the same, or label thereupon, in any of the particulars specified..

128. Smucker's unlawful conduct as described in this Complaint allowed Smucker to knowingly realize substantial revenues from selling its product at the expense, and to the detriment and/or impoverishment, of the Plaintiff and Class Members, and to Smucker's benefit and enrichment. Smucker has thereby violated fundamental principles of justice, equity, and good conscience.

129. Plaintiff and Class Members conferred significant financial benefits and paid substantial compensation to Smucker for a product that was not as Smucker represented.

130. Under common law principles of unjust enrichment, it is inequitable for Smucker to retain the benefits conferred by Plaintiff's and Class Members' overpayments.

131. Plaintiff and Class Members seek disgorgement of all profits resulting from such overpayments and establishment of a constructive trust from which Plaintiff and Class Members may seek restitution.

JURY DEMAND

Plaintiff demands a trial by jury on all issues.

WHEREFORE, Plaintiff, on behalf of himself and the Class, prays for judgment as follows:

(a) Declaring this action to be a proper class action and certifying Plaintiff as the representative of the Class under Rule 23 of the FRCP;

(b) Entering preliminary and permanent injunctive relief against Smucker, directing Smucker to correct its practices and to comply with the law;

(c) Awarding monetary damages, including treble damages, pursuant to GBL § 349 and GBL § 350, and punitive damages;

(d) Awarding Plaintiff and Class Members their costs and expenses incurred in this action, including reasonable allowance of fees for Plaintiff's attorneys and experts, and reimbursement of Plaintiff's expenses; and

(e) Granting such other and further relief as the Court may deem just and proper.

Dated: October 21, 2014

THE SULTZER LAW GROUP, P.C.

By: _____

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Jason P. Sultzer, Esq. (Bar ID #: JS4546)
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Counsel for Plaintiff and the Class

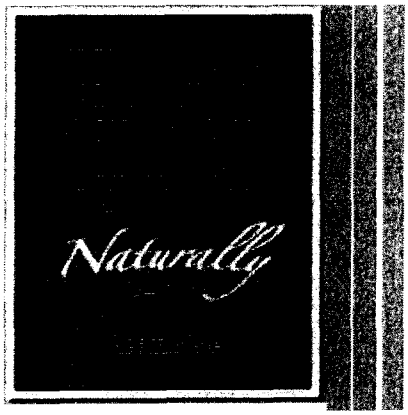
EXHIBIT A

BLENDING TRADITION AND QUALITY... NATURALLY

Naturally brewed, naturally delicious

Natural Brew® beverages are made from all natural ingredients...no artificial colors, flavors or additives, ever.
We've searched the world for the finest ingredients to create unique, invigorating taste sensations, unlike anything you've experienced before!

Learn More About Our Products



Draft Root Beer

Outrageous Ginger Ale

Vanilla Creme Soda

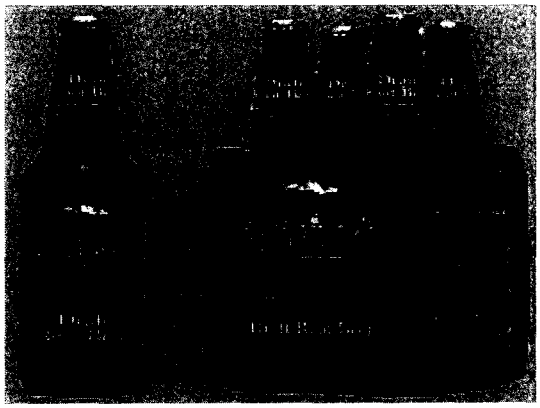
Chai Cola

OUR MICRO-BREW PROCESS

STORE LOCATOR

Draft Root Beer

Natural Brew® Draft Root Beer is brewed in small batches with the finest natural ingredients, including sweet birch, licorice root, sarsaparilla, and - for an unexpectedly rich and creamy flavor - pure vanilla.



> Where to Buy

Nutrition Facts

Serving Size: one bottle
Calories: 170

AMOUNT/SERVING	%DV*
Total Fat 0g	0%
Sodium 10mg	0%
Carbohydrate 43g	14%
Sugar 41g	
Protein 0g	

Not a significant source of other nutrients.
*Percent Daily Values (DV) are based on a 2,000 caloriet diet.

INGREDIENTS

SPARKLING FILTERED WATER, SUGAR, NATURAL FLAVORS, BOURBON VANILLA EXTRACT, ANISE, LICORICE ROOT, BIRCH OIL, WINTERGREEN OIL, CARAMEL COLOR, PHOSPHORIC ACID.

EXHIBIT B

Draft Root Beer

Outrageous Ginger Ale

Vanilla Creme Soda

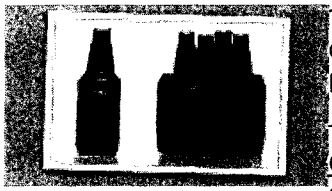
Chai Cola

WHY WE BREW WHAT WE DO...

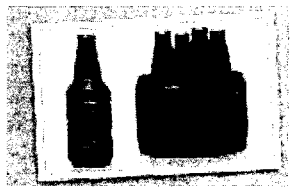
Born in the summer of 1994, **Natural Brew®** was specially formulated to meet the consumer's need for a quality-crafted, natural carbonated beverage. We make **Natural Brew** using old-fashioned micro-brewing techniques to bring out the robust flavor of all key ingredients.
Unlike most other soft drink companies, **Natural Brew** is brewed in small batches allowing the ingredients to blend together forming a full, rich flavor, free from any artificial additives or preservatives.

FOUR FLAVORS, ENDLESS ENJOYMENT

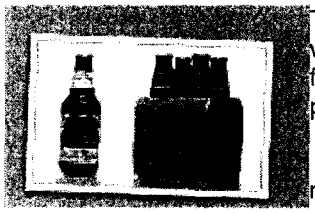
Natural Brew® offers unique flavors and sensations from our premium selection.



The **Draft Root Beer** is made from a complex recipe that combines vanilla, anise, sarsaparilla, licorice root, birch, and a proprietary blend of other natural flavors.



The slow-brewed **Outrageous Ginger Ale** is made from premium ginger root for a crisp bite and is combined with natural ginger flavor for a complex, robust flavor. Each small batch is produced to exacting specifications for consistent quality and flavor.



The **Vanilla Creme Soda** is a delicious, creamy treat made with bourbon vanilla extract, which offers an unmatched, rich flavor. The high quality vanilla beans we use are boiled and pressed into vanilla - a vanilla you are sure to rememeber.

Chai is the Hindi word for "tea," a centuries-old beverage often mixed with a complex blend of spices.By using only the finest natural ingredients, **Natural Brew** **Chai Cola** offers a spicy, aromatic pleasure accompanied by a unique and refreshing taste.

About the J.M. Smucker Company

For more than 115 years, The J.M. Smucker Company has been committed to offering consumers quality products that bring families together to share memorable meals and moments. Today, Smucker is a leading marketer and manufacturer of fruit spreads, retail packaged coffee, peanut butter, shortening and oils, ice cream toppings, sweetened condensed milk, and natural foods

products in North America. Its family of brands includes Smucker's®, Folgers®, Dunkin' Donuts®, Jif®, Crisco®, Pillsbury®, Eagle Brand®, R.W. Knudsen Family®, Hungry Jack®, Café Bustelo®, Café Pilon®, truRoots®, White Lily® and Martha White® in the United States, along with Robin Hood®, Five Roses®, Carnation® and Bick's® in Canada. The Company remains rooted in the Basic Beliefs of Quality, People, Ethics, Growth and Independence established by its founder and namesake more than a century ago. For more information about the Company, visit www.jmsmucker.com.

The J.M. Smucker Company is the owner of all trademarks referenced herein, except for the following, which are used under license: Pillsbury® is a trademark of The Pillsbury Company, LLC; Carnation® is a trademark of Societe des Produits Nestle S.A.; and Dunkin' Donuts® is a registered trademark of DD IP Holder LLC.

Dunkin' Donuts® brand is licensed to The J.M. Smucker Company for packaged coffee products sold in retail channels such as grocery stores, mass merchandisers, club stores, and drug stores. This information does not pertain to Dunkin' Donuts® coffee or other products for sale in Dunkin' Donuts® restaurants.

EXHIBIT C

Naturally

Intro to Our Process...

1. Quality Ingredients
2. Traditional Methods
3. Natural Sweeteners
4. Small Batch Brewing
5. Better Bottles
6. Shipping to You!

Our Process

We chose the name **Natural Brew®** to reflect the hand-crafted, premium nature of our products. Far from the typical options, our sodas are lovingly brewed in small batches from high-quality natural and organic ingredients, using time-honored traditional methods.

The results are old-fashioned, robust flavors that you might remember from your childhood, and that you'll definitely crave for the rest of your life.

QUALITY INGREDIENTS

EXHIBIT D

Naturally

Intro to Our Process...

1. Quality Ingredients
2. Traditional Methods
3. Natural Sweeteners
4. Small Batch Brewing
5. Better Bottles
6. Shipping to You!

Step-2 Simple process, complex flavor

We utilize traditional brewing methods that have been perfected over centuries. These simple processes allow the true essences of the ingredients to stand out, creating an honest and bold flavor experience in [illegible] bottle.

The flavor essences are then carefully blended with other natural ingredients to give our flavors [illegible] bottle. That intensity of flavor only comes from creating the best [illegible] ingredients using time-honored [illegible] methods.

NEXT STEP NATURAL SWEETENERS

EXHIBIT E

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

About FDA

What is the meaning of 'natural' on the label of food?

From a food science perspective, it is difficult to define a food product that is 'natural' because the food has probably been processed and is no longer the product of the earth. That said, FDA has not developed a definition for use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.

Show all related FDA Basics Questions

How helpful was this information?

1 ○ **2** ○ **3** ○ **4** ○ **5** ○

Not Helpful ——————————→ **Very Helpful**

Please let us know why you chose the rating above so we can continue to improve these questions

Please limit your feedback to 1000 characters.

What other questions and answers would you like to see featured?

Please limit your feedback to 1000 characters.

To prevent the submission of spam, please enter the word FOOD in the box below.

Submit

If you would like to ask a specific question, please visit our "Contact Us[26]" page for more information about how to contact FDA.

Please note that any information you submit may become public or subject to release under the Freedom of Information Act (FOIA). For more information, read about our privacy policies[27] and the FOIA[28].

Page Last Updated: 04/04/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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

Links on this page:

1. /AboutFDA/Transparency/Basics/ucm194330.htm
2. /AboutFDA/Transparency/Basics/ucm214869.htm
3. /AboutFDA/Transparency/Basics/ucm210073.htm
4. /AboutFDA/Transparency/Basics/ucm204717.htm
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8. /AboutFDA/Transparency/Basics/ucm214870.htm
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10. /AboutFDA/Transparency/Basics/ucm214867.htm
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25. /AboutFDA/Transparency/Basics/ucm194302.htm
26. /AboutFDA/ContactFDA/default.htm
27. /AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm
28. /RegulatoryInformation/FOI/default.htm

EXHIBIT F

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 6, 2014

The Honorable Yvonne Gonzalez Rogers
United States District Court
Northern District of California
1301 Clay St., Suite 400S
Oakland, CA 94612-5212

The Honorable Jeffrey S. White
United States District Court
Northern District of California
450 Golden Gate Avenue, Box 36060
San Francisco, CA 94102-3489

The Honorable Kevin McNulty
United States District Court
District of New Jersey
Frank R. Lautenberg U.S. Post Office and Courthouse
2 Federal Square
Newark, NJ 07101-0999

Re: Referrals to the United States Food and Drug Administration in *Cox v. Gruma Corp.*, No. 4:12-cv-6502-YGR (N.D. Cal.), *Barnes v. Campbell Soup Co.*, No. 3:12-cv-05185-JSW (N.D. Cal.), and *In Re General Mills, Inc. Kix Cereal Litigation*, No. 2:12-cv-00249-KM-MCA (D.N.J.)

Dear Judges Gonzalez Rogers, White, and McNulty:

This letter responds to your Orders issued on July 11, July 25, and November 1, 2013, respectively, in the above-referenced cases, which referred the question of whether food products containing ingredients produced using bioengineered ingredients may be labeled "Natural" or "All Natural" or "100% Natural" to the Food and Drug Administration ("FDA" or "agency") for an administrative determination under 21 C.F.R. § 10.25(c). In those cases, the plaintiffs allege that the "Natural," "All Natural," and/or "100% Natural" labeling on the Defendants' products are misleading because the products contain corn grown from bioengineered, genetically modified seeds. The *Cox* and *Barnes* cases were stayed for six months with the potential for a further extension; the *Kix Cereal Litigation* was administratively terminated pending FDA's response to the referrals.

FDA has not promulgated a formal definition of the term "natural" with respect to foods. The agency has, however, stated that its policy regarding the use of the term "natural" on food labeling means that "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." *See* 58 Fed. Reg. 2302, 2407 (1993).

If FDA were inclined to revoke, amend, or add to this policy, we would likely embark on a public process, such as issuing a regulation or formal guidance, in order to determine whether to make such a change; we would not do so in the context of litigation between private parties. Issuance of a regulation or guidance document allows an agency to obtain data, information, and views from all stakeholders wishing to engage on an issue. Here, given the complexities of the current request, including the competing concerns among and between stakeholders (e.g., various consumer organizations, diverse industry segments), it would be prudent and consistent with FDA's commitment to the principles of openness and transparency to engage the public on this issue.

We note that defining the term "natural" on food labeling necessarily involves interests of Federal agencies other than FDA, including the United States Department of Agriculture ("USDA"), as well as competing views on the part of stakeholders. FDA has discussed the complexities of such a definition with USDA and both agencies have been considering the issue. Any definition of "natural" on food labeling has implications well beyond the narrow scope of genetically engineered food ingredients about which the Court's referral pertains. For example, if the agencies were to define the term, they would likely need to consider among other things: relevant science; consumer preferences, perceptions, and beliefs; the vast array of modern food production technologies in addition to genetic engineering (e.g., use of different types of fertilizer, growth promotion drugs, animal husbandry methods); the myriad food processing methods (e.g., nanotechnology, thermal technologies, pasteurization, irradiation); and any strictures flowing from the First Amendment. Thus, even if we were to embark on a public process to define "natural" in the context of food labeling, there is no assurance that we would revoke, amend, or add to the current policy, or develop any definition at all. [1]

At present, priority food public health and safety matters are largely occupying the limited resources that FDA has to address foods matters. These matters include developing food safety regulations that implement the FDA Food Safety Modernization Act of 2011, many of which have statutory and/or court-ordered deadlines; issuing nutrition labeling regulations, including regulations that implement the Patient Protection and Affordable Care Act of 2010; other actions with direct public health impact (such as addressing the legal status of partially hydrogenated oils); and numerous other matters, such as responding to outbreaks of food-borne illness and overseeing the safety of imported foods. Because, especially in the foods arena, FDA operates in a world of limited resources, we necessarily must prioritize which issues to address.

[1] FDA was notified by letter dated December 5, 2013, that the Grocery Manufacturers Association ("GMA") intends to file a citizen petition early in 2014 asking FDA to "issue a regulation authorizing foods containing ingredients derived from biotechnology to be labeled 'natural.'" For all of the reasons set forth previously, we believe that, if the agency were to decide to examine this policy question, the public would be better served if the agency used its administrative processes, rather than providing a response in the context of private litigation on the issue.

Based on the foregoing considerations, we respectfully decline to make a determination at this time regarding whether and under what circumstances food products containing ingredients produced using genetically engineered ingredients may or may not be labeled "natural."

Sincerely,

Leslie Kux
Assistant Commissioner for Policy

cc: The Honorable Madeline Cox Arleo
United States District Court for the District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street Room 4015
Newark, NJ 07101

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301 Carnegie Center, 3rd Floor
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EXHIBIT G

CHRONIC TOXICITY SUMMARY

PHOSPHORIC ACID

(Orthophosphoric acid)

CAS Registry Number: 7664-38-2

I. Chronic Toxicity Summary

Inhalation reference exposure level	**7 µg/m^3**
Critical effect(s)	Bronchiolar fibrosis of the respiratory tract in rats
Hazard index target(s)	Respiratory system

II. Chemical Property Summary (HSDB, 1995; 1999)

Description	Clear syrupy liquid or unstable crystals; odorless
Molecular formula	H_3PO_4
Molecular weight	98
Boiling point	213°C
Melting point	42.35°C
Vapor pressure	0.03 torr @ 20°C
Solubility	Very soluble in hot water; 548 g/100 ml cold water; soluble in alcohol
Conversion factor	4.0 µg/m^3 per ppb at 25°C

III. Major Uses and Sources

Phosphoric acid has varied uses (HSDB, 1995). In manufacturing, it is a chemical intermediate or reagent in the production of numerous phosphate fertilizers, agricultural feeds, waxes, polishes, soaps, and detergents. It is added to foods as a preservative, acidifying agent, flavor enhancer, and clarifying agent. Phosphoric acid is also used in processes such as the coagulation of rubber latex, electropolishing, soil stabilization, and as a catalyst in the production of propylene and butene polymers, ethylbenzene, and cumene. By far, largest use of phosphoric acid comes in the production of fertilizers (>75%). The annual statewide industrial emissions from facilities reporting under the Air Toxics Hot Spots Act in California, based on the most recent inventory, were estimated to be 81,103 pounds of phosphoric acid (CARB, 1999).

Airborne phosphoric acid can be produced by the hydrolysis of phosphorus oxides generated from either the spontaneous ignition of white phosphorus in air or the combustion of red phosphorus (Burton *et al.*, 1982; US Department of Defense (US DOD), 1981).

IV. Effects of Human Exposures

The toxic effects to 48 workers exposed (28 unexposed control workers) to oxidation products of phosphorus during the course of phosphorus production were reported (Hughes *et al.*, 1962). Exposure duration ranged from 1 to 17 years. No differences were observed between exposed and control workers with respect to leukocyte count, an effect observed in acute intoxications, or hand bone density, an effect observed in experimentally exposed animals (Inuzuka, 1956).

A prospective study of 131 workers exposed to several compounds including phosphoric acid, phosphorus pentoxide, fluorides and coal tar pitch in the air was conducted at an industrial refinery (Dutton *et al.*, 1993). Mean duration of exposure (employment) was 11.4 years and the maximum exposure level measured was 2.23 mg/m^3 (phosphorus pentoxide). Pulmonary function tests were performed annually over a 3 to 7 year period. No significant residual effect was found after adjusting for age and smoking status.

V. Effects of Animal Exposures

Two 13-week inhalation studies of the effects of exposure to the combustion products of 95% red phosphorus and 5% butyl rubber were conducted in male Sprague-Dawley rats, with the first group exposed to 0, 300, 750, or 1200 mg/m^3 combustion products, and the second exposed to 0, 50, 180, or 300 mg/m^3 combustion products (Aranyi *et al.*, 1988a; Aranyi *et al.*, 1988b). Group numbers in the first study were 176, 84, 176, and 176, respectively. The second study used 40 animals/group. Animals were exposed for 2¼ hours/day on 4 consecutive days/week. Control animals were exposed to filtered air only. Daily particle measurements showed MMADs of 0.49-0.65 μm and σ_gs of 1.56-1.83. Fractional content of phosphoric acid in the aerosol was 71-79%. Nineteen of the 176 animals in the 1200 mg/m^3 dose group died of treatment related effects. Post-mortem examination of animals that died during the course of the study showed damage to the laryngeal mucosa, which was probably contributory to mortality. The two highest dose groups in the first study also showed decreased weight gain. Twelve animals from each dose group in the first study were examined histologically and neurobehavioral studies were conducted on other animals. Half the animals in the second study were examined strictly for toxic effects on the respiratory tract, with examination of the trachea, 2 sections of the nasal turbinates, and 5 lobes of the lung. Surviving animals in the high-dose study were observed to have moderate to severe fibrosis of the terminal bronchioles, with minimal severity of this effect in the animals in the low-dose study. The reported incidence of this lesion was 9/20 at 300 mg/m^3, 4/20 at 180 mg/m^3, and 0/20 at 50 mg/m^3. Little to no involvement of pulmonary tissue was observed.

The effects of acid aerosols (particularly sulfuric and phosphoric acid) were studied by U.S. EPA (1989). The respiratory tract was the primary target of toxicity resulting from the irritational effect of the acid on the tissues of the larynx and trachea. The nature of the effect was dependent upon the aerosol particle size, duration of exposure, and the hygroscopic character of the acid.

Sprague-Dawley rats were exposed to the smoke and combustion products of white phosphorus in felt pellets at 192.5 (18 animals/sex), 589 (24 animals/sex), or 1161 mg/m^3 (34 males, 43 females) phosphoric acid equivalents for 15 minutes/day, 5 days/week, for 13 weeks (US Department of Defense (US DOD), 1981). Control animals numbering half the size of the treated groups were exposed to air only. Groups of animals were sacrificed at 6 and 13 weeks, and 4 weeks post-exposure. Endpoints examined included: hematology, clinical chemistry, gross- and histo-pathology, ECG, pulmonary function, and behavior. Of the animals in the highest dose group, 56% died as a result of exposure, with the only other death occurring in the control group. Findings were restricted to effects on the respiratory system, with tracheitis and laryngitis incidences of 2/35, 32/47, and 28/31among surviving animals in the three dose groups. In the post-exposure examination, bronchiolitis occurred with a frequency of 0/12, 5/24, and 6/16in the three dose groups.

The toxicity of the combustion products of 95% amorphous red phosphorus and 5% polyvinyl butyral BL18 to female Wistar rats, Porton-strain mice, and guinea pigs was reported (Marrs *et al.*, 1989). Rats (50/group), mice (100/group), and guinea pigs (42-48/group) were exposed to concentrations of 0, 16, or 128 mg/m^3 for 1 hour/day, 5 days/week for 36 weeks (mice) or 40 weeks (rats and guinea pigs), with an examination conducted at 19 months or when animals appeared unhealthy. All groups, including controls, showed high mortality. Mice showed accumulation of alveolar macrophages with incidences of 2/41, 9/37, and 9/22 in the control, low-, and high-dose groups, respectively. Guinea pigs appeared to be particularly intolerant to the effects of the smoke.

Female rabbits and rats (10/group) were examined for acute toxic effects of smoke generated by the combustion of either 95% red phosphorus / 5% butyl rubber (Smoke I) or 97% red phosphorus / 3% butadiene styrene (Smoke II) (Marrs, 1984). Animals were exposed for 30 minutes and examined one and 14 days later. Smoke I produced inflammation of the larynx and trachea in rats at 1 day with some inflammation still observed at 14 days. Tracheal inflammation was also reported in rabbits exposed to Smoke I. Four of the rats exposed to Smoke II died within the first day, with severe pulmonary congestion observed in the animals.

One hour exposure to the combustion products of 95% red phosphorus / 5% butyl rubber (plus 1% mineral oil) produced epiglottal deformation, laryngeal edema, and laryngeal and tracheal lesions in rats (Burton *et al.*, 1982). A four-hour exposure produced more severe effects of a similar nature plus some hemorrhaging.

Rats (number unspecified) exposed to 150-160 mg/m^3 elemental phosphorus for 30 minutes/day for 60 days were examined for toxic effects (Inuzuka, 1956). Limb bone abnormalities were noted and effects included delayed ossification, widening of the epiphysis, and abnormal axial development.

Two studies have addressed the reproductive and developmental toxicity from exposure to the combustion products of white phosphorus and felt for 15 minutes/day during gestational days 6-15 in rats (24/group) (US Department of Defense (US DOD), 1981; US Department of Defense (US DOD), 1982). Fetal effects included increased incidence of some visceral variations and hypoplasia of the xiphoid process although data were incompletely reported. Another study,

which exposed dams 3 weeks prior to mating, throughout gestation, and through lactation and males for 10 weeks prior to and during mating, showed decreased pup body weight, 24-hour and 21-day survival, and lactation. An oral study in which elemental phosphorus was administered to male and female rats by gavage in corn oil showed no statistically significant effects (Condray, 1985).

VI. Derivation of the Chronic Reference Exposure Level

Study	Aranyi *et al.*, 1988a
Study population	Male Sprague-Dawley rats (40-176/group)
Exposure method	Discontinuous whole body inhalation
Critical effects	Bronchiolar fibrosis of the respiratory tract
LOAEL	180 mg/m^3
NOAEL	50 mg/m^3
BMC_{05}	64 mg/m^3
Exposure continuity	2¼ hours/day, 4 days/week
Exposure duration	13 weeks
Average experimental exposure	2.7 mg/m^3 for NOAEL group (estimated as 3.5 mg/m^3 at BMC_{05})
Human equivalent concentration	2.2 mg/m^3 at BMC_{05} (particle with respiratory effects, RDDR = 0.63) (3.5 x 0.63)
LOAEL uncertainty factor	1 (BMC_{05} assumed to be similar to NOAEL)
Subchronic uncertainty factor	10
Interspecies uncertainty factor	3
Intraspecies uncertainty factor	10
Cumulative uncertainty factor	300
Reference exposure level	0.007 mg/m^3 (7 $\mu g/m^3$)

OEHHA has used the same study, which U.S. EPA used in the development of its Reference Concentration (RfC) of 10 $\mu g/m^3$. The U.S. EPA has used a benchmark dose methodology for the derivation of the RfC for phosphoric acid from the toxicity data in the Aranyi *et al.* (1988) study (U.S. EPA, 1995). The RfC is restricted to "aerosols of phosphoric acid and phosphorus oxidation products and does not apply to elemental phosphorus or other forms of phosphorus, such as phosphorus salts".

The U.S. EPA, using the Weibull model, estimated the lower 95% confidence level bound on the maximum likelihood estimate (MLE = 150 mg/m^3) resulting in 10% incidence of lesions in the tracheo-bronchiolar region to be 100 mg/m^3 (the BMC_{10}). The U.S. EPA considered 10% incidence level to be a correlate to the NOAEL, based on a precedent in the analysis of data with developmental toxicity endpoints (Allen *et al.*, 1994; Faustman *et al.*, 1994). After correction for exposure continuity, a regional deposited dose ratio (RDDR) for the tracheobronchial region of 0.64 was applied due to the availability of data concerning the growth and deposition of phosphoric acid aerosol particles in humans and the similarities in the effects of phosphoric and better-characterized sulfuric acid aerosols. Key assumptions in the generation of this factor include: (1) the lowest σ_g of 1.56 μm cited in the study was used in the calculation; (2) geometric

rather than aerodynamic diameter approximations were used; (3) particles of this size reach the deposition / lesion site (bronchioles); 4) these hygroscopic particles become more uniform with growth; and (5) particle growth is similar in humans and rodents. An uncertainty factor of 10 was applied because of the subchronic duration of the study. A factor of 3 was applied for interspecies extrapolation in light of the fact that some correction for human equivalency was made with the RDDR. Finally, a factor of 10 was applied for protection of potentially sensitive human subpopulations. The resulting RfC for phosphoric acid is 0.01 mg/m^3.

OEHHA uses a BMC_{05} for development of acute Reference Exposure Levels (OEHHA, 1999; Fowles *et al.*, 1999). OEHHA staff believe that the BMC_{05} is more likely to approximate a NOAEL than a BMC_{10} since 5% is closer than 10% to the lower end of average risk levels associated with a NOAEL (Leisenring and Ryan, 1992). A BMC_{05} is more likely to represent a value close to the limit of most studies to detect an effect, and is therefore more like a NOAEL. In contrast, a BMC_{10} is more likely to represent a LOAEL since it is usually in the detectable range of responses. In the specific case of phosphoric acid the BMC_{10} of 100 mg/m^3 was twice the NOAEL of 50 mg/m^3. The BMC_{05} was calculated to be 64 mg/m^3, much closer to the NOAEL. Use of the BMC_{05} results in a chronic REL of 7 $\mu g/m^3$.

VII. Data Strengths and Limitations for Development of the REL

The strengths of the inhalation REL for phosphoric acid include the availability of subchronic inhalation exposure data from a well-conducted study with histopathological analysis and the observation of a NOAEL. Major areas of uncertainty are the lack of adequate human exposure data, the lack of chronic inhalation exposure studies, and the discontinuous nature of exposures (only 2 1/4 hours per day).

The Aranyi *et al.* (1988a) study represents the most adequate study for the quantitative evaluation of the toxicity of phosphoric acid. It was conducted with a large number of animals with multiple doses, produced good dose-response data, and examined likely targets of toxicity (respiratory system) of smoke generated from the combustion of phosphorus and butyl rubber. Uncertainties associated with these data, however, include that (1) the study used combustion products of phosphorus rather than phosphoric acid itself, (2) the total exposure time was relatively short and discontinuous over the duration of the experiment, and (3) only one species/strain/sex was studied.

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EXHIBIT H

National Toxicology Program
U.S. Department of Health and Human Services

http://ntp.niehs.nih.gov/go/13651

Abstract for TR-535 - 4-Methylimidazole (CASRN 822-36-6)

Toxicology and Carcinogenesis Studies of 4-Methylimidazole (CAS No. 822-36-6) in F344/N Rats and B6C3F$_1$ Mice (Feed Studies)

Link to the full study report in PDF. If you have difficulty accessing the document, please send email to the NTP Webmaster [Send Email] and identify documents/pages for which access is required.

Chemical Formula: $C_4H_6N_2$ - **Molecular Weight:** 82.11

4-Methylimidazole is used in the manufacture of pharmaceuticals, photographic chemicals, dyes and pigments, cleaning and agricultural chemicals, and rubber. It has been identified as a by-product of fermentation in foods and has been detected in mainstream and sidestream tobacco smoke. 4-Methylimidazole was nominated by the National Cancer Institute for a long-term study because of the high potential for human exposure. Male and female F344/N rats and B6C3F$_1$ mice were exposed to 4-methylimidazole (99.5% pure) in feed for 2 years. Fifteen-day and 14-week toxicity studies of 4-methylimidazole in F344/N rats and B6C3F$_1$ mice are reported in NTP Toxicity Report No. 67. Genetic toxicology studies were conducted in *Salmonella typhimurium*, rat and mouse bone marrow cells, and mouse peripheral blood.

2-YEAR STUDY IN RATS

Groups of 50 male and 50 female rats were fed diets containing 0, 625, 1,250, or 2,500 ppm 4-methylimidazole (males) or 0, 1,250, 2,500, or 5,000 ppm 4-methylimidazole (females) (equivalent to average daily doses of approximately 30, 55, or 115 mg 4-methylimidazole/kg body weight to males and 60, 120, or 260 mg/kg to females) for 106 weeks. Survival of all exposed groups of male and female rats was similar to that of the control groups. Mean body weights of males in the 1,250 and 2,500 ppm groups and females in the 2,500 and 5,000 ppm groups were less than those of the control groups throughout the study; mean body weights of 1,250 ppm females were less after week 41. Feed consumption by 5,000 ppm females was less than that by the controls. Clonic seizures, excitability, hyperactivity, and impaired gait were observed primarily in 2,500 and 5,000 ppm females.

The incidence of mononuclear cell leukemia in 5,000 ppm females was significantly greater than that in the controls, and the incidence exceeded the historical range in feed study controls. The incidences of hepatic histiocytosis, chronic inflammation, and focal fatty change were generally significantly increased in all exposed groups of male and female rats. The incidences of hepatocellular eosinophilic and mixed cell focus were significantly increased in 2,500 ppm males and 5,000 ppm females.

2-YEAR STUDY IN MICE

Groups of 50 male and 50 female mice were fed diets containing 0, 312, 625, or 1,250 ppm 4-methylimidazole (equivalent to average daily doses of approximately 40, 80, and 170 mg 4-methylimidazole/kg body weight to males and females) for 106 weeks. Survival of all exposed groups of male and female mice was similar to that of the control groups. Mean body weights of males and females in the 1,250 ppm groups were less than those of the control groups after weeks 17 and 12, respectively. Mean body weights of 312 and 625 ppm females were less after weeks 85 and 65, respectively. Feed consumption by exposed groups of male and female mice was generally similar to that by the controls.

The incidences of alveolar/bronchiolar adenoma in all exposed groups of females, alveolar/bronchiolar carcinoma in 1,250 ppm males, and alveolar/bronchiolar adenoma or carcinoma (combined) in 1,250 ppm males and 625 and 1,250 ppm females were significantly greater than those in the control groups. The incidence of alveolar epithelium hyperplasia was significantly increased in 1,250 ppm females.

GENETIC TOXICOLOGY

4-Methylimidazole was not mutagenic in the *S. typhimurium* mutation assay when tested in strains TA97, TA98, TA100, and TA1535, with and without hamster or rat liver metabolic activation enzymes. No consistent or significant increases in the frequencies of micronucleated erythrocytes were seen in the bone marrow of male rats or mice treated with 4-methylimidazole by intraperitoneal injection, or in peripheral blood samples from male and female mice administered the compound in dosed feed for 14 weeks.

CONCLUSIONS

Under the conditions of these 2-year studies, there was *no evidence of carcinogenic activity* of 4-methylimidazole in male F344/N rats exposed to 625, 1,250, or 2,500 ppm. There was *equivocal evidence of carcinogenic activity* of 4-methylimidazole in female F344/N rats based on increased incidences of mononuclear cell leukemia. There was *clear evidence of carcinogenic activity* of 4-methylimidazole in male and female B6C3F_1 mice based on increased incidences of alveolar/bronchiolar neoplasms.

Exposure to 4-methylimidazole resulted in nonneoplastic lesions in the liver of male and female rats and the lung of female mice and in clinical findings of neurotoxicity in female rats.

Synonyms: 1H-Imidazole, 4-methyl (9Cl); imidazole, 4-methyl; 4(5)-methylglyoxaline; 4(5),4(5)-methylimidazole; 5-methylimidazole
Trade name: 4-MeI

Summary of the 2-Year Carcinogenesis and Genetic Toxicology Studies of 4-Methylimidazole

	Male F344/N Rats	Female F344/N Rats	Male B6C3F_1 Mice	Female B6C3F_1 Mice
Concentrations in feed	0, 625, 1,250, or 2,500 ppm	0, 1,250, 2,500, or 5,000 ppm	0, 312, 625, or 1,250 ppm	0, 312, 625, or 1,250 ppm
Body weights	1,250 and 2,500 ppm groups less	1,250, 2,500, and 5,000 ppm groups	1,250 ppm group less than the control group	625 and 1,250 ppm groups less than the control group

	than the control group	less than the control group		
Survival rates	31/50, 34/50, 33/50, 32/50	43/50, 39/50, 34/50, 35/50	45/50, 44/50, 42/50, 46/50	43/50, 40/50, 43/50, 40/50
Nonneoplastic effects	Liver: histiocytosis (38/50, 45/50, 50/50, 50/50); chronic inflammation (18/50, 32/50, 31/50, 36/50); hepatocyte, focal fatty change (21/50, 24/50, 37/50, 33/50); eosinophilic focus (4/50, 3/50, 7/50, 12/50); mixed cell focus (5/50, 7/50, 11/50, 27/50)	Liver: histiocytosis (40/50, 50/50, 48/48, 50/50); chronic inflammation (17/50, 28/50, 34/48, 35/50); hepatocyte, focal fatty change (16/50, 29/50, 29/48, 32/50); eosinophilic focus (1/50, 2/50, 5/48, 11/50); mixed cell focus (10/50, 7/50, 6/48, 18/50)	None	Lung: alveolar epithelium hyperplasia (3/50, 2/50, 3/50, 11/50)
Neoplastic effects	None	None	Lung: alveolar/bronchiolar carcinoma (2/50, 4/50, 4/50, 8/50); alveolar/bronchiolar adenoma or carcinoma (combined) (9/50, 13/50, 16/50, 22/50)	Lung: alveolar/bronchiolar adenoma (0/50, 8/50, 16/50, 8/50); alveolar/bronchiolar carcinoma (3/50, 0/50, 2/50, 7/50); alveolar/bronchiolar adenoma or carcinoma (combined) (3/50, 8/50, 17/50, 14/50)
Equivocal findings	None	Monoluclear	None	None

10/50, 20/50)

		cell leukemia: (9/50, 7/50, 16/50, 20/50)		
Level of evidence of carcinogenic activity	No evidence	Equivocal evidence	Clear evidence	Clear evidence
Genetic toxicology				
Salmonella typhimurium gene mutations:	Negative in strains TA97, TA98, TA100, and TA1535 with and without S9			
Micronucleated erythrocytes				
Rat bone marrow *in vivo*	Negative when administered by intraperitoneal injection			
Mouse marrow *in vivo*:	Negative when administered by intraperitoneal injection			
Mouse peripheral blood *in vivo*:	Negative in males and females			

Report Date: January 2007

Pathology Tables, Survival and Growth Curves from NTP 2-year Studies

Target Organs & Incidences from 2-year Studies

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