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United States District Court
Southern District of New York

1:20-cv-04936

William Marsella, Robert Paterson, individually and on behalf of all others similarly situated,

Plaintiffs,

- against -

The Hain Celestial Group, Inc.,

Defendant

Class Action Complaint

Plaintiffs by attorneys allege upon information and belief, except for allegations pertaining to plaintiffs, which are based on personal knowledge:

1. The Hain Celestial Group, Inc. ("defendant") manufactures, distributes, markets, labels and sells organic vanilla soymilk with added nutrients under the Westsoy brand labeled as Organic Plus Vanilla Soymilk ("Product").

2. The Product is available to consumers from retail and online stores of third-parties and is sold in cartons of 32 OZ and 64 OZ.

3. The relevant front label representations include "Westsoy," "Organic Plus," "Vanilla," "Soymilk," "American Heart Association Certified, Meets Criteria for Heart-Healthy Food," and "With Vitamins A, E & D & Calcium."

4. The representations are misleading because the front label and ingredient list fail to disclose artificial flavors and the ingredient list conceals the addition of sugar through misleading terms.

5. Today's consumers are especially attentive to the foods and beverages they consume.

6. 62% of consumers surveyed by Nielsen say they try to avoid artificial flavors.[3]

[3] Nielsen, Reaching For Real Ingredients: Avoiding The Artificial, Sept. 6, 2016.

7. Another study by New Hope Network concludes that "71% of consumers today are avoiding artificial flavors."[4]

8. Label Insight, a marketing company focused on consumer products, determined that 76% of consumers avoid products with artificial flavors.[5]

I. "Vanilla" Without Qualification Tells Consumers All of Product's Flavor and Vanilla Taste is from Vanilla Beans

9. If a product makes a representation as to its primary flavor, the common or usual name is required to designate the source and amount of flavor in a specific way so that consumers will not be misled:

> If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor…
>
> 21 C.F.R. § 101.22(i)(1).

10. These regulations have been adopted in their entirety and without modification by New York State, through the regulations accompanying N.Y. AGM Article 17:

> the commissioner hereby adopts the current regulations as they appear in title 21 of the Code of Federal Regulations (revised as of April 1, 2013; U.S. Government Printing Office, Washington, DC 20402), in the area of food packaging and labeling as follows…(3) Part 101 of title 21 of the Code of Federal Regulations, containing the Federal definitions and standards for Food Labeling (including Appendices) at pages 10-172.
>
> 1 NYCRR 259.1(a)(3) contained in Section 259.1 ("Packaging and labeling of food.")

11. Vanilla products are the only flavorings subject to standards of identity. *See* 21 C.F.R. Part 169 ("Food dressings and flavorings"); 21 C.F.R. §169.3 ("Definitions"); 21 C.F.R. §

[4] Alex Smolokoff, Natural color and flavor trends in food and beverage, Natural Products Insider, Oct. 11, 2019.
[5] Thea Bourianne, Exploring today's top ingredient trends and how they fit into our health-conscious world, March 26-28, 2018.

169.175 – 21 C.F.R. § 169.182 (vanilla products); *see also* 1 NYCRR § 250.1(a)(17) ("the commissioner hereby adopts the following as the standards of identity and/or standards of quality, and tolerances for food and food products as published in title 21 of the Code of Federal Regulations…21 CFR part 169, containing the Federal definitions and standards for *Food Dressings and Flavorings* at pages 600-606.") (italics in original).[27]

12. Federal regulations require that a food which is not subject to a standard of identity is required to bear a "common or usual name of a food" which "accurately identif[ies] or describe[s], in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients." *See* 21 C.F.R. § 102.5(a).

13. The "common or usual name" requirement is incorporated in its entirety and without modification through the regulations accompanying N.Y. AGM Article 17:

> the commissioner hereby adopts the current regulations as they appear in title 21 of the Code of Federal Regulations (revised as of April 1, 2013; U.S. Government Printing Office, Washington, DC 20402), in the area of food packaging and labeling as follows…(4) Part 102 of title 21 of the *Code of Federal Regulations*, containing the Federal definitions and standards for Common or Usual Name for Nonstandardized Foods at pages 173-180.
>
> 1 NYCRR § 259.1(a)(4), Section 259.1, Packaging and labeling of food, Part 259, Packaging and labeling of food, Subchapter C, Food and Food Products, Chapter VI, Food Control, Title 1.

14. New York State has adopted and incorporated in its entirety, all provisions of the Federal Food, Drug and Cosmetic Act ("FFDCA") through its Agriculture and Markets Law ("AGM") and the accompanying regulations. *See* Title 1, Department of Agriculture and Markets, Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR").

15. If the labeling of organic vanilla soymilk is inconsistent with the federal standards,

[27] 1 NYCRR § 250.1(a)(17), Section 250.1, Foods, Part 250, Definitions and Standards, Subchapter C, Food and Food Products, Chapter VI, Food Control, Title 1.

then it also violates what New York requires.

16. Consumers expect the Product's flavor to be supplied only from the characterizing food ingredient of vanilla beans because (1) the front label lacks qualifiers such as "flavored," "naturally flavored," "artificial flavors" and "with other natural flavors" and (2) vanilla's standard of identity and its consistent usage gives consumers the impression it contains an exclusively vanilla ingredient. *See* 21 C.F.R. § 101.22(i)(1)(i) ("e.g., 'natural strawberry flavored shortcake,' or 'strawberry flavored shortcake'."); 21 C.F.R. § 101.22(i)(1)(ii) and 21 C.F.R. § 101.22(i)(2) ("artificially flavored"); 21 C.F.R. § 101.22(i)(1)(iii) ("with other natural flavor"); *see also* 21 U.S.C. §343(g).

17. Despite the front label, the Product contains artificial flavors and non-vanilla flavors, which provide its vanilla taste, in contrast to the expectation that all of its vanilla taste was provided by vanilla beans.

18. This evident from the ingredient list which designates "Vanilla Flavor With Other Natural Flavors" ("Vanilla WONF").

INGREDIENTS: ORGANIC SOYMILK (FILTERED WATER, WHOLE ORGANIC SOYBEANS), ORGANIC EVAPORATED CANE JUICE, TRICALCIUM PHOSPHATE, POTASSIUM CITRATE, VANILLA FLAVOR WITH OTHER NATURAL FLAVORS, SEA SALT, CARRAGEENAN, MAGNESIUM CHLORIDE, VITAMIN E (D-ALPHA TOCOPHERYL ACETATE), VITAMIN A PALMITATE, VITAMIN D2, VITAMIN B2 (RIBOFLAVIN), VITAMIN B12.

INGREDIENTS: ORGANIC SOYMILK (FILTERED WATER, WHOLE ORGANIC SOYBEANS), ORGANIC EVAPORATED CANE JUICE, TRICALCIUM PHOSPHATE, POTASSIUM CITRATE, VANILLA FLAVOR WITH OTHER NATURAL FLAVORS, SEA SALT, CARRAGEENAN, MAGNESIUM CHLORIDE, VITAMIN E (D-ALPHA TOCOPHERYL ACETATE), VITAMIN A PALMITATE, VITAMIN D2, VITAMIN B2 (RIBOFLAVIN), VITAMIN B12.

19. "Vanilla With Other Natural Flavors" means the Product has some flavor "from the product whose flavor is simulated [vanilla] and other natural flavor [non-vanilla] which simulates, resembles or reinforces the characterizing flavor." *See* 21 C.F.R. § 101.22(i)(1)(iii) ("the food shall

be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words 'with other natural flavor'") ("WONF").

20. However, the Product's front label fails to even disclose the presence of "Other Natural Flavor."

21. Vanilla's standards of identity mean that where a product's primary characterizing flavor is vanilla, the vanilla regulations take precedence over the general flavor regulations and the "WONF" labeling structure. *Compare* 21 C.F.R. § 101.22 with 21 C.F.R. § 169.175-21 C.F.R. § 169.182 (vanilla products).

22. The vanilla standards permit only glycerin, propylene glycol, sugar, dextrose, corn sirup or vanillin to be added to vanilla and control how such combinations should be named. *See* 21 C.F.R. § 169.175(a)(1)-(5) (ingredients permitted for addition to vanilla extract); *see also* 21 C.F.R. § 169.180(a) (permitting "not more than 1 ounce of added vanillin" for "each unit of vanilla constituent, as defined in 169.3(c)" in the combination labeled "Vanilla-vanillin extract.").

23. The purpose of these requirements is to prevent a trace of vanilla from being spiked with artificial vanilla flavors such as vanillin. Exhibit "A," Memorandum of Conference, Status of Vanilla Flavoring with other Natural Flavors, July 8, 1996 ("The vanilla Standard determines vanilla as a standardized product. If other flavorings are added, then the vanilla is no longer a standardized product and should therefore be labeled artificial or imitation.")

24. Defendant's "Other Natural Flavor" contains vanillin, an artificial flavor. *See* Vanilla-vanillin extract at 21 C.F.R. § 169.180(b) ("The specified name of the food is 'Vanilla-vanillin extract _-fold' or '_-fold vanilla-vanillin extract', followed immediately by the statement 'contains vanillin, an artificial flavor (or flavoring)'.").

25. The Product's front label and ingredient list fail to disclose vanillin, an artificial flavor.

26. According to representatives of FEMA:

> The standards for vanilla extract and the other standardized vanilla products at 21 CFR 169 expressly do not provide WONF designation. This means that a flavoring mixture of vanilla extract and vanillin produced through a "natural" process (i.e. a process consistent with the definition of natural flavor at 21 CFR Section 101.22(a)(3)) cannot be described as "vanilla extract WONF," "vanilla WONF" or other similar descriptive terms.
>
> Exhibit B, John B. Hallagan and Joanna Drake, The Flavor and Extract Manufacturers Association of the United States, "Labeling Vanilla Flavorings and Vanilla-Flavored Foods in the U.S.," Perfumer & Flavorist, Vol. 43 at p. 46, Apr. 25, 2018.

27. Including vanillin as part of the "other natural flavors" in the organic vanilla soymilk Product is misleading because, when read with the unqualified front label of "vanilla," it implies that the Product contains only natural flavors and natural vanilla flavors, even though the added vanillin is not derived from vanilla beans.

28. The FDA addressed the issue of labeling products purporting to be flavored with vanilla.

29. A flavor company representative inquired, "when a food or beverage product is marketed (labeled) as (natural) vanilla, does the characterizing (vanilla) flavor have to be derived from vanilla beans and conform to the vanilla standard of identity?"

30. The FDA responded:

> According to our regulation in Title 21 of the Code of Federal Regulations (CFR), section 101.22(i)(l), if a food contains no artificial flavor that simulates, resembles or reinforces the characterizing flavor, the name of the food on the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla."
>
> Exhibit C, FDA, Letter, Cataline Ferré-Hockensmith, August 5, 2008, p. 2.

31. If a product such as defendant's soymilk does not contain artificial flavors, it would

be called “vanilla soymilk” and it should be made from vanilla beans.

32. If defendant’s soymilk “does not contain enough of the characterizing ingredient, vanilla beans, to characterize the food or it does not contain such ingredient, and contains vanilla flavor,” it could be labeled “natural vanilla flavored soymilk” or “vanilla flavored soymilk.”

33. However, the flavors used to make such product must be derived from vanilla beans such as vanilla extract or vanilla flavor that are subject to standards of identity.

34. Products made from vanillin should not be named "vanilla __," e.g., "vanilla ice cream," or "vanilla flavored __ ," e.g., "vanilla flavored ice cream" because these products are not made from vanilla beans or vanilla flavors made from vanilla beans.

35. Defendant’s ingredient listing of “Vanilla With Other Natural Flavors” gives consumers the false impression the Product and its flavoring are natural

36. Though a naturally derived vanillin may be designated “‘natural flavor’” in the context of the general flavor regulations at 21 C.F.R. § 101.22, this is outside the context of the standardized vanilla ingredients “under sections 169.180, 169.181, and 169.182 in 21 CFR.” Exhibit C, FDA, Letter, Cataline Ferré-Hockensmith, August 5, 2008, p. 2.

37. A reasonable consumer cannot follow up or learn the truth that the Product contains non-vanilla artificial vanillin from reading the Product’s ingredient list because defendant labels this incorrectly and deceptively as “Other Natural Flavor” as opposed to “Artificial Flavor.”

II. Product’s Ingredient List Designates “Evaporated Cane Juice,” a Misleading Term for Sugar

38. Consumers expect ingredients on a product to be declared by their common or usual name that describes their basic source, function and properties. *See* 21 C.F.R. § 101.4(a)(1).

39. Where an ingredient contains the term “juice,” consumers expect that ingredient to be derived from a consumable fruit or vegetable.

40. Defendant's Product lists "Evaporated Cane Juice" shown below, retrieved from the Product website on June 26, 2020.[28]

INGREDIENTS: ORGANIC SOYMILK (FILTERED WATER, WHOLE ORGANIC SOYBEANS), ORGANIC EVAPORATED CANE JUICE, TRICALCIUM PHOSPHATE, POTASSIUM CITRATE, VANILLA FLAVOR WITH OTHER NATURAL FLAVORS, SEA SALT, CARRAGEENAN, MAGNESIUM CHLORIDE, VITAMIN E (D-ALPHA TOCOPHERYL ACETATE), VITAMIN A PALMITATE, VITAMIN D2, VITAMIN B2 (RIBOFLAVIN), VITAMIN B12.

41. "Juice" is defined as "the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree."[29]

42. Fruit and vegetable juices are consumed for their nutritive value as they contain many

[28] http://www.westsoymilk.com/products/organic-plus/organic-plus-vanilla/
[29] 21 C.F.R. § 120.1(a).

vitamins and minerals.

43. "Evaporated cane juice" on the Product's label, according to the FDA, "suggest[s] that the ingredients are made from or contain fruit or vegetable "juice" as defined in 21 CFR 120.1."[30]

44. However, defendant's "evaporated cane juice" has little in common with the types of juices that Americans consume because it is another name for the ingredient commonly known as "sugar."

45. The FDA concluded that where an ingredient is described as "evaporated cane juice," consumers can be, and are misled because "cane juice" refers to a sweetener.

46. By hiding "sugar" through a term which fails to truthfully and non-deceptively describe the source, function and qualities of the ingredient, reasonable consumers are deceived into purchasing a product with a greater amount of added sugar.

47. Given that the Product is marketed towards consumers looking to stay healthy, consumers will expect that "evaporated cane juice" bears a relationship to an actual fruit or vegetable source they are familiar with, such as soybeans, the main ingredient in the Product.

48. This results in the impression that the Product is a better nutritional choice than other comparable products which truthfully and non-deceptively identify "sugar" on their ingredient lists.

49. The Product's deceptive labeling is especially egregious because defendant sells products intended to appeal to health-minded consumers.

50. A growing number of consumers, including plaintiffs, are paying more attention to the ingredients contained in the foods they eat and are shunning excess, added sugars due to their

[30] FDA Guidance, Ingredients Declared as Evaporated Cane Juice (May 2016).

association and contribution to ailments and conditions like coronary heart disease, obesity and diabetes.

51. The misleading ingredient name has a material bearing on price and consumer acceptance of the Product because consumers pay more for products with the positive qualities associated with actual juice, including fiber and naturally occurring vitamins and minerals.

III. Conclusion

52. Defendant's branding and packaging of the Product is designed to – and does – deceive, mislead, and defraud plaintiff and consumers.

53. Defendant sold more of the Product and at higher prices than it would have in the absence of this misconduct, resulting in additional profits at the expense of consumers like plaintiff.

54. The value of the Product that plaintiff purchased and consumed was materially less than its value as represented by defendant.

55. Had plaintiff and class members known the truth, they would not have bought the Product or would have paid less for them.

56. As a result of the false and misleading labeling, the Product is sold at a premium price, approximately no less than $2.99 and $4.99 for cartons of 32 OZ and 64 OZ, excluding tax, compared to other similar products represented in a non-misleading way.

Jurisdiction and Venue

57. Jurisdiction is proper pursuant to 28 U.S.C. § 1332(d)(2) (Class Action Fairness Act of 2005 or "CAFA").

58. Under CAFA, district courts have "original federal jurisdiction over class actions involving (1) an aggregate amount in controversy of at least $5,000,000; and (2) minimal

diversity[.]" *Gold v. New York Life Ins. Co.*, 730 F.3d 137, 141 (2d Cir. 2013).

59. Plaintiff William Marsella is a citizen of Florida.

60. Defendant The Hain Celestial Group, Inc. is an Delaware corporation with a principal place of business in New Hyde Park, Nassau County, New York and therefore is a citizen of New York.

61. "Minimal diversity" exists because plaintiff and defendant are citizens of different states.

62. Venue is proper in this judicial district because a substantial part of the events or omissions giving rise to the claim occurred, *viz*, the purchase of the Product and the misleading representations relied upon by plaintiff Paterson.

63. This court has personal jurisdiction over defendant because it conducts and transacts business, contracts to supply and supplies goods within New York.

Parties

64. Plaintiff William Marsella is a citizen of Punta Gorda, Charlotte County, Florida.

65. Plaintiff Robert Paterson is a citizen of New York, New York County, New York.

66. Defendant The Hain Celestial Group, Inc. is a Delaware corporation with a principal place of business in New Hyde Park, New York, Nassau County.

67. During the relevant statutes of limitations, plaintiffs purchased the Product within their district and/or State for personal consumption and/or use in reliance on the representations the Product's flavor contained only vanilla flavoring from vanilla beans and was not enhanced by non-vanilla flavors including artificial flavors.

68. Plaintiff William Marsella bought the Product on multiple occasions, including in April 2020 at Publix, Burnt Store Marketplace, 3941 Tamiami Trl Unit 3145 Punta Gorda, FL 33950.

69. Plaintiff Robert Paterson bought the Product on multiple occasions, including in September 2019 at Whole Foods in the Time Warner Center in Manhattan.

70. Plaintiffs bought the Product because they liked the product type for its intended use and expected it to be flavored only by vanilla beans and not contain artificial flavors and not contain hidden sugar disguised as evaporated cane juice.

71. Plaintiffs would buy the Product again if assured it did not contain artificial vanilla flavor nor added undisclosed sugar.

72. Plaintiffs are unable to rely on the labels of the Products in the future though they want to in order to evaluate the Product for purchase.

Class Allegations

73. The classes will consist of all purchasers of the Product who reside in New York and Florida during the applicable statutes of limitations.

74. Plaintiffs seek to certify injunctive relief class under Rule 23(b).

75. Common questions of law or fact predominate and include whether defendant's representations were and are misleading and if plaintiffs and class members are entitled to damages.

76. Plaintiffs' claims and basis for relief are typical to other members because all were subjected to the same unfair and deceptive representations and actions.

77. Plaintiffs are adequate representatives because their interests do not conflict with other members.

78. No individual inquiry is necessary since the focus is only on defendant's practices and the class is definable and ascertainable.

79. Individual actions would risk inconsistent results, be repetitive and are impractical

to justify, as the claims are modest relative to the scope of the harm.

80. Plaintiffs' counsel is competent and experienced in complex class action litigation and intends to adequately and fairly protect class members' interests.

81. Plaintiffs seek class-wide injunctive relief because the practices continue.

New York General Business Law ("GBL"), §§ 349 & 350,
Florida Statute s. 501.201 et seq. ("FDUPTA") (Consumer Protection Statutes)

82. Plaintiffs incorporate by reference all preceding paragraphs.

83. Plaintiffs and class members desired to purchase and consume products which were as described and marketed by defendant and expected by reasonable consumers, given the product type.

84. Defendant's acts and omissions are not unique to the parties and have a broader impact on the public.

85. Defendant misrepresented the substantive, quality, compositional, organoleptic and/or nutritional attributes of the Product.

86. The amount and proportion of the characterizing component, vanilla, has a material bearing on price and consumer acceptance of the Product and consumers do not expect that non-vanilla, artificial flavors where a product is labeled "vanilla" without more.

87. The ingredient list declaration of evaporated cane juice deceives consumers about the presence of added sugar.

88. Plaintiffs relied on the statements, omissions and representations of defendant, and defendant knew or should have known the falsity of same.

89. Plaintiffs and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Negligent Misrepresentation

90. Plaintiffs incorporate by reference all preceding paragraphs.

91. Defendant misrepresented the substantive, quality, compositional, organoleptic and/or nutritional attributes of the Product.

92. The amount and proportion of the characterizing component, vanilla, has a material bearing on price and consumer acceptance of the Product and consumers do not expect that non-vanilla, artificial flavors where a product is labeled "vanilla" without more.

93. The ingredient list declaration of "natural flavor" fails to tell consumers and plaintiff that a trace amount of vanilla is present and what they taste as vanilla is from artificial flavors.

94. Defendant had a duty to disclose and/or provide non-deceptive marketing of the Product and knew or should have known same were false or misleading.

95. This duty is based on defendant's position as an entity which has held itself out as having special knowledge and experience in the production, service and/or sale of the product type.

96. The representations took advantage of consumers' cognitive shortcuts made at the point-of-sale and their trust in defendant, a well-known and respected brand or entity in this sector.

97. Plaintiffs and class members reasonably and justifiably relied on these negligent misrepresentations and omissions, which served to induce and did induce, the purchase of the Product.

98. Plaintiffs and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Breaches of Express Warranty, Implied Warranty of Merchantability and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*

99. Plaintiffs incorporate by reference all preceding paragraphs.

100. The Product were manufactured, labeled and sold by defendant and warranted to

plaintiffs and class members that they possessed substantive, functional, nutritional, qualitative, compositional, organoleptic, sensory, physical and other attributes which they did not.

101. The amount and proportion of the characterizing component, vanilla, has a material bearing on price and consumer acceptance of the Product and consumers do not expect that non-vanilla, artificial flavors where a product is labeled "vanilla" without more.

102. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.

103. This duty is based, in part, on defendant's position as one of the most recognized companies in the nation in this sector.

104. Plaintiffs provided or will provide notice to defendant, its agents, representatives, retailers and their employees.

105. Defendant received notice and should have been aware of these misrepresentations due to numerous complaints by consumers to its main office over the past several years regarding the Product, of the type described here.

106. The Product did not conform to its affirmations of fact and promises due to defendant's actions and were not merchantable.

107. Plaintiffs and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Fraud

108. Plaintiffs incorporate by reference all preceding paragraphs.

109. The amount and proportion of the characterizing component, vanilla, has a material bearing on price and consumer acceptance of the Product and consumers do not expect that non-vanilla, artificial flavors where a product is labeled "vanilla" without more.

110. Defendant hid the sugar content knowingly.

111. Defendant's fraudulent intent is evinced by its failure to accurately identify the Product on the front label and ingredient list, when it knew its statements were neither true nor accurate and misled consumers.

112. Plaintiffs and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Unjust Enrichment

113. Plaintiffs incorporate by reference all preceding paragraphs.

114. Defendant obtained benefits and monies because the Product was not as represented and expected, to the detriment and impoverishment of plaintiffs and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiffs demand a jury trial on all issues.

WHEREFORE, Plaintiffs pray for judgment:

1. Declaring this a proper class action, certifying plaintiffs as representatives and the undersigned as counsel for the class;
2. Entering preliminary and permanent injunctive relief by directing defendant to correct the challenged practices to comply with the law;
3. Injunctive relief to remove, correct and/or refrain from the challenged practices and representations, and restitution and disgorgement for members of the class pursuant to the applicable laws;
4. Awarding monetary damages and interest pursuant to the common law and other statutory claims;
5. Awarding costs and expenses, including reasonable fees for plaintiffs' attorneys and

experts; and

6. Other and further relief as the Court deems just and proper.

Dated: June 26, 2020

Respectfully submitted,

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1:20-cv-04936
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William Marsella, Robert Paterson, individually and on behalf of all others similarly situated,

Plaintiffs,

- against -

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Defendant

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Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information, and belief, formed after an inquiry reasonable under the circumstances, the contentions contained in the annexed documents are not frivolous.

Dated: June 26, 2020

/s/ Spencer Sheehan
Spencer Sheehan

EXHIBIT “A”

FLAVOR EXTRACT MFG. ASSOC. (3)

MEMORANDUM OF CONFERENCE

July 8, 1966

PRESENT:	Daniel R. Thompson Attorney	Carr, Bonner, O'Connell, Kaplan & Scott representing FEMA
	Walter B. Jacobson	Borden Company
	Howard Smith	Virginia Dare Extract Co.
	Willis S. Steinitz	American Food Laboratories, Inc.
	and	
	Mr. J. K. Kirk	Acting Associate Commissioner for Compliance, FDA
	Arthur R. Johnson	Food Technology Branch, DFSA

SUBJECT: Status of Vanilla Flavoring with other Natural Flavors.

It was brought out that some flavoring manufacturers have been marketing products labeled "Vanilla with other Natural Flavors." As an example vanilla extract might be supplied in admixture with other cheaper botanicals such as St. John's Bread, Peru Balsam or prune juice. As a trade association, the Flavor Extract Manufacturers Association has been receiving many inquiries about the legal status of this type of product. It appears, that at the present time, the Association does not feel that the present Federal Regulations fully determine this status. They believe that the Vanilla standard and the Ice Cream standard could be re-written to better clarify these points:

The vanilla Standard determines Vanilla as a standardized product. If other flavorings are added, then the vanilla is no longer a standardized product and should therefore be labeled artificial or imitation. If this Vanilla with other natural flavors were to be used in ice cream, it would make the ice cream a category two product rather than a category one product.

Mr. Thompson, with agreement from the others, suggested the problem could be alleviated through voluntary compliance action on the part of the FEMA. Information about the interpretation of the standards would be circularized throughout the Association.

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DEC

Mr. Kirk, in turn suggested that the FEMA submit to his office, a draft of the proposal which they wish to make. This proposal would consider first the interpretation of the standards to limit the use of category one for ice cream containing only vanilla flavoring and limit the use of Vanilla WONF to category two ice cream. Secondly the FEMA proposal would suggest means for solving the problem through favorable interpretation of the standards and regulations. It was also suggested that the association submit to Mr. Kirk's office evidence of the use of these products in the form of labels commonly used on the products.

cc: DFSA/RF
Beacham, DFSA
Johnson, DFSA
SCI
Records
Mr. Kirk, OC
Vanilla File
Standards File

ARJohnson:ds:7/20/66

EXHIBIT “B”

Labeling Vanilla Flavorings and Vanilla-Flavored Foods in the U.S.

Vanilla flavorings are the only flavorings subject to a federal standard of identity. An understanding of the vanilla standard and the general flavoring labeling regulations is necessary to properly label vanilla flavorings and the foods to which they are added.

■ BY JOHN B. HALLAGAN and JOANNA DRAKE, The Flavor and Extract Manufacturers Association of the United States.

Vanilla has been one of the most popular flavors in the United States for many years with vanilla ice cream as the most recognizable and popular vanilla-flavored food. When consumers purchase ice cream labeled as "vanilla ice cream" they expect it to be flavored with vanilla flavoring derived from vanilla beans unless labeled otherwise. As we shall see, this expectation is codified in two U.S. federal standards of identity, one for vanilla flavorings and one for ice cream.

Adulteration of vanilla flavorings and foods containing them has long been a problem in the U.S. and there continue to be modern examples.[4] In 2008, the Food and Drug Administration (FDA) published a consumer update warning U.S. consumers against purchasing a product manufactured in Mexico and labeled as "pure vanilla" because the "Mexican vanilla is frequently made with extract of beans from the tonka tree."[13] Such adulteration is of concern to the FDA not only because the product was being sold in ethnic stores in the US and did not meet the standard of identity for vanilla extract, but also because tonka bean extract is a source of coumarin, a substance banned for use in food in the US since 1954.[13]

Issues of adulteration seem to fluctuate in frequency with the supply and price of vanilla beans. For example, two severe supply and price dislocations occurred in the past fifteen years resulting from increased global demand and decreased crop availability in Madagascar, the world's primary source of vanilla beans. In such instances there may be migration for economic reasons away from vanilla flavorings derived from vanilla beans that comply with the federal standard of identity. Non-compliant labeling for foods, including ice cream, may result. Recent increased emphasis on consumers' desires for foods containing "natural" food ingredients has resulted in the exploration of vanilla flavoring alternatives that are not derived from vanilla beans.[5]

The regulations relevant to vanilla extract and vanilla flavorings are codified in the U.S. Code of Federal Regulations (CFR), and are supplemented by a formal FDA Advisory Opinion, and a collection of FDA-issued regulatory correspondence. The regulatory environment related to flavors can therefore be confusing, especially when the federal standards for vanilla flavorings[a] and ice cream[b] are read with the labeling regulations for flavors and foods containing added flavors that are not subject to federal standards of identity[c]. However, clarity is possible with a careful reading and proper interpretation of the regulations. Two key points are:

1. The federal standards of identity for vanilla flavorings at 21 CFR Section 169 and ice cream at 21 CFR Section 135, and their labeling requirements, take precedence over the general flavor and food labeling regulations at 21 CFR Section 101.22.
2. The federal standard of identity for vanilla flavorings at 21 CFR Section 169 applies to both the flavorings sold directly to consumers and to food manufacturers.

Approximately 425 million gallons of vanilla ice cream are commercially produced annually in the U.S., comprising about 28% of the ice cream produced each year.

This paper will review the statutory authority granted to FDA to promulgate standards of identity for food and the proper labeling of foods subject to standards, examine the US labeling regulations for flavors and foods containing flavors, examine the standards of identity for vanilla products and ice cream, address issues related to vanillin and spent vanilla beans, and finally, consider the appropriate analysis when determining proper labeling of vanilla flavoring or foods containing vanilla flavoring.

Vanilla Supply and Quantity

In addition to large-volume use in food manufacturing, vanilla flavorings, primarily vanilla extract, are the largest volume flavorings sold at retail in the U.S. vanilla extract is by far the most popular extract used in home cooking. Annual surveys have shown vanilla ice cream to be the long-standing favorite among American consumers. Approximately 425 million gallons of vanilla ice cream are commercially produced annually in the U.S., comprising about 28% of the ice cream produced each year. The second most popular ice cream flavor is chocolate comprising about 10% of annual ice cream production. But, vanilla is popular in more food products

[a] 21 CFR §169.
[b] 21 CFR §135.
[c] 21 CFR §101.22.

than just ice cream. Vanilla is in high demand for additional applications such as plant-based beverages like soy and almond milk, protein bars, yogurts and cereals.[1]

Vanilla (*Vanilla planifolia Andrews* and *Vanilla tahitensis Moore*) originated in Mexico where it was first cultivated. The vanilla orchid produces a fruit pod, the vanilla bean, which is the raw material for vanilla flavorings. The cultivation of vanilla is labor intensive, and outside of Mexico requires hand pollination of the orchid and consistent growing conditions. Today, a large majority of vanilla is imported into the U.S. as cured beans from the primary growing area of Madagascar with lesser amounts imported into the U.S. from Indonesia and a few other tropical countries. Vanilla is not cultivated in the U.S. although attempts have been made from time to time to cultivate vanilla in Hawaii and Puerto Rico.

The popularity of vanilla means that large volumes of vanilla beans must be imported into the U.S. annually to manufacture the large volume of vanilla extract and other vanilla flavorings produced in the U.S. According to statistics compiled by the U.S. Department of Commerce, **T-1** shows whole vanilla beans imported into the U.S. in the following amounts over the past five years with the corresponding customs value and per kilogram cost noted:

Of the whole bean imports, imports from Madagascar varied between 70-80% of the total for these years. In 2012, the Commerce Department began reporting totals of "crushed or ground" vanilla beans and these totals are reported in **F-1**.

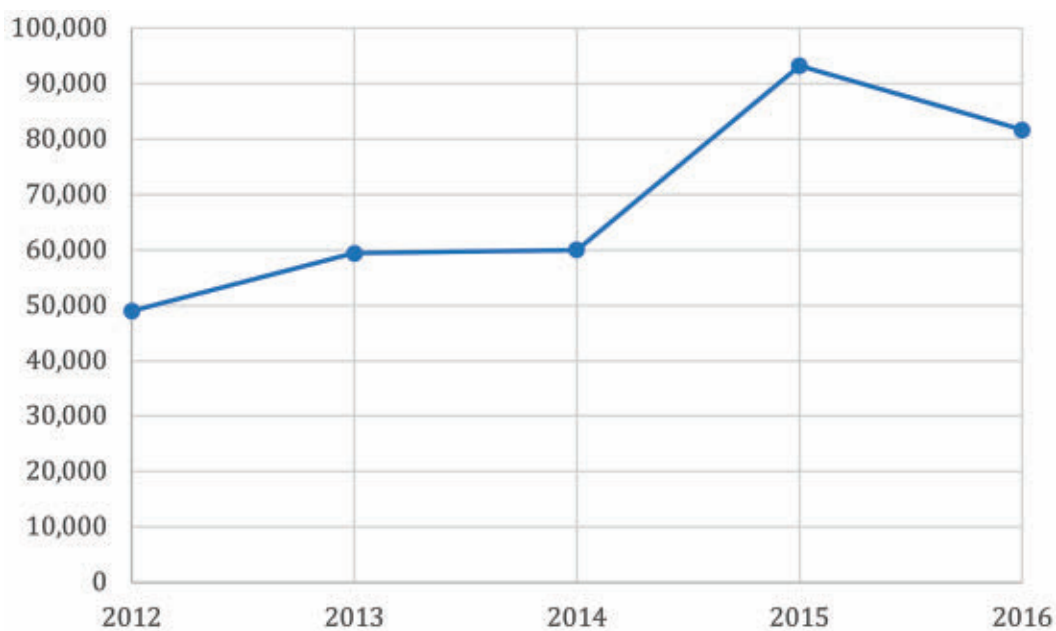
Prices for vanilla beans vary depending on supply and quality. In times of extreme shortages when, for example, severe typhoons destroyed significant portions of the Madagascar vanilla crop, prices have risen to over five hundred dollars per kilogram depending on quality. Severe price and supply dislocations have historically coincided with changes in practices related to the composition and labeling of vanilla flavorings. For example, synthetic vanillin-based flavorings may be used to replace vanilla extract, or to adulterate vanilla extract in violation of the federal standard of identity, when ample supplies of reasonably priced vanilla beans are not available.

T-1. U.S.-imported whole vanilla beans, 2012-2016

	Quantity	Value	Cost/kg
2012	1,988,643 kg	$43,940,046	$21.65/kg
2013	1,746,951 kg	$56,965,580	$31.67/kg
2014	1,648,879 kg	$83,387,776	$48.93/kg
2015	2,098,046 kg	$142,547,298	$66.05/kg
2016	1,527,185 kg	$302,468,670	$195.36/kg

Source: U.S. Department of Commerce

F-1.Total kilograms of crushed or ground vanilla beans



Vanilla is in high demand for additional applications such as plant-based beverages like soy and almond milk, protein bars, yogurts and cereals.

U.S. Federal Standards of Identity and the Proper Labeling of Foods Subject to Standards

Section 401 of the Federal Food, Drug, and Cosmetic Act (FFDCA) directs FDA through notice and comment rulemaking to establish standards for food where necessary to promote honesty and fair dealing in the interest of consumers. The authority granted by Congress to FDA enables the agency to combat an economic problem: the marketing of foods from which traditional constituents were removed or in which new or different (often cheaper) ingredients were substituted.[17] As such, the federal food standards are not safety standards, but rather, as FDA explains, are intended to "protect consumers from contaminated products and economic fraud" and have served as "a trusted barrier against substandard and fraudulently packaged food since their enactment in the 1938 FFDCA."[12] Additionally, the federal food standards help create a "level playing field" environment "where competitors (can) not cut prices by selling inferior products."[12]

Federal food standards allow consumers to trust that a standardized food is what it purports to be because they establish explicit specifications for the standardized food. A food standard typically defines the components of a food, listing both mandatory and any permitted optional ingredients as well as fixing the amounts or relative proportions of ingredients. Many food standards also prescribe a method of production. As such, the food standard regulation resembles a recipe for the standardized food. An additional and critical aspect of a food standard is its assigned common or usual name under which only conforming products can be sold. Once a food has a promulgated standard, only products that meet the compositional and applicable production requirements of the standard may be marketed under the food standard name. In other words, and strictly speaking, a food labeled with the name of the food that is subject to the standard must be composed of the ingredients specified in the standard.

As it relates to vanilla, FDA established a series of standards of identity for vanilla products promulgated at 21 CFR 169.175 – 169.182. The commercial landscape of vanilla products facing the agency at the time the vanilla standards were promulgated was one in which products purporting to be "vanilla extract" were often formulations including blends of vanilla beans with other flavoring components or mixtures of materials containing no vanilla bean at all.[4] FDA's standards for vanilla products were intended to alleviate potential consumer fraud by

establishing specific requirements for vanilla extract and other standardized vanilla products. As such, the primary basis for the vanilla product standards, including for vanilla extract, is FDA's definition of vanilla beans at 21 CFR 169.3(a):

> "The term vanilla beans means the properly cured and dried fruit pods of *Vanilla planifolia Andrews* and of *Vanilla tahitensis Moore*."

Both the foundation of the standard of identity for vanilla extract and the other standardized vanilla products at 21 CFR 169 and the basis of FDA's efforts to eliminate consumer and economic fraud with respect to vanilla products requires, in addition to proper labeling in accordance with the standards, that standardized vanilla products be derived from fruit pods: 1) of specific botanical origin; and, 2) which are properly cured and dried.

Vanilla flavorings are the only flavoring materials subject to a federal standard of identity.

No new standards of identity have been promulgated in recent years and existing standards have not been an area of particular enforcement emphasis for FDA as the agency has focused its limited resources on safety issues. However, FDA has clear statutory authority to take action against violations of standards of identity. The controlling section of the FFDCA is section 403(g) which states that a food is misbranded if there is a standard of identity in the regulation but the food does not conform to the standard. As such, a reading of the plain language of the statute suggests that a product which "purports to be or is represented as a standardized food either must meet the standard or it may not be sold as such."[18] Given its clear statutory authority regarding food standards, a violation of a standard is a relatively simple enforcement action for FDA to take because proving a violation is usually quite easy – the agency need simply compare the product label with the composition of the product listed in the ingredient statement or as confirmed through appropriate analytical methods. A recent FDA enforcement action involving Hampton Creek, the plant-based food manufacturer of "Just Mayo," provides an illustrative example.

In August 2015, FDA issued a warning letter to Hampton Creek noting that, among other issues, "Just Mayo" was misbranded under section 403 of the Federal Food Drug and Cosmetic Act for two reasons: 1) Just Mayo's label was false and misleading; and, 2) "Just Mayo" inappropriately purported to be a food for which a standard of identity has been established. First, FDA explained that the use of the term "mayo" in the product name and the image of an egg prominently positioned on the front label were misleading to consumers because they suggested that the product was the standardized food mayonnaise, which must contain eggs [d]. FDA also explained that using "Just" with "Mayo" seemed to qualify the product and "reinforce(d) the impression that the products are real mayonnaise by suggesting that they are "all mayonnaise" or "nothing but" mayonnaise."[16]

Second, in addition to being misleading, FDA determined that "Just Mayo" was misbranded because the name of the product and imagery used suggested that the product was standardized mayonnaise. Indeed, a simple review of its ingredient statement demonstrated that "Just Mayo" did not contain eggs, a required ingredient in mayonnaise. Additionally, Just Mayo's ingredient statement revealed that the product contained a number of other ingredients not permitted by the mayonnaise standard including: modified food starch, pea protein and beta-carotene. In this instance, Hampton Creek worked with FDA and modified its label to mitigate consumer confusion between "Just Mayo" and standardized mayonnaise by adding qualifying language on the front label to clearly differentiate "Just Mayo" from mayonnaise.

As a result of these label changes, the company was permitted to continue use of its "Just Mayo" brand name. However, this case demonstrates that allusion to a food with a federal standard on a food label through naming (even if the name is shorthand or a colloquial term for the standardized food) or imagery of mandatory ingredients is improper because it is misleading to consumers and renders the product misbranded under the FFDCA.

Federal standards were most commonly established for ready-to-eat foods such as peanut butter, bread, mayonnaise and ice cream, and generally not for a food ingredient that is not consumed as such and is only consumed after mixing with other food ingredients either in food production or in the home. Vanilla flavorings are the only flavoring materials subject to a federal standard of identity.

As noted above, in addition to the statutory authority for food standards, Congress also provided

[d] 21 CFR §169.140(c).

Today, a large majority of vanilla is imported into the U.S. as cured beans from the primary growing area of Madagascar with lesser amounts imported into the U.S. from Indonesia and a few other tropical countries.

in FFDCA section 403 requirements for labeling standardized foods.

> A food shall be deemed to be misbranded . . .
> (g) If it purports to be or is represented as a food for which a definition and a standard of identity has been prescribed by regulations as provided by Section 401 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients present in such food.

Therefore, reading FFDCA Sections 401 and 403 together, it is apparent that if a flavoring is represented as "vanilla" and/or tastes like vanilla it is subject to the standards of identity for vanilla flavorings and must comply with the labeling requirements for the standards. FDA's implementing regulations further reflect the legal principle that standards of identify supersede the general flavor labeling regulations since, where there "is a flavor for which a standard of identity has been promulgated," then "it shall be labeled as provided in the standard[e]."

An alternative interpretation of the statute and accompanying regulations that flavorings represented as "vanilla" and/or tasting like vanilla may be properly labeled consistent with the existing flavor and food labeling regulations for non-standardized foods[f] is not likely to be accepted by FDA. The Hampton Creek "Just Mayo" case provides insight into how FDA would likely enforce potential violations of the vanilla standards. As a result, FDA would likely consider any food product labeled as or displaying depictions which create an allusion that the food product contains "vanilla extract" or another standardized vanilla product to be misleading and misbranded if it too did not strictly meet the appropriate vanilla standard.

However, how would FDA consider enforcement in a nuanced circumstance? For example, how might FDA consider the extraction of the total sapid and odiferous principles from properly cured and dried vanilla beans by carbon dioxide rather than by aqueous alcohol solution, which is required in the vanilla extract standard? Carbon dioxide and aqueous alcohol extraction yield nearly identical extracts. A strict interpretation of the standard would likely lead to the conclusion that such an extract from vanilla beans does not meet the standard and is

(Continued on Page 42)

[e] 21 CFR §101.22(g).

[f] 21 CFR §101.22.

(Continued from Page 39)

misbranded under the statute. FDA is free, however, in exercising enforcement discretion in such a case to balance the primary intent of the vanilla standard: the total flavoring components of a vanilla extract be derived from vanilla beans against a strict interpretation of the standard.

In addition to federal regulatory enforcement, food manufacturers should also consider the relative risks associated with private consumer class action litigation which may arise from misleading labeling of vanilla products. Over the last several years, class-action lawsuits involving some aspect of alleged false advertising of food products has become one of the fastest growing areas in class litigation. More recently, there has been a growing number of class-actions filed in district courts across the U.S. in which the plaintiff class alleges that a food product is unlawfully misleading because the food product does not contain ingredients which the product, through labeling and pictorial vignettes, purports to contain.

Over the last several years, class-action lawsuits involving some aspect of alleged false advertising of food products has become one of the fastest growing areas in class litigation.

For example, plaintiffs have challenged ginger ale manufacturers for claiming that their products are "made with real ginger" but the ginger flavor used in the products is not derived from ginger. In another recently filed case, the plaintiff alleged that a flavored carbonated water designated as "coconut" flavored did not contain any actual coconut.[20, 21, 22] Due to the popularity of vanilla flavored food products and the growing sophistication of the plaintiff's bar, mislabeled vanilla products may be an area potentially ripe for private litigation.

U.S. Labeling Regulations for Flavors and Foods Containing Flavors

A key principle in determining proper labeling for flavors and foods containing flavors is that FDA policy is in most instances not to prohibit the use of certain flavoring substances (assuming that regulatory authority to use exists). Rather, policy is set to assure that clear labeling allows consumers to be informed of the presence of the flavorings with the most important information being whether the flavoring would be considered "natural" or "artificial." One can argue the merits of this distinction but the fact remains that this distinction is at the center of FDA's flavor and food labeling regulations.

The U.S. regulations governing the labeling of flavorings and foods containing flavorings are among the most complicated and confusing regulations administered by FDA. These regulations, found at 21 CFR Section 101.22, apply to all foods except for those subject to a federal standard of identity and this has often resulted in some confusion with the standards governing vanilla flavorings[g] and ice cream[h] that have their own requirements for proper labeling as required in FFDCA Section 403. FDA noted this requirement stating clearly, "The general flavor regulations[i] are not applicable to this standardized food (ice cream)."[17] Although the general flavor labeling regulations do not apply to vanilla flavorings or ice cream, an understanding of these regulations is necessary to identify the proper labeling of these two standardized foods.

FDA's general flavor labeling regulations provide specific rules for how flavors and food containing added flavors must be labeled depending on whether they contain natural[j] or artificial[k] flavorings or a combination of the two. The definition of "natural flavor" consists of three key parts: the starting material for the production of the natural flavor, the process by which it is produced, and the fact that the end product must have flavoring as its function[l].

The definition of artificial flavor is written to simply state that flavoring substances that are not natural are artificial[m].

The regulations at 21 CFR Section 101.22(g) apply to "bulk" flavors to be shipped to a food manufacturer and require that the flavor manufacturer provide adequate information to their food manufacturing customer so that the food containing the added flavor can be properly labeled in compliance with the regulations at 21 CFR Sections 101.22(i)(1), (2) and (3). It is important to emphasize that these regulations apply only to foods that are not subject to a federal standard of identity.

A key concept in the flavor labeling regulations at 21 CFR Section 101.22 is the "characterizing flavor" concept. According to the FDA, the characterizing

[g] 21 CFR §169.
[h] 21 CFR §135.110.
[i] 21 CFR §101.22.
[j] 21 CFR §101.22(a)(3).
[k] 21 CFR §101.22(a)(1).
[l] 21 CFR §101.22(a)(3).
[m] 21 CFR §101.22(a)(1).

flavor of a food is the flavor of the food (i.e. what the food tastes like) as indicated by the food's packaging, advertising or labeling including words and pictures[n].

For example, a package of ice cream that depicts white ice cream and vanilla beans would be interpreted by FDA to have vanilla as its characterizing flavor whether or not the word "vanilla" appeared on the packaging.

Another key concept in the FDA regulations is the concept that if a food contains a flavoring that "simulates, resembles or reinforces" a characterizing flavor then specific labeling requirements apply. In its preamble to the final rule establishing its flavor and food labeling regulations, FDA explained the characterizing flavor concept further:

In determining whether added flavor does or does not simulate, resemble, or reinforce the characterizing flavor, the principal test will be to separate such added flavor from the product to determine whether it tastes like the characterizing natural flavor or approximates the flavor characteristics of any principal or key flavor note. Thus, the vanillin added to a chocolate pudding would clearly not be a characterizing flavor because it does not taste like chocolate, whereas the benzaldehyde added to a cherry juice would be an artificial flavor because it does reinforce and extend the cherry taste[o]."

FDA explained further that "the test is not solely whether" a flavor "simulates or is chemically identical to the characterizing natural flavor, but also more broadly whether it resembles, reinforces or extends it[p]." (see **side panel**). For example, the regulations state:

If the food is one that is commonly expected to contain a characterizing food ingredient, e.g. strawberries in "strawberry shortcake" and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored." For example, 21 CFR Section 101.22(i)(1)(i) states "natural strawberry flavored shortcake" or "strawberry flavored shortcake."

The Federal Standard of Identity for Vanilla Flavorings

The federal standard of identity for vanilla flavorings was established by the FDA in the 1960s in response to a petition submitted by a prominent manufacturer of vanilla extract. At the time, there was growing concern over the adulteration of vanilla extract with less valuable substances such as synthetic vanillin manufactured from lignin that can be obtained as a by-product of paper production. While the concern at the time was for the "economic" adulteration of vanilla extract with an artificial and less valuable substance—synthetic vanillin—there was also some concern over the use of other adulterants such as coumarin that were thought to pose a possible safety concern.[13]

The standard of identity for vanilla flavorings is actually a series of individual standards that describe the common or usual name and recipes for eight flavorings:

vanilla extract, concentrated vanilla extract, vanilla flavoring, concentrated vanilla flavoring, vanilla powder, vanilla-vanillin extract, vanilla-vanillin flavoring, and vanilla-vanillin powder.

These eight individual standards are supported by specific requirements for the vanilla beans that may be used to produce vanilla extract and other vanilla products.

Vanilla products subject to the federal standard of identity must be produced from vanilla beans from two species of vanilla, *Vanilla planifolia Andrews* and *Vanilla tahitensis Moore*, and the beans must be "properly cured and dried[t]." When vanilla beans are

ADDITIONAL SECTIONS OF FLAVOR REGULATIONS:

- Foods containing a natural flavor consistent with 21 CFR Section 101.22(a)(3) but for which none of the flavor is derived from "the product whose flavor is simulated" result in a product labeled as "artificially flavored[q]."
- Foods containing both a characterizing flavor and other natural flavor that simulates, resembles or reinforces the characterizing flavor result in a product labeled as the primary recognizable flavor (the characterizing flavor) followed by the words "with other natural flavors[r]."
- Foods containing any artificial flavor that simulates, resembles or reinforces the characterizing flavor result in a product labeled as the primary recognizable flavor accompanied by the words "artificial" or "artificially flavored[s]."

[n] 21 CFR §101.22(i).
[o] 38 Fed. Reg. 33284 at 33286 (Dec. 3, 1973).
[p] *ibid*.
[q] 21 CFR §101.22(i)(1)(ii).
[r] 21 CFR §101.22(i)(1)(iii).
[s] 21 CFR §101.22(i)(2).
[t] 21 CFR §169.3(a).

Vanilla products subject to the federal standard of identity must be produced from vanilla beans from two species of vanilla, Vanilla planifolia Andrews *and* Vanilla tahitensis Moore*, and the beans must be "properly cured and dried*[z]*."*

ripe they are picked, washed and dried, most often on racks in open air under shelter. Properly cured and dried vanilla beans will vary in moisture content but the standard specifies that vanilla products must be produced from specific amounts of vanilla beans with specific moisture content assuring that vanilla products contain the proper amount of "sapid and odorous" (volatile) flavoring substances[u].

The vanilla standard that receives the most attention is the standard for vanilla extract[v]. The standard requires that the name of the product is either "vanilla extract" or "extract of vanilla" and that it complies with the standard's recipe, of which the most important ingredient is the "vanilla constituent." Vanilla extract must be comprised of "not less than one unit (of vanilla constituent) per gallon" of extract. One unit of vanilla constituent "means the total sapid and odorous principles (volatile flavoring substances, most important of which is vanillin) extractable from one unit weight of vanilla beans[w]." One unit weight of vanilla beans means 13.35 ounces of properly cured and dried beans containing not more than 25% moisture. In the case of beans containing more than 25% moisture it means the weight of beans equivalent in content of moisture-free solids to 13.35 ounces of beans containing 25% moisture[x]. In 1987, the Bureau of Alcohol, Tobacco, and Firearms (BATF – now the Alcohol and Tobacco Tax and Trade Bureau, TTB) issued a policy statement clarifying the use of vanilla beans of varying moisture content explaining that 10 ounces of "dry weight" vanilla beans would be equivalent to 13.35 ounces of beans with 25% moisture content, thereby establishing a minimum amount of beans for the production of a gallon of vanilla extract. The BATF statement refers to FDA policy and a future publication of such policy in the *Federal Register* – the publication did not occur.[3]

The standard requires that the total flavoring principles be extracted from the vanilla beans using an aqueous ethyl alcohol solution containing at least 35% alcohol and that the final extract be composed of the vanilla constituents suspended in aqueous ethyl alcohol[y].

These requirements are intended to assure that when a consumer purchases a product labeled as vanilla extract, or a food labeled as containing vanilla extract, that the vanilla extract contains a minimum, standard amount of vanilla bean-derived flavoring substances and no other added flavoring substances not derived from properly cured and dried vanilla beans that simulate, resemble

[u] 21 CFR §169.3(b) and (c).
[v] 21 CFR §169.175.
[w] 21 CFR §169.3(c).
[x] 21 CFR §169.3(b).
[y] 21 CFR §169.3 (c); 21 CFR §169.175; and 21 CFR §169.176.
[z] 21 CFR §169.3(a).

or reinforce the characterizing flavor, vanilla. Therefore, when a consumer purchases vanilla extract at retail the product should meet the recipe in the standard. Likewise foods labeled as containing vanilla extract should be flavored only with standardized vanilla extract and not other flavorings that may be characterizing for vanilla.

The seven standards for vanilla flavorings in addition to vanilla extract are not of the degree of importance and interest as the standard for vanilla extract because vanilla extract is the vanilla flavoring most often encountered by consumers. Three of the standards are for flavorings that combine vanilla extract with the primary chemically defined flavoring substance in vanilla beans, vanillin[aa]. The standards clearly require that the presence of added vanillin must be declared through the name of the product – "vanilla-vanillin extract," "vanilla-vanillin flavoring," or "vanilla-vanillin powder." These product names are seldom used.

The federal standard of identity for vanilla was established by the FDA in the 1960s over growing concern of adulteration of vanilla extract with less valuable substances

Even though the flavor and food labeling regulations at 21 CFR Section 101.22 do not apply to foods subject to standards of identity, it is important to note that vanilla extract produced consistently with the standard of identity[bb] complies with the requirements for natural flavor at 21 CFR Section 101.22(a)(3); as do the four other related standards for concentrated vanilla extract, vanilla flavoring, concentrated vanilla flavoring, and vanilla powder [cc].

The three standards for the vanilla-vanillin products could, in certain instances, be interpreted to meet the requirements for "natural flavor" as defined in 21 CFR Section 101.22(a)(3). For example, if the vanillin used is produced through a process consistent with the regulation[dd] then the vanilla-vanillin product could be considered a natural flavor except for the fact that FDA has rendered an opinion that this vanillin does not "qualify as natural vanillin because it is not obtained from vanilla beans whose flavor it simulates."[9] FDA also has long considered vanillin obtained from lignin as a "synthetic flavoring substance" as listed by the agency at 21 CFR Section 182.60.

The general FDA flavor and food labeling regulations provide for the designation of certain flavors as "_____ with other natural flavors[ee]." Such flavors are commonly known as "WONF" flavors. The U.S. federal standard of identity for vanilla flavorings[ff] does not provide for the designation of any vanilla flavorings as "vanilla with other natural flavors" or "vanilla WONF." However, the interpretation of these provisions depends heavily on the characterizing concept.

The primary question in this area is whether a WONF description can be used in the context of vanilla flavorings. The standards for vanilla extract and the other standardized vanilla products at 21 CFR 169 expressly do not provide WONF designation. This means that a flavoring mixture of vanilla extract and vanillin produced through a "natural" process (i.e. a process consistent with the definition of natural flavor at 21 CFR Section 101.22(a)(3)) cannot be described as "vanilla extract WONF," "vanilla WONF" or other similar descriptive terms. However, what if a natural strawberry flavor is mixed with vanilla extract and the characterizing flavor remains vanilla? FDA may not object to labeling of such a flavoring or a food by listing "vanilla (or vanilla extract) with other natural flavors" provided that the ingredient statement clearly describes the contents of the product to eliminate confusion with standardized vanilla flavorings.

In its response to an inquiry from its sister agency, BATF, FDA specifically addressed the issue of the use of WONF labeling for vanilla products in the context of the secondary extraction of vanilla beans – a second extraction of beans after the first extraction has removed the majority of the flavoring substances to produce vanilla extract. If a solvent other than ethyl alcohol is used to extract vanilla beans in a secondary extraction, flavoring substances different than those recovered in the primary extraction to produce vanilla extract may be obtained. In general, a WONF description cannot be used when the "other natural flavor" is characterizing for vanilla. However, in this limited context, FDA noted that vanilla extract produced consistently with the standard of identity could be combined with extractives produced through a secondary extraction with the resulting product labeled as "vanilla with other natural flavors." FDA seems to recognize that the distinction in this case is that

[aa] 21 CFR §169.180; 21 CFR §169.181; and 21 CFR §169.182.
[bb] 21 CFR §169.
[cc] 21 CFR §169.176; 21 CFR §169.177; 21 CFR §169.178; and 21 CFR §169.179.
[dd] 21 CFR §101.22(a)(3).
[ee] 21 CFR §101.22(i)(1)(iii).
[ff] 21 CFR §169.

The federal standard of identity for ice cream and frozen custard is structured similar to other food standards – a common or usual name is assigned (ice cream) and a recipe is specified[kk].

all the flavoring constituents, both from the initial and secondary extraction, are derived from vanilla beans. However, FDA also noted that such a product is not a "standardized vanilla extract or flavoring" and shall not be labeled or depicted as such.[8]

The Federal Standard of Identity for Ice Cream and Frozen Custard

The federal standard of identity for ice cream and frozen custard is similarly structured to other food standards – a common or usual name is assigned (ice cream) and a recipe is specified[gg]. The key section of the standard relevant to flavorings is Section 135.110(f) that specifies the nomenclature for ice cream and three other similar frozen desserts - frozen custard, French ice cream or French custard ice cream. The labeling analysis for all four of these foods is the same.

If the ice cream contains no artificial flavor[hh] then the label of the ice cream "shall be accompanied by the common or usual name of the characterizing flavor, e.g., vanilla . . ." – i.e. "vanilla ice cream[ii]."

This is often referred to as "Category 1" ice cream. Reading this regulation together with the vanilla standard of identity means that the characterizing flavor for this ice cream must be provided only by vanilla extract complying with the standard at 21 CFR Section 169.175, or another standardized vanilla flavoring derived solely from vanilla beans. If non-vanilla bean source vanillin were included in this product then it must be labeled as "Vanilla Flavored Ice Cream" as described below for "Category 2" ice cream. If a natural flavor that is not characterizing for vanilla is included in a vanilla ice cream then the ice cream could be labeled as "vanilla ice cream with other natural flavors" if the requirements of the ice cream standard were met.

If the ice cream contains both a natural characterizing flavor and an artificial flavor simulating it, and the natural flavor is predominant, then the ice cream must be labeled with the common or usual name of the characterizing flavor accompanied by the word "flavored[ij]." For example, this ice cream may be flavored predominantly with vanilla extract with an artificial flavoring simulating vanilla such as vanillin.

[gg] 21 CFR §135.110.
[hh] 21 CFR §101.22(a)(1).
[ii] 21 CFR §135.110(f)(2)(i).
[ij] 21 CFR §135.110(f)(2)(ii).
[kk] 21 CFR §135.110.

This is often referred to as "Category 2" ice cream. It is important to note that the "artificial" flavor referred to in this regulation may meet the definition of "natural flavor" at 21 CFR Section 101.22(a)(3) but for the purposes of this regulation it is "artificial" because it is not derived from the source of the named characterizing flavor.

If the ice cream contains both a natural characterizing flavor and an artificial flavor simulating it, and the artificial flavor is predominant, or if the ice cream is flavored only with an artificial flavoring, then the ice cream must be labeled with the common or usual name of the characterizing flavor preceded by the word "artificial" or "artificially flavored[ll]" This ice cream may be flavored predominantly or solely with vanillin and labeled as "artificial vanilla ice cream" or "artificially flavored vanilla ice cream." This is often referred to as "Category 3" ice cream.

> The federal standard of identity for ice cream and frozen custard is similarly structured to other food standards.

Vanillin

The flavor perceived by humans as vanilla is a complex mixture of substances some of which have their own use as individual flavoring substances. The single most important individual flavoring substance in vanilla beans, and therefore in vanilla extract and other standardized vanilla flavorings, is vanillin. Vanillin is a component of three standardized vanilla flavorings and is often used in a wide variety of artificial vanilla flavorings. Vanillin has also been used to adulterate vanilla extract as the addition of vanillin allows a manufacturer to use less of the extractives of vanilla beans. FDA commented:

> The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction of the amount of vanilla bean derived flavor that would otherwise be used . . . Thus, a flavor that permits less of the characterizing flavor to be used than would otherwise be the case simulates that flavor [7]

This comment, from FDA's 1983 advisory opinion, establishes the position that the agency has maintained in recent years that vanillin is characterizing for vanilla and that the addition of vanillin, whether derived from lignin or from other sources, must be clearly declared as in one of the three standardized vanilla flavorings or else the flavoring (most likely to be vanilla extract) is adulterated as would be any food containing it.

Vanillin may be produced through processes recognized as yielding an artificial flavor consistent with the FDA definition of "artificial flavor" such as the production of vanillin from lignin[mm]. Vanillin may also be produced through processes that yield a natural flavor consistent with the FDA definition of "natural flavor[nn]." However, FDA has clearly stated that the only vanillin that the agency will regard as "natural vanillin" is vanillin derived from vanilla beans, which is rarely if ever produced for economic reasons. FDA first suggested this position in 1983 stating, "FDA will treat natural flavor compounds that simulate vanilla but are not derived from vanilla beans as artificial flavors that simulate the natural characterizing flavor."[7] FDA later specifically explained in regulatory correspondence that while some vanillin may comply with the definition of natural flavor [oo] it "would not qualify as natural vanillin . . . because the vanillin is not obtained from vanilla beans whose flavor it simulates."[9]

FDA has issued regulatory correspondence in recent years on the proper labeling of vanillin that is produced consistently with processes described in the definition of "natural flavor." Regarding vanillin produced using a fermentation process, FDA stated that the common or usual name for this material is "vanillin" and that it should be labeled as "vanillin derived naturally through fermentation."[10] FDA also explained that the labeling for this material "should not imply that the vanillin is a natural flavor or that a finished food containing it is natural" and that such vanillin "may not be used to make natural vanilla flavors in standardized foods."[11] FDA further elaborated that:

> When vanillin manufactured through a natural process . . . is used . . . in a finished food it should be listed in the ingredient list as "vanillin" or "natural flavor" but it should not be done in a way to imply that it is a natural vanilla flavor because it is not derived from vanilla beans.[14]

[ll] *ibid.*

[mm] 21 CFR §101.22(a)(1).

[nn] 21 CFR §101.22(a)(3).

[oo] *ibid.*

FDA also stated that a food containing vanillin produced consistent with the FDA definition of natural flavor[pp] "can bear the term 'vanillin,' 'natural flavor,' or 'contains natural flavor' but the term natural flavor must not be used in such a way to imply that it is 'natural vanilla flavor' because it is not derived from vanilla beans."[15] The Alcohol and Tobacco Tax and Trade Bureau (TTB) has stated that it will not approve formulas containing vanillin that are produced consistently with the FDA definition of natural flavor[qq] if the material is "being called natural vanillin."[19] TTB does, however, in its electronic Drawback Tutorial, refer to certain vanillin materials produced through fermentation processes as "natural products," which TTB may not otherwise consider to be a restricted ingredient. However, TTB's interpretation is relevant to the use of flavors in alcoholic beverages only.

> Vanillin has also been used to adulterate vanilla extract as the addition of vanillin allows the manufacturer to use less of the extractives of vanilla bean.

The synthetic flavoring substance ethyl vanillin is a vanillin analog that may also be used to impart a vanilla flavor and is considered several times more potent than vanillin. Ethyl vanillin has not been identified in vanilla beans or otherwise in nature and is produced by synthesis methods that do not meet the FDA definition of "natural flavor[rr]."

Spent Vanilla Bean

During the production of vanilla extract, the flavoring substances that developed within the vanilla bean pod (the "sapid and odorous principles" present in "properly cured and dried" vanilla beans) are extracted from the fibrous pod material with ethyl alcohol. The fibrous pod material, usually deep brown or black in color, is a byproduct of the extraction process and is referred to as "spent" or "exhausted" vanilla beans. Two federal regulatory agencies have authority over the spent beans, TTB and FDA. TTB has authority because of the use of ethyl alcohol that may be considered "beverage" alcohol in the vanilla bean extraction process and therefore subject to tax. FDA has authority to the extent that spent vanilla beans are added to food.

Spent vanilla beans are regulated by TTB in the context of the disposition of recovered alcohol and material from which alcohol can be recovered from the vanilla bean extraction process. TTB's regulations state:

> Specific approval from the appropriate TTB official is not required when spent vanilla beans containing residual alcohol are destroyed on the manufacturer's premises by burning, or when they are removed from those premises after treatment with sufficient kerosene, mineral spirits, rubber hydrocarbon solvent, or gasoline to prevent recovery of residual alcohol[ss].

TTB's authority over alcohol and its use as an extractive solvent has led the agency to be involved in some vanilla labeling issues. In 1960, in response to an inquiry from a vanilla extract manufacturer, BATF stated that "exhausted vanilla beans do not constitute a legitimate item of commerce for food use in that the valuable constituents, the flavoring principles, have been omitted or abstracted therefrom."[2] In 1986, FDA responded to an inquiry from BATF on the subject of the secondary extraction of vanilla beans – a second extraction of beans after the first extraction has removed the majority of the flavoring substances to produce vanilla extract. FDA informed BATF that the product of a secondary extraction should be labeled "by a truthful, descriptive term such as extractives from spent vanilla beans."[8] As mentioned previously, FDA also noted that under certain limited circumstances a flavoring containing vanilla extract and the flavoring constituents from secondary extraction could be labeled as "vanilla WONF" provided that consumers would not be led to conclude that the flavoring was a "standardized vanilla extract."[8]

Given the statements by FDA and TTB (BATF), can spent vanilla beans be included in vanilla flavorings? It appears that an appropriate interpretation of the body of information is that if spent beans (most likely small pieces thereof) are included in a vanilla extract or other standardized vanilla flavoring as a direct result of the manufacturing process, then such inclusion and labeling of the flavoring as a standardized vanilla flavoring would not be interpreted to be deceptive to consumers. However, spent vanilla beans added directly to foods in the

[pp] *ibid.*
[qq] *ibid.*
[rr] *ibid.*
[ss] 19 CFR §17.183(c).

According to the FDA, *the term "vanilla flavor" tends to be deceptive leading one to believe that the product is standardized vanilla extract or vanilla flavoring;*[8] *and therefore requires additional labeling to assure that consumers can determine that the product is not vanilla extract.*

absence of a corresponding amount of a standardized vanilla flavoring would likely be viewed by FDA and TTB as a violation of the vanilla standards and general labeling regulations unless the presence of the spent beans was clearly declared in a manner that is not deceptive to consumers.

Determining Proper Labeling

When trying to determine the proper labeling of a vanilla flavoring or a food containing vanilla flavoring, the first question is whether vanilla is the characterizing (primary recognizable) flavor. The analysis may seem straight-forward if one is dealing with a vanilla flavoring because if vanilla is the characterizing flavor then the flavoring is subject to the standard of identity at 21 CFR Part 169. For example, if one has a flavoring that tastes like vanilla or is represented as tasting like vanilla (vanilla is the characterizing flavor) then it must be labeled as required in the standard with the appropriate common or usual name such as "vanilla extract."

When seeking to interpret and understand the requirements of the vanilla standard it is advisable to read the regulations side-by-side with relevant regulatory correspondence. In addition to the regulations describing the standards of identity for vanilla flavorings[tt] and frozen desserts[uu] there is a substantial body of information that, in addition to the standards, can facilitate interpretation, understanding and proper labeling. These resources include a formal advisory opinion issued by FDA and a variety of regulatory correspondence issued by FDA in response to inquiries from other federal agencies, industry, and the public. It is important to note that FDA regulations state that regulatory correspondence issued by the agency constitutes an agency advisory opinion.

If one is trying to determine the appropriate labeling of a vanilla flavoring that combines vanilla extract with vanillin not derived from vanilla beans, the first place to check is the standard for vanilla which specifies that such a product must meet the recipe for "vanilla-vanillin extract[vv]" and must be labeled as such. However, a person with knowledge of the general flavor labeling regulations[ww] may ask whether such a product may be labeled as "vanilla WONF." Reviewing the available regulatory correspondence yields the answer – such a product may be labeled as "vanilla WONF" (with the exception of the spent vanilla bean example) only if it is clearly labeled as containing natural flavor constituents not derived from vanilla beans. FDA stated in regulatory correspondence that:

> A flavoring composed of 50% vanilla extract and 50% natural flavors not derived from vanilla beans . . . may be identified as vanilla *flavor*

[tt] 21 CFR §169.
[uu] 21 CFR §135.
[vv] 21 CFR §169. 180.
[ww] 21 CFR §101.22.

(emphasis added) with other natural flavors" if it is accompanied by a labeling declaration that states that the product "contains 50% vanilla extract and 50% non-vanilla flavors.[6]

FDA further explained its thinking in 1986 on the use of the term "vanilla flavor" when the agency stated that, "The term 'vanilla flavor' tends to be deceptive leading one to believe that the product is standardized vanilla extract or vanilla flavoring"[8] and therefore requires additional labeling to assure that consumers can determine that the product is not vanilla extract.

Furthermore, FDA, as noted above, explained in later regulatory correspondence that vanillin that complies with the definition of natural flavor[xx] "would not qualify as natural vanillin . . . because the vanillin is not obtained from vanilla beans whose flavor it simulates."[9]

> The consumer preference for "natural" drives the consumer preference for vanilla extract and therefore presents an opportunity for higher economic returns.

Analyses to determine proper labeling for foods for which vanilla is the characterizing flavor can be even more complicated and one must often use all of the available resources to determine proper labeling. Evaluating the proper labeling of vanilla frozen desserts provides an example of the difficulties. What is the proper labeling of ice cream using the vanilla-vanillin extract described above to impart a vanilla flavor to the ice cream? Should this ice cream be labeled as "vanilla flavored" ice cream (i.e. "Category 2") rather than "vanilla ice cream" (i.e "Category 1") or should it be labeled an "artificially flavored vanilla ice cream" (i.e. "Category 3)? FDA addressed this issue in 2008 stating that ice cream flavored predominantly with vanillin:

(S)hould not be named 'vanilla ice cream' or 'vanilla flavored ice cream' because these products are not made from vanilla beans or vanilla flavors made from vanilla beans. If a food contains any artificial flavor which resembles or reinforces the characterizing flavor, the name of the food on the label should be accompanied by the common or usual name of the characterizing flavor and the word(s) 'artificial' or 'artificially flavored' e.g. 'artificial vanilla,' 'artificially flavored vanilla' or 'vanilla artificially flavored.'[14]

A similar analysis applies for a food not subject to a standard of identity. What is the proper labeling of a vanilla-tasting cookie (vanilla is the characterizing flavor) that is flavored with the same vanilla-vanillin extract? In this instance the general flavor and food labeling regulations at 21 CFR Section 101.22 apply. Vanillin is characterizing for vanilla but in this instance even though it qualifies as "natural flavor" under 21 CFR Section 101.22(a)(3) the labeling for the cookie on the principal display panel must indicate that it contains an "artificial" flavor – the vanillin not from vanilla beans. Proper principal display panel labeling could be a cookie called "Vanilla Cookie" with a sub-label also on the principal display panel of "Contains artificial flavor." This case illustrates, however, the important distinction between appropriately labeling the flavor added to food on the principal display panel versus the ingredient statement on the back of a food package. While in this case the principal display panel must acknowledge the non-vanilla bean derived vanillin as artificial, the ingredient statement could contain a statement of "natural and artificial favors."

What if the cookie tasted like cherry with the cherry flavor imparted by natural cherry extract and also contained the same vanilla-vanillin extract described above? Proper labeling could be "Cherry Cookie" on the principal display panel with a sub-label that states "Natural flavor." The ingredient statement could state "Natural flavors." The difference in the two examples, the vanilla cookie and the cherry cookie, is the result of the difference in the characterizing flavors – vanilla vs. cherry. The vanillin in the cherry cookie is not characterizing and therefore can be declared in the ingredient statement as part of the "natural flavor."

Conclusions

With respect to the use of vanilla flavorings to provide a vanilla flavor to foods, there are few practices that are prohibited by FDA regulation and policy regarding the flavoring substances that may be used to provide the vanilla flavor. However, FDA regulations clearly require that food products be labeled accurately so that consumers can determine whether the product is flavored with a vanilla

[xx] 21 CFR §101.22(a)(3).

flavoring derived from vanilla beans, in whole or in part, or whether the food's vanilla flavor is provided by flavorings not derived from vanilla beans.

There are many current examples of food products that are labeled as "vanilla" that are clearly mislabeled and therefore in violation of FDA regulations. A common violation is to label a food product such as ice cream in a way that leads consumers to believe that it is flavored with vanilla extract, or another vanilla flavoring derived solely from vanilla beans, as defined in the federal standard of identity when in fact it is not. The consumer preference for "natural" drives the consumer preference for vanilla extract and therefore presents an opportunity for higher economic returns. In addition, it seems clear that consumers do not understand the FDA's labeling requirements and may not distinguish between a food labeled as "strawberry shortcake" vs. one labeled as "strawberry flavored shortcake." Or, in the case of ice cream, the difference between "vanilla ice cream" and "vanilla flavored ice cream."

Increased education among flavor manufacturers, food manufacturers and consumers may result in improved compliance with the FDA's labeling regulations. The agency's limited resources have led it to focus on safety issues rather than the enforcement of its labeling regulations, the compliance with which may be appropriately considered an economic issue rather than a higher priority safety issue. It is important, as reflected in FDA's governing statute and implementing regulations, that vanilla-flavored foods are properly labeled allowing consumers to confidently purchase the products that they believe they are purchasing.

When trying to determine the proper labeling of a vanilla flavoring or a food containing vanilla flavoring, the first question is whether vanilla is the characterizing (primary recognizable) flavor.

A variety of resources are available to flavor and food manufacturers and consumers that facilitate an understanding of the proper labeling of vanilla flavorings and vanilla-flavored foods. A comprehensive annotated bibliography is available from the authors upon request that contains the relevant regulations and regulatory agency policy statements.

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EXHIBIT “C”

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740-38

AUG 05 2008

Richard J. Brownell Jr.
Vice President Vanilla Products
Virginia Dare Extracts, Inc.
882 Third Avenue
Brooklyn, New York 11232

Dear Mr. Brownell:

This is in response to your letter to the Food and Drug Administration (FDA) dated March 16, 2007, on the labeling of finished foods or beverages where vanilla is the characterizing flavor and the label refers to natural vanilla, vanilla flavor or some other similar description. We regret the delay in responding to your inquiry, and hope the following information is still helpful to you.

You specifically asked when a food or beverage product is marketed (labeled) as (natural) vanilla, does the characterizing (vanilla) flavor have to be derived from vanilla beans and conform to the vanilla standard of identity. According to our regulation in Title 21 of the Code of Federal Regulations (CFR), section 101.22(i)(1), if a food contains no artificial flavor that simulates, resembles or reinforces the characterizing flavor, the name of the food on the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla." For example, the common or usual name of an ice cream product that does not contain artificial flavors would be "vanilla ice cream," and it should be made from vanilla beans. On the other hand, if a product such as ice cream does not contain enough of the characterizing ingredient, vanilla beans, to characterize the food or it does not contain such ingredient, and contains vanilla flavor, the product must be labeled "natural vanilla flavored ice cream" or "vanilla flavored ice cream." However, the flavors used to make such product must be derived from vanilla beans such as vanilla extract or vanilla flavor that are subject to standards of identity. Products made from vanillin should not be named "vanilla ____," e.g., "vanilla ice cream," or "vanilla flavored ____," e.g., "vanilla flavored ice cream" because these products are not made from vanilla beans or vanilla flavors made from vanilla beans. Furthermore, if a food contains any artificial flavor which resembles or reinforces the characterizing flavor, the name of the food on the label should be accompanied by the common or usual name of the characterizing flavor and the word(s) "artificial" or "artificially flavored", e.g., "artificial vanilla," "artificially flavored vanilla" or "vanilla artificially flavored."

In our April 19, 2005, letter to you on the labeling of a Rhodia, Inc. vanillin product derived from a natural source such as ferulic acid via a natural process such as fermentation, we stated that this vanillin product "would not qualify as natural vanillin." In our April 19, 2005, letter we also stated that although we would not object to a statement on the label indicating that vanillin is derived naturally through a fermentation process, such a statement should not imply that the vanillin is a natural flavor or that a finished food containing vanillin is natural. However, upon further consideration on this issue, we realize that our views about vanillin expressed in the April 19, 2005, letter were based on the food standards regulations under sections 169.180, 169.181, and 169.182 in 21 CFR.

These regulations pertain to standardized vanilla extract ingredients that contain added vanillin and require the designation "contains vanillin, an artificial flavor (or flavoring"). However, it should be noted that these regulations pre-date the fermentation process that Rhodia uses to produce vanillin. Also, 21 CFR 101.22(a)(1) provides that fermentation products are not considered to be artificial flavors. Thus, the new Rhodia process produces a natural flavor and consequently, the ingredient label of a finished food containing the vanillin product made by Rhodia can bear the term "vanillin," "natural flavor" or "contains natural flavor" but the term "natural flavor" must not be used in such a way to imply that it is a "natural vanilla flavor" because it is not derived from vanilla beans. Furthermore, the term "natural" is not a part of the common or usual name of Rhodia's product when sold as the finished food. The common or usual name of Rhodia's product is "vanillin," regardless of the type of method used to produce it. Therefore, the statement of identity of the product sold as the finished food is "vanillin."

If we may be of further assistance, please let us know.

Sincerely yours,

Catalina Ferré-Hockensmith

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