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United States District Court  
Eastern District of New York

1:19-cv-06551

Lorenzo Benites, individually and on behalf  
of all others similarly situated,

Plaintiff,

Complaint

- against -

7-Eleven, Inc.,

Defendant

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

1. 7-Eleven, Inc. (“defendant”) manufactures, distributes, markets, labels and sells ice cream products purporting to contain flavor from their natural characterizing flavor, vanilla beans, under their 7-Select GO!Yum brand (“Products”).

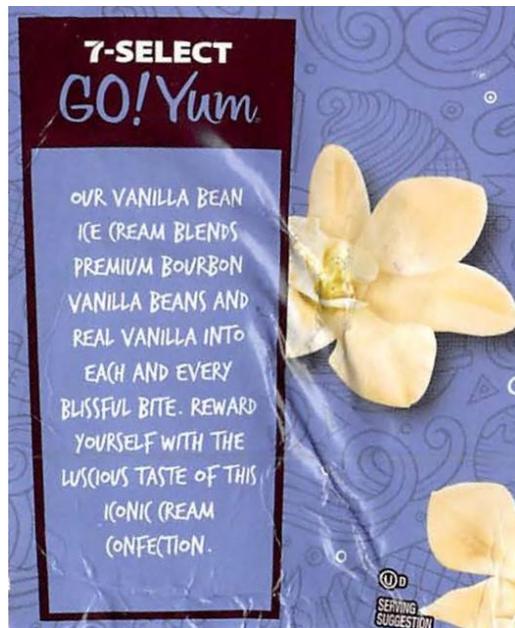
2. The Products are available to consumers from defendant's retail stores and defendant’s website and are sold in units of 1 pint (473 ML).

3. The front label representations include “7-Select GO!Yum,” “Vanilla Bean,”

“Vanilla Bean Ice Cream,” “Ice Cream Made With Natural Flavors,” a scoop of vanilla bean ice cream with “specks” and vignettes of the flower of the vanilla plant.



4. The side panel states “Our Vanilla Bean Ice Cream Blends Premium Bourbon Vanilla Beans and Real Vanilla into Each and Every Blissful Bite. Reward Yourself with the Luscious Taste of this Iconic Cream Confection.”



I. Vanilla is Perennial Favorite Ice Cream Flavor

5. Ice cream is a year-round treat enjoyed by 96% of Americans.<sup>1</sup>

6. Its popularity is attributed “to the perfect combination of elements – sugar, fat, frozen water, and air – that make up the mouthwatering concoction.”<sup>2</sup>

7. Ice cream is defined by a minimum of 10 percent milkfat, weighing no less than 4.5 pounds to the gallon and containing less than 1.4 % egg yolk solids.<sup>3</sup>

8. Vanilla is the consistent number one flavor for 28% of Americans, confirmed two groups who would know – the International Dairy Foods Association (IDFA) (ice cream producers) and National Ice Cream Retailers Association (ice cream parlors).

9. The reasons for vanilla’s staying power are “not only because it is creamy and delicious, but also because of its ability to enhance so many other desserts and treats.”<sup>4</sup>

10. By some estimates, approximately two-thirds of “all ice cream eaten is either vanilla or vanilla with something stirred into it, like chocolate chips.”<sup>5</sup>

11. The applications of vanilla ice cream include its centerpiece between chocolate wafers (“sandwich”), enrobed in chocolate on a stick (“bar”), topping a warm slice of fresh-baked pie (“à la Mode”), drizzled with hot fudge, sprinkled with crushed nuts and topped by a maraschino cherry (“sundae”) or dunked in a cold frothy glass of root beer (“float”).<sup>6</sup>

A. Philadelphia-style v. French Ice Cream

12. In the development of ice cream, the two main types were Philadelphia-style and

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<sup>1</sup> Arwa Mahdawi, [The big scoop: America's favorite ice-cream flavor, revealed](#), The Guardian, July 11, 2018

<sup>2</sup> Vox Creative, [The Reason You Love Ice Cream So Much Is Simple: Science](#), Eater.com, October 12, 2017.

<sup>3</sup> 21 C.F.R. § 135.110(a)(2) (“Ice cream and frozen custard.”).

<sup>4</sup> Press Release, IDFA, [Vanilla Reigns Supreme; Chocolate Flavors Dominate in Top Five Ice Cream Favorites Among Americans](#), July 1, 2018

<sup>5</sup> Bill Daley (the other one), [Which vanilla ice cream is the cream of the crop? We taste test 12 top brands](#), Chicago Tribune, July 18, 2018

<sup>6</sup> [The True Wonders of Vanilla Ice Cream](#), FrozenDessertSupplies.com.

French ice cream, flavored of course, with vanilla.

13. Like many confections in the United States, ice cream was brought here from France, courtesy of two statesmen who served as ambassadors to that nation: Thomas Jefferson and Ben Franklin.

14. While these two Founding Fathers could agree on the terms of the Declaration of Independence and Constitution, they could not agree on which type of vanilla ice cream was superior.

15. Future President Thomas Jefferson was a partisan of the egg yolk base, describing this treat as “French ice cream.”<sup>7</sup>

16. The egg yolk solids, when mixed with vanilla, distinguish a “French” vanilla ice cream from its Philadelphia-style counterpart by providing a:<sup>8</sup>

- smoother consistency and silkier mouthfeel;
- caramelized, smoky and custard-like taste; and
- deep-yellow color.<sup>9</sup>

17. Due possibly to Jefferson’s efforts at popularizing this variety, ice cream with 1.4% or more egg yolk solids as part of its base is referred to as “french ice cream.”<sup>10</sup>

18. According to legend, Ben Franklin’s “crème froid” was “one of the earliest recorded ice cream recipes from the United States,” introduced during the sweltering summer of the

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<sup>7</sup> [Thomas Jefferson’s Handwritten Vanilla Ice Cream Recipe](#), Open Culture, July 13, 2014; [Thomas Jefferson’s Vanilla Ice Cream](#), Taste of Home, June-July 2012; [Thomas Jefferson’s Original Vanilla Ice Cream Recipe](#), Jefferson Papers, Library of Congress; Anna Berkes, “[Ice Cream](#)” in Thomas Jefferson Encyclopedia, Thomas Jefferson Foundation, Inc., [Monticello.org](#), June 28, 2013

<sup>8</sup> The descriptor “French” or “french” preceding “vanilla” does not modify the word “vanilla.”

<sup>9</sup> Sheela Prakash, [What’s the Difference Between Vanilla and French Vanilla Ice Cream?](#), The Kitchn, June 7, 2017.

<sup>10</sup> 21 C.F.R. § 135.110(f)(1) (“The name of the food is ‘ice cream’; except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of the food is ‘frozen custard’ or ‘french ice cream’ or ‘french custard ice cream’.”)

Constitutional Convention of 1787.<sup>11</sup>

19. Ever the inventor, Franklin adapted his ice cream recipe to the situation by relying on the abundance of dairy farms in the Philadelphia region, the lack of hens to provide an egg yolk base (compared to their prevalence in pre-Revolutionary France) and foregoing the cooking step to more quickly deliver batches of this refreshing treat for the delegates.<sup>12</sup>

20. Philadelphia-style and French ice creams also differed in the form of vanilla they used to provide flavor.

21. The French variety used vanilla extract, the liquid created when the flavor molecules of a vanilla bean are extracted by alcohol.<sup>13</sup>

22. The Philadelphia-style relied on the dark brown seeds contained inside vanilla bean pods which had not been subject to extraction – referred to as “caviar,” “specks” or “flecks.”

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<sup>11</sup> Julia Reed, [Ice cream two ways: A tale of two continents](#), King Arthur Flour, Blog, Aug. 24, 2018; *but see* Jeff Keys, *Ice Cream Mix-ins*, N.p., Gibbs Smith (2009) at 14.

<sup>12</sup> [Vanilla Ice Cream, Philadelphia-Style](#), The Perfect Scoop, Epicurious.com, Dec. 2011; Dr. Annie Marshall, [Vanilla Bean Ice Cream Two Ways, and Ice Cream Basics](#), July 8, 2011, Everyday Annie Blog (“Varieties of ice cream generally fall into two main categories: Philadelphia-style or French-style. Philadelphia style ice creams are quicker and simpler, with a heavy cream/milk mixture for the base. French-style ice creams have a custard base, with cooked egg yolks to help achieve a creamy texture and rich flavor.”).

<sup>13</sup> 21 C.F.R. §§ 169.175 (Vanilla extract.) (at least thirty-five (35) percent ethyl alcohol).

Vanilla Extract



Vanilla Beans



23. Each of these forms of vanilla has its appeal – vanilla beans offer a more intense and flavor, while vanilla extract wins for ease of use, portability and price.

24. Vanilla bean ice cream is expected to contain vanilla extract or vanilla flavoring and vanilla beans as the only sources of flavoring, and the vanilla beans deliver a more intense and pure flavor with strong visual appeal through the “specks” of the vanilla beans used in the product.<sup>14</sup>

25. Vanilla extract and vanilla flavoring offer greater portability, consistency, ease of use and costs less than unexhausted vanilla beans.

26. Vanilla ice cream provides a subtle and smoother vanilla taste, with a tan-orange hue evoking the colors of true vanilla extract (similar to caramel in color) and the rich shades of yellow,

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<sup>14</sup> Lisa Weiss and Gale Gand, *Chocolate and Vanilla: A Baking Book*, United States: Potter/Ten Speed/Harmony/Rodale (2012) at 113-14; Louisa Clements, [Pantry 101: Vanilla extract vs. vanilla beans](#), Chat Elaine, Nov. 30, 2015; David Lebovitz, *The Perfect Scoop: Ice Creams, Sorbets, Granitas, and Sweet Accompaniments*. United States: Potter/TenSpeed/Harmony (2011) at 26.

consistent with butter and milkfat produced by this country's dairy cattle.

27. In the best tradition of American compromise, the majority of ice cream today is made in the Philadelphia-style, but flavored with vanilla extract.

## II. Vanilla is Constantly Subject to Efforts at Imitation Due to High Demand

28. The tropical orchid of the genus *Vanilla* (*V. planifolia*) is the source of the prized flavor commonly known as vanilla, defined by law as “the total sapid and odorous principles extractable from one-unit weight of vanilla beans.”<sup>15</sup>

29. Vanilla's “desirable flavor attributes...make it one of the most common ingredients used in the global marketplace, whether as a primary flavor, as a component of another flavor, or for its desirable aroma qualities.”<sup>16</sup>

30. Though the Pure Food and Drugs Act of 1906 (“Pure Food Act”) was enacted to “protect consumer health and prevent commercial fraud,” this was but one episode in the perpetual struggle against those who have sought profit through sale of imitation and lower quality commodities, dressed up as the genuine articles.<sup>17</sup>

31. It was evident that protecting consumers from fraudulent vanilla would be challenging, as E. M. Chace, Assistant Chief of the Foods Division of the U.S. Department of Agriculture's Bureau of Chemistry, noted “There is at least three times as much vanilla consumed [in the United States] as all other flavors together.”<sup>18</sup>

32. This demand could not be met by the natural sources of vanilla, leading

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<sup>15</sup> 21 C.F.R. §169.3(c).

<sup>16</sup> Daphna Havkin-Frenkel, F.C. Bellanger, Eds., *Handbook of Vanilla Science and Technology*, Wiley, 2018.

<sup>17</sup> Berenstein, 412; some of the earliest recorded examples of food fraud include unscrupulous Roman merchants who sweetened wine with lead.

<sup>18</sup> E. M. Chace, “The Manufacture of Flavoring Extracts,” *Yearbook of the United States Department of Agriculture 1908* (Washington, DC: Government Printing Office, 1909) pp.333–42, 333 quoted in [Nadia Berenstein, "Making a global sensation: Vanilla flavor, synthetic chemistry, and the meanings of purity," History of Science 54.4 \(2016\): 399-424 at 399.](#)

manufacturers to devise clever, deceptive and dangerous methods to imitate vanilla’s flavor and appearance.

33. Today, headlines tell a story of a resurgent global threat of “food fraud” – from olive oil made from cottonseeds to the horsemeat scandal in the European Union.<sup>19</sup>

34. Though “food fraud” has no agreed-upon definition, its typologies encompass an ever-expanding, often overlapping range of techniques with one common goal: giving consumers less than what they bargained for.

#### A. Food Fraud as Applied to Vanilla

35. Vanilla is considered a “high-risk [for food fraud] product because of the multiple market impact factors such as natural disasters in the source regions, unstable production, wide variability of quality and value of vanilla flavorings,” second only to saffron in price.<sup>20</sup>

36. The efforts at imitating vanilla offers a lens to the types of food fraud regularly employed across the spectrum of valuable commodities in today’s interconnected world.<sup>21</sup>

<u>Type of Food Fraud</u>	<u>Application to Vanilla</u>
➤ Addition of markers specifically tested for instead of natural component of vanilla beans	• Manipulation of the carbon isotope ratios to produce synthetic vanillin with similar carbon isotope composition to natural vanilla
➤ Appearance of <i>more</i> and/or higher quality of the	• Ground vanilla beans and/or seeds to provide visual appeal as “specks” so consumer thinks the product contains real

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<sup>19</sup> Jenny Eagle, [‘Today’s complex, fragmented, global food supply chains have led to an increase in food fraud’](#), FoodNavigator.com, Feb. 20, 2019; M. Dourado et al., [Do we really know what’s in our plate?](#), *Annals of Medicine*, 51(sup1), 179-179 (May 2019); Aline Wisniewski et al., [“How to tackle food fraud in official food control authorities in Germany.”](#) *Journal of Consumer Protection and Food Safety*: 1-10. June 11, 2019.

<sup>20</sup> Société Générale de Surveillance SA, (“SGS”), [Authenticity Testing of Vanilla Flavors – Alignment Between Source Material, Claims and Regulation](#), May 2019.

<sup>21</sup> Kathleen Wybourn, DNV GL, [Understanding Food Fraud and Mitigation Strategies](#), PowerPoint Presentation, Mar. 16, 2016.

- valued ingredient
- vanilla beans, when the ground beans have been exhausted of flavor
- Caramel to darken the color of an imitation vanilla so it more closely resembles the hue of real vanilla<sup>22</sup>
  - Annatto and turmeric extracts in dairy products purporting to be flavored with vanilla, which causes the color to better resemble the hue of rich, yellow butter
  - Tonka beans, though similar in appearance to vanilla beans, are banned from entry to the United States due to fraudulent use
  - Coumarin, a toxic phytochemical found in Tonka beans, added to imitation vanillas to increase vanilla flavor perception
- Substitution and replacement of a high quality ingredient with alternate ingredient of lower quality
- Addition of less expensive substitute ingredient to mimic flavor of more valuable component
- Compounding, Diluting, Extending
- Synthetically produced ethyl vanillin, derived from recycled paper, tree bark or coal tar, to imitate taste of real vanilla
  - “to mix flavor materials together at a special ratio in which they [sic] compliment each other to give the desirable aroma and taste”<sup>23</sup>
  - Combination with flavoring substances such as propenyl guaethol (“Vanitrope”), a “flavoring agent [, also] unconnected to vanilla beans or vanillin, but unmistakably producing the sensation of vanilla”<sup>24</sup>

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<sup>22</sup> Renée Johnson, “Food fraud and economically motivated adulteration of food and food ingredients.” Congressional Research Service R43358, January 10, 2014.

<sup>23</sup> Chee-Teck Tan, “[Physical Chemistry in Flavor Products Preparation: An Overview](#)” in Flavor Technology, ACS Symposium Series, Vol. 610 1995. 1-17.

<sup>24</sup> Berenstein, 423.

- “Spiking” or “fortification” of vanilla through addition of natural and artificial flavors including vanillin, which simulates vanilla taste but obtained from tree bark
  - Alleged injection of vanilla beans with mercury, a poisonous substance, to raise the weight of vanilla beans; *see International Flavors and Fragrances (IFF), Inc. v. Day Pitney LLP and Robert G. Rose*, 2005. Docket Number L-4486-09, Superior Court of New Jersey, Middlesex County.
  - Subtle, yet deliberate misidentification and obfuscation of a product’s components and qualities as they appear on the ingredient list
    - “ground vanilla beans” gives impression it describes unexhausted vanilla beans when actually it is devoid of flavor and used for aesthetics
    - “natural vanilla flavorings” – “-ing” as suffix referring to something *like* that which is described
    - “Vanilla With Other Natural Flavors” – implying – wrongly – such a product has a sufficient amount of vanilla to characterize the food; often containing high amount of vanillin, which must be disclosed as an *artificial* flavor when paired with vanilla
- Addition of fillers to give the impression there is more of the product than there actually is
- Ingredient List Deception<sup>25</sup>

#### B. The Use of Vanillin to Simulate Vanilla

37. The most persistent challenger to the authenticity of real vanilla has been synthetic versions of its main flavor component, vanillin.

38. First synthesized from non-vanilla sources by German chemists in the mid-1800s,

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<sup>25</sup> Recent example of this would be “evaporated cane juice” as a more healthful sounding term to consumers to identify sugar.

vanillin was the equivalent of steroids for vanilla flavor.

39. According to Skip Roskam, a professor of vanilla at Penn State University and former head of the David Michael flavor house in Philadelphia, “one ounce of vanillin is equal to a full gallon of single-fold vanilla extract.”<sup>26</sup>

40. Today, only 1-2% of vanillin in commercial use is vanillin obtained from the vanilla plant, which means that almost all vanillin has no connection to the vanilla bean.

41. Nevertheless, disclosure of this powerful ingredient has always been required where a product purports to be flavored with vanilla. *See* [Kansas State Board of Health, Bulletin, Vol. 7, 1911, p. 168](#) (cautioning consumers that flavor combinations such as “vanilla and vanillin...vanilla flavor compound,” etc., are not “vanilla [extract] no matter what claims, explanations or formulas are given on the label.”).

42. Since vanilla is the only flavor with its own standard of identity, its labeling is controlled not by the general flavor regulations but by the standards for vanilla ingredients.

43. This means that if a product is represented as being characterized by vanilla yet also contains non-vanilla vanillin, the label and packaging must declare the presence of vanillin and identify it as 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)”; *see also* 21 C.F.R. § 169.181(b), § 169.182(b) (similar declarations required for Vanilla-vanillin flavoring and Vanilla-vanillin powder).

44. This prevents consumers from being misled by products which may taste similar to real vanilla and but for consumer protection requirements, would be sold at the price of real vanilla.

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<sup>26</sup> Katy Severson, [Imitation vs. Real Vanilla: Scientists Explain How Baking Affects Flavor](#), Huffington Post, May 21, 2019.

C. “Natural Vanillins” are Produced in a Non-Natural Manner

45. The past ten years have seen the introduction of vanillin ingredients that purport to be a “natural flavor,” based on the raw material being a natural source and undergoing a natural production process.

46. However, the starting material, eugenol, is subjected to high heat and high pressure in conversion to vanillin.

47. This method is actually considered by the FDA to be a synthetic method of producing a flavor by the FDA.

48. This “natural vanillin” is produced by the ton in China, with little transparency or verification, before it is delivered to the flavor companies for blending.

49. Even if a vanillin ingredient can be labeled a “natural flavor,” when used with vanilla, it must still be declared as an artificial flavor.

D. Vanilla “WONF” (in sheep’s clothing) to Imitate Real Vanilla

50. The global shortage of vanilla beans has forced the flavor industry to “innovate[ing] natural vanilla solutions...to protect our existing customers.”<sup>27</sup>

51. These “customers” do not include the impoverished vanilla farmers who are at the mercy of global conglomerates nor consumers, who are sold products labeled as “vanilla” for the same or higher prices than when those products contained *only* vanilla.

52. According to Suzanne Johnson, vice president or research at a North Carolina laboratory, “Many companies are trying to switch to natural vanilla with other natural flavors [WONF] in order to keep a high-quality taste at a lower price.”

53. According to industry leaders like the head of “taste solutions” at Irish conglomerate

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<sup>27</sup> Amanda Del Buono, [Ingredient Spotlight](#), Beverage Industry, Oct. 3, 2016.

Kerry, flavor manufacturers must “[G]et creative” and “build a compounded vanilla flavor with other natural flavors.”

54. These compounded flavors typically exist in a “black box” and “consist of as many as 100 or more flavor ingredients,” blended together in a special ratio to complement and enhance the vanilla component.<sup>28</sup>

55. A compounded vanilla flavor “that matches the taste of pure vanilla natural extracts” can supposedly “provide the same vanilla taste expectation while requiring a smaller quantity of vanilla beans. The result is a greater consistency in pricing, availability and quality.”<sup>29</sup>

56. That high level executives in the flavor industry openly boast of their stratagems to give consumers less vanilla for the same price is a **stark contrast from when this industry engaged in self-policing its members**, *specifically* as to their use and labeling of vanilla products, and had a separate vanilla sub-group, to protect consumers against the abuses it now appears to encourage.

### III. Ice Cream Flavor Labeling

57. Daphna Havkin-Frenkel, editor of the *Handbook of Vanilla Science and Technology*, and a leading scholar and researcher on vanilla, summarized the flavoring requirements in the context of ice cream flavored by vanilla:<sup>30</sup>

There are three categories of vanilla ice cream, as defined by the FDA Standard of Identity. Vanilla ice cream Category I contains only vanilla extract. Vanilla ice cream Category II contains vanilla made up of 1 oz of synthetic vanillin per 1 gallon of 1-fold vanilla extract. Vanilla ice

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<sup>28</sup> Hallagan and Drake, FEMA GRAS and U.S. Regulatory Authority: U.S. Flavor and Food Labeling Implications, *Perfumer & Flavorist*, Oct. 25, 2018; Charles Zapsalis et al., *Food chemistry and nutritional biochemistry*. Wiley, 1985, p. 611 (describing the flavor industry’s goal to develop vanilla compound flavors “That *Seem[s]* to be Authentic or at Least Derived from a Natural Source”) (emphasis added).

<sup>29</sup> Donna Berry, [Understanding the limitations of natural flavors](#), BakingBusiness.com, Jan. 16, 2018.

<sup>30</sup> Daphna Havkin-Frenkel and Faith C. Belanger, eds., *Handbook of Vanilla Science and Technology*, Wiley, 2018 (221).

cream Category III contains synthetic ingredients.

58. Carol McBride, U.S. vanilla category manager for global flavor giant Symrise, noted these requirements and their effect on consumers: “If the flavor comes partially or fully from another source, the company must stamp ‘vanilla flavored’ or ‘artificial vanilla’ on the front of the package, a likely turnoff to consumers.”<sup>31</sup>

A. Early Ice Cream Flavoring Debate is “Stirring”

59. Before formal regulations were enacted, Congressional Hearings from the 1930s offered the legislature the opportunity to state their position on the non-misleading designation of flavors on ice cream products.

60. Unsurprisingly, the starting point for the debate was how to label vanilla ice cream flavored with vanillin obtained not from vanilla beans but from clove oil, a natural source material.

61. Why, the lobbyists, asked Congress, could they not label their products as “vanilla ice cream” if it contained vanillin from sources other than vanilla beans?

62. In response, Congressmen E.A. Kenny of New Jersey and Virgil Chapman of Kentucky inquired of the ice cream lobby’s representative, Mr. Schmidt:

Mr. Kenney: Do you not think, though, Mr. Schmidt, that if you label it vanilla ice cream, it ought to be vanilla; and if it is made with vanillin extracted from oil of cloves, you ought to label it manufactured with such vanillin?

Mr. Schmidt: Well, we, of course, do not think so. That is why we are here making our protest. We think, after all, the consuming public is accustomed to accepting as vanilla artificial vanillas.

Mr. Kenney: *We agree that Barnum educated us along that line a long time ago.*  
(emphasis added)

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Mr. Chapman: I do think that if it is chocolate it ought to be labeled "chocolate";

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<sup>31</sup> Melody M. Bomgardner, “[The problem with vanilla](#),” Chemical & Engineering News, Sept. 12, 2016.

and if it is flavored with vanillin made from oil of cloves, it ought to be labeled to show that it is flavored with vanillin made from oil of cloves; and if it is flavored with vanilla, it ought to be labeled "vanilla"; and if it is "flavored with lemon, it ought to be labeled lemon"; and if it is cherry, it ought to be labeled "cherry."

63. Later in the hearing, Mr. Chapman and another industry representative engaged over the proper declaration of flavor for ice cream:

Mr. Chapman: Do you make raspberry?

Mr. Hibben: Yes.

Mr. Chapman: And you put that on the label?

Mr. Hibben We say "raspberry ice cream."

Mr. Chapman And if it is peach, you put that on the label?

Mr. Hibben It Is peach ice cream; yes.

Mr. Chapman And If you call it vanilla, what do you put on?

Mr. Hibben We put "vanilla ice cream" on our labels. That Is what we want to continue to do. We want to put vanilla on those labels.

Mr. Chapman But you say you put in It oil of cloves instead of vanilla.

Mr. Hibben We do not use cloves. We use vanillin derived from the oil of cloves.

Mr. Chapman If you put out strawberry ice-cream, you would not want to use raspberry to make it, would you?

Mr. Hibben No; but we use vanillin, which is an ingredient of the vanilla bean and, its true to name.

Mr. Chapman Is it an extract from the vanilla bean?

Mr. Hibben It is both. It is taken both from the eugenol and the vanilla bean and is the same product. If you were a chemist you could not tell the difference, and if you were a doctor, you would say that one is just as harmless as the other.

Mr. Chapman I do not object to buying artificial vanilla ice cream if it is pure, but if it is artificial. I would like to know what I am

getting.<sup>32</sup>

64. The above highlighted portions reveal that even before ice cream standards were established, the central question for ice cream flavoring was whether the flavor source was entirely derived from the characterizing flavor – whether raspberry for raspberry ice cream, vanilla for vanilla ice cream and so on.

#### B. Ice Cream Flavoring Regulations

65. The ice cream standard of identity, 21 C.F.R. § 135.110, established in the early 1960s “provided for a system for designating characterizing flavors in ice cream which has come to be referred to as the ‘3 category flavor labeling.’” Exhibit “A,” FDA, Taylor M. Quinn, Associate Director for Compliance, Bureau of Foods, to Glenn P. Witte, International Association of Ice Cream Manufacturers, May 31, 1979 (“Quinn Letter, May 31, 1979”).

66. The requirements “recognize[s] three distinct types of ice cream, based on the use of natural and various combinations of natural and various combinations of natural and artificial flavors that characterize this food.” Exhibit “A,” Quinn Letter, May 31, 1979; *see* 21 C.F.R. § 135.110(f)(2)(i)-(iii); 21 C.F.R. § 135.110(f)(3)-(5).

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<sup>32</sup> One of the reasons for the emphasis on flavor derived from the characterizing flavor was ice cream’s status as a high value, expensive product, made mainly from milk and cream. The use of ersatz flavoring lowered the quality of an otherwise valued item.

### Vanilla Ice Cream Labeling Quick Chart

<u>Category</u>	<u>Label Diagram</u>	<u>Flavor Source</u>	<u>Authority</u> <u>(21 C.F.R.)</u>
I	["characterizing flavor"] + ["ice cream"] → "Vanilla Ice Cream" or "Strawberry Ice Cream"	Vanilla Beans	§135.110(f)(2)(i)
II	["characterizing flavor"] + ["flavored"] + ["ice cream"] → "Vanilla Flavored Ice Cream" or "Peach Flavored Ice Cream"	Vanilla Beans; Non-Vanilla Beans	§135.110(f)(2)(ii)
III	["artificial" or "artificially flavored"] + ["characterizing flavor"] + ["ice cream"] → "Artificially Flavored Vanilla Ice Cream" or "Artificially Flavored Strawberry Ice Cream"	Vanilla Beans; Non-Vanilla Beans	§135.110(f)(2)(iii)

67. The key distinction between labeling flavors in ice cream compared to other foods is in the meaning of "natural flavor."

68. In ice cream, "natural flavor" refers to flavor derived only from the characterizing flavor, while "artificial flavor" refers to flavors derived from sources other than the characterizing flavor.

69. For a category 1 ice cream, which "contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., 'vanilla,' in letters not less than one-half the height of the letters used in the words 'ice cream.'" 21 C.F.R. §135.110(f)(2)(i); *see* Quinn Letter, May 31, 1979 ("the designation of a characterizing flavor for category I ice cream is based on the premise that only natural flavor derived from the product whose flavor is simulated may be used.").

70. Category II and III both may contain a natural characterizing flavor and artificial flavor simulating it, but differ based on whether the natural characterizing flavor predominates. *See* 21 C.F.R. §135.110(f)(2)(ii) ("Category II") ("If the food contains both a natural characterizing

flavor and an artificial flavor simulating it, and if the natural flavor predominates”); 21 C.F.R. §135.110(f)(2)(iii) (“Category III”) (“If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates”); Exhibit “A,” Quinn Letter, May 31, 1979 (“The flavor designation for category II ice cream is on the basis that the product contains both natural and artificial flavor, but the natural flavor predominates, whereas in category III the artificial flavor predominates.”).

71. The non-vanilla flavor which simulates the natural characterizing vanilla flavor is deemed to predominate when “the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent.” *See* 21 C.F.R. §135.110(f)(5)(i); Exhibit “B,” FDA, R.E. Newberry, Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods, to Daniel P. Thompson, October 30, 1979 (“Newberry Letter, October 30, 1979”) (a non-vanilla flavor “is deemed to simulate [resemble or reinforce] vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream...such a product would come under category III and have to be labeled as ‘artificial vanilla.’”).

72. The requirements – and resulting consumer expectations for almost fifty years – are clear: “the flavor agent for vanilla ice cream (a category I product) is limited to vanilla bean and/or flavor derived from vanilla beans.” Exhibit “A,” Quinn Letter, May 31, 1979; *see also* Exhibit “C,” Summers Letter, April 10, 1979 (“A product identified as ‘Vanilla Ice Cream’ is subject to the category 1 ice cream requirements and, therefore, must contain only the characterizing flavor derived from vanilla beans,” “the standard for ice cream does not provide for the label designation of “With other [natural] flavors” (WONF).”).

#### IV. Flavoring Regulations for Ice Cream are Distinct from Other Foods

73. The flavor regulations for ice creams are separate from the general flavor regulations for other foods. *Compare* 21 C.F.R. § 135.110(f)(2)-(5) with 21 C.F.R. § 101.22; Exhibit “A,” Quinn Letter, May 31, 1979 (“The general flavor regulations are not applicable to this standardized food.”).

74. The ice cream flavor designations were “established long before the development of the general flavor regulations published under 21 CFR 101.22.” Exhibit “C,” FDA, J.L. Summers, Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods, April 10, 1979 to David B. Daugherty (“Summers Letter, April 10, 1979”) (“Consequently, the labeling requirements for the declaration of flavors in the name of ice cream are specifically provided for by the standard and is separate and apart from the general flavor regulations.”).<sup>33</sup>

75. Under 21 C.F.R. § 101.22(a)(3), “natural flavor” is defined generally as “the essential oil, oleoresin, essence or extractive...which contains the flavoring constituents” from a natural source such as plant material and can refer to combinations of natural flavors.

76. “Artificial flavor” in contrast is any substance whose function is to impart flavor that is not derived from a natural source. *See* 21 C.F.R. § 101.22(a)(1).

77. For the purposes of designating the type of ice cream on the front label, whether a flavor complies with the general definition of natural flavor in other regulations has no relevance. Exhibit “C,” Summers Letter, April 10, 1979 (“A product identified as ‘Vanilla Ice Cream’ is subject to the category I ice cream requirements and, therefore, must contain only the characterizing flavor derived from vanilla beans.”); Exhibit “A,” Quinn Letter, May 31, 1979 (“It is our understanding that there are available in the market place, natural flavoring compounds that resemble, simulate and/or enhance vanilla flavor but are not derived from vanilla bean. These

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<sup>33</sup> Compare 21 C.F.R. § 135.110(f)(2)-(5) with 21 C.F.R. § 101.22.

flavor compounds would not comply with the intent of the flavor provisions of Category I ice cream”).

78. This is because 21 C.F.R. § 135.110(f) “makes no provision for any natural flavors other than natural characterizing flavors.” Exhibit “D,” Joseph Hile, Associate Commissioner for Regulatory Affairs, February 9, 1983, Formal Advisory Opinion at p. 9 (“Hile Letter, February 9, 1983”) (“FDA must treat all natural flavors that simulate the characterizing flavor as artificial flavors when deciding what name should appear on the principal display panel”).<sup>34</sup>

79. At best, “[N]atural flavors not derived from vanilla beans may be used in combination with the standardized items included under 21 CFR 169 (vanilla-vanillin extract or vanilla-vanillin flavoring) for category II vanilla flavored ice cream provided that the flavoring contributed by or derived from the vanilla beans predominates.” Exhibit “E,” FDA, Quinn to Kenneth Basa, August 22, 1979 (“Quinn Letter, August 22, 1979”).

#### V. The Products are Misleading Because they Contain Non-Vanilla Flavoring

80. The front label statements of “Vanilla Bean Ice Cream” and “Vanilla Bean” are understood by consumers to identify a product where (1) vanilla is the characterizing flavor, (2) vanilla is contained in a sufficient amount to flavor the product, (3) the flavor is derived from vanilla extract or vanilla flavoring *and* unexhausted vanilla beans, (4) no other flavors in the simulate, resemble, reinforce, or enhance flavoring from vanilla and (5) vanilla is the exclusive source of flavor.

81. The front label states “Ice Cream Made with Natural Flavors” which fails to adequately inform consumers that the Products actually contain “non-vanilla flavors.”

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<sup>34</sup> 21 C.F.R. § 135.110(f) was previously 21 C.F.R. § 135.110(e).

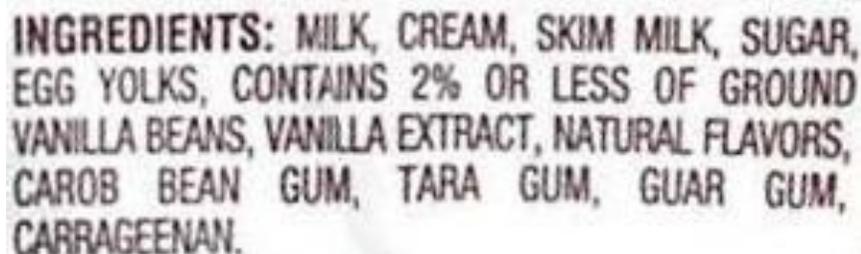
82. The Product’s use of the term “Natural Flavors” is outside of a regulatory shield provided by the general flavoring regulations because this term’s meaning in the context of ice cream is distinct, which consumers have come to expect over decades of non-misleading ice cream descriptions.

83. Had the Product sought to adequately inform consumers of the presence of *non-vanilla* flavors, it could have been described as “vanilla bean flavored ice cream” or another such term, depending on criteria currently known only to defendant (i.e., components of the “natural flavor” ingredient).

A. Ingredient List Declaration of “Natural Flavor” Reveals Flavor is Not Exclusively Vanilla

84. The ingredient list reveals the Product contains non-vanilla flavors because “Natural Flavors” is declared.

Ingredient List



INGREDIENTS: MILK, CREAM, SKIM MILK, SUGAR, EGG YOLKS, CONTAINS 2% OR LESS OF GROUND VANILLA BEANS, VANILLA EXTRACT, NATURAL FLAVORS, CAROB BEAN GUM, TARA GUM, GUAR GUM, CARRAGEENAN.

**INGREDIENTS:** MILK, CREAM, SKIM MILK, SUGAR, EGG YOLKS, CONTAINS 2% OR LESS OF GROUND VANILLA BEANS, VANILLA EXTRACT, **NATURAL FLAVORS**, CAROB BEAN GUM, TARA GUM, GUAR GUM, CARRAGEENAN.

85. Where a product is labeled vanilla bean ice cream without any or adequate qualification, but the ingredient list identifies “natural flavor” in addition to exclusively vanilla flavoring ingredients such as vanilla extract, it means (1) the flavoring in the food is not exclusively from vanilla, (2) the non-vanilla flavor may contain vanillin, not disclosed as an artificial flavor when paired with vanilla and (3) the non-vanilla flavors simulate, resemble and reinforce the

vanilla flavor.

86. The ingredient list does not *only* declare the common or usual names of the exclusively vanilla ingredients, *viz*, Vanilla Extract, Concentrated Vanilla Extract, Vanilla Flavoring and Concentrated Vanilla Flavoring. *See* 21 C.F.R. §§ 169.175 to 169.178.

87. These exclusively vanilla ingredients – vanilla flavoring, vanilla extract, etc. – differ only in that the former is at least thirty-five (35) percent ethyl alcohol while the latter is less than this amount.<sup>35</sup>

88. Because ice cream is a standardized food and the vanilla ingredients are subject to their own standards of identity, the designation of these vanilla ingredients is controlled by 21 U.S.C. §343(g) – they are required to be specifically declared:<sup>36</sup>

A food shall be deemed to be misbranded –

(g) Representation as to definition and standard of identity

If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 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 (other than spices, flavoring, and coloring) present in such food.

B. “Natural Flavor” is Non-Vanilla Flavor, an Admission the Product Fails to Deliver Only Vanilla Flavor

89. Though the Product lists “Vanilla Extract” and “Natural Flavors” separately and consecutively in the ingredient list, it is probable that these ingredients were added to the ice cream mix *together*, in one flavoring package.

90. When companies use vanilla and non-vanilla flavors in a product, they are often purchased in one package or container.

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<sup>35</sup> 21 C.F.R. §§ 169.175 (Vanilla extract.), 169.177 (Vanilla flavoring.); also concentrated versions of each of these.

<sup>36</sup> 21 U.S.C. § 343(g)(2) read with 21 C.F.R. § 135.110(f)(2)(i) and 21 C.F.R. §§ 169.175 – 169.178.

91. The reasons for this include (1) having to manage fewer suppliers, (2) formulation and blending of the flavor components to enhance and modify other components or product ingredients, (4) consistency within the product batches the flavor is added to, (5) volatile nature of flavoring constituents, (6) the ability to make misleading representations with respect to a product's flavor and ingredients and (7) ease of use.

92. Where a multicomponent ingredient is included in a food, it can be declared by (1) indicating the common or usual name of the ingredient with the components declared in parentheses in order of predominance by weight and (2) by splitting the components of the ingredient and incorporating them into the ingredient list in order of predominance by weight.<sup>37</sup>

93. When a food manufacturer receives a flavor component from a flavor supplier that consists of two or more natural flavor ingredients, it can be labeled by declaring each ingredient by its common or usual name such as "strawberry flavor, banana flavor."<sup>38</sup>

94. Flavorings are not subject to the provisions which allow for the components of an ingredient to be incorporated into the statement of ingredients in order of predominance by weight such that when "strawberry flavor, banana flavor" is added to a fabricated food, it will be designated as "natural flavor."

95. However, on the labels for foods intended for consumers, this flavor combination is required to be labeled "natural flavor," as long as the flavor is not exclusively vanilla extract or vanilla flavoring – in which case the vanilla standards of identity would apply.<sup>39</sup>

96. One of the reasons for the exception requiring designation of non-exclusively vanilla

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<sup>37</sup> 21 C.F.R. § 101.4(b)(2).

<sup>38</sup> 21 C.F.R. § 101.22(g)(2).

<sup>39</sup> See 21 C.F.R. § 101.4(b)(1) ("Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of 101.22.") with 21 C.F.R. § 101.22(h)(1) ("The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way: (1) Spice, natural flavor, and artificial flavor may be declared as "spice", "natural flavor", or "artificial flavor", or any combination thereof, as the case may be.")

ingredients to be labeled as “natural flavor” is because components of a flavor are often highly concentrated.

97. Consider a flavor containing real strawberry ingredients – the flavoring strength of this component would be orders of magnitude *less* than flavor compounds – formulated from strawberries or from other natural sources.

98. One drop of the concentrated flavor molecules would be equivalent of an entire strawberry.

99. If companies were allowed to list components of flavor by the standard order of predominance by weight, strawberries would appear ahead of “natural flavor” on the ingredient list and consumers would be deceived that the product’s flavoring is from real strawberries, when in fact it was from the highly concentrated flavor compounds – either from strawberries or other natural sources.

100. The Product’s declaration of “Vanilla Extract, Natural Flavors” does not have any significance as to the amount of these ingredients in the Product by weight because “[T]he descending order of predominance requirements of [21 C.F.R. § 101.4(a)(1)] do not apply to ingredients present in amounts of 2 percent or less by weight.” *See* 21 C.F.R. § 101.4(a)(2).

101. Nevertheless, the Product is misleading because it appears what is a “Vanilla With Other Natural Flavors” ingredient was subject to “ingredient splitting.”

102. The ingredients – “Vanilla Extract, Natural Flavors” are plausibly and credibly the compounded Vanilla WONF ingredient that contains potentiators and enhancers, like maltol, and often contains vanillin.

## VI. Product Analysis Would Reveal or Reveals Presence of Non-Vanilla Flavors

103. Gas chromatography-mass spectrometry (“GC-MS”) can determine the presence of

flavor compounds typically associated with vanilla (“marker compounds”).

104. The four marker compounds for vanilla from real vanilla beans are present in consistent amounts, identified below.

<u>Compounds</u>	<u>Percent Present in Vanilla Beans</u>
vanillin	1.3-1.7 %
p-hydroxybenzaldehyde	0.1%
vanillic acid	0.05%
p-hydroxybenzoic acid	0.03%

105. GC-MS analysis of the Products is likely to show mismatched ratios of vanilla marker compounds and/or the non-detection of certain of said compounds.

106. This would be due to the highly concentrated “Natural Flavors” ingredient, which would compensate for a *de minimis* amount of actual vanilla ingredient – extract or flavoring.

## VII. Misleading Use and/or Description of Vanilla Beans

107. The Products are misleading with respect to the ground vanilla beans listed on the ingredient list.

108. After all of the flavor has been extracted from vanilla beans, the exhausted, or spent beans achieve a secondary usage.

109. The first (re-)use of the spent vanilla beans involves a drying, chopping and sining process and then are added to a product “strictly in a cosmetic manner, as they are flavorless.”<sup>40</sup>

110. The second usage involves infusing the exhausted beans with synthetic vanillin or other flavoring substances prior to being incorporated into food.

111. This second method is more misleading than the first because the spent beans now

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<sup>40</sup> Chat Nielsen, Jr., *The Story of Vanilla*, p. 15.

have flavor, but unbeknownst to consumers, it is not the flavor which is present in a vanilla bean that has not been exhausted.

112. The presence of “ground vanilla beans” on the Product’s ingredient list is deceptive and misleading because (i) these ground vanilla beans are devoid of flavor and (ii) the ingredient name fails to indicate this by accurately describing it as “spent (or exhausted) ground vanilla beans.”

113. The use of the term “ground vanilla beans” does not imply or disclose the vanilla beans are already spent or exhausted since unexhausted vanilla beans may be “ground” prior to inclusion in a product.

114. Consumers will see vanilla beans in the product images, descriptive text and ingredient list and reasonably expect the Product contains a greater amount and an additional type or form of vanilla when it does not.

115. It is plausible and likely that the “ground vanilla beans” on the ingredient list of the Products are exhausted or spent for several reasons.

116. First, in a mass produced, private label product, the inclusion of ground vanilla beans would result in inconsistent flavoring from batch to batch.

117. Second, the use of ground vanilla beans not devoid of flavor requires unique equipment and processes.

118. Currently, only a handful of renowned, regional companies, such as Graeters of Ohio, which use actual, non-exhausted vanilla beans in their ice cream products.

119. The Products here are made by a large dairy products manufacturer making it less likely it can employ the practices of Graeters on a large scale.

120. Third, the global scarcity of vanilla beans means that almost all vanilla beans are

used for extraction purposes.

121. The liquid extract form has more uses than unexhausted vanilla beans, and is easier to sell.

122. Fourth, numerous industry reports have taken notice of the proliferation of vanilla beans – referred to in some publications as seeds – on the market.

123. Cook’s Vanilla, an established vanilla supplier, has seen “an inordinate increase in demand for seeds, even while demand for pure vanilla extract has dropped,”

124. The last two years, companies have requested:

thousands of pounds of vanilla bean seeds accompanying much smaller orders for blended (Category II) vanillas made from both artificial and pure extract.

The mismatch between demand for vanilla seeds and vanilla extract makes it impossible to supply enough seeds. Since the seeds are a small by-product of vanilla extract, and we cannot obtain them unless we buy (extremely expensive) whole vanilla bean pods and make (extremely expensive) pure vanilla extract from them.

Even the cheapest, lowest-grade vanilla bean pods cost more than \$100 per pound. So it unequivocally makes no sense to purchase vanilla bean pods for the sole purpose of getting their seeds.

Which means that some of the seeds you see are not vanilla bean seeds at all. Just as with pure vanilla extract, we suspect significant adulteration of exhausted vanilla bean seeds in the industry.<sup>41</sup>

125. Aust & Hachman, a vanilla trading company, recently noted that “[T]he demand for exhausted or spent vanilla, (vanilla waste after extraction), and vanilla seeds sifted from this material has exploded over the last 12 months” because the amount of actual vanilla has been at low levels, in part due to climactic conditions.<sup>42</sup>

126. Fifth, the Product’s ingredient list contains two other ingredients which, by

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<sup>41</sup> Cook’s Blog, [Vanilla Bean Seeds: A Troubling New Trend](#), June 13, 2019.

<sup>42</sup> [Aust & Hachman Canada, May 2019 Update](#).

definition, *only* impart flavor – vanilla extract and natural flavors.

127. Therefore, the vanilla beans – part of the product name and conspicuous in the scoop of ice cream on the front label – do not need to provide flavor, since other ingredients fulfill that function.

VIII. Vanilla Bean Ice Cream Products are Misleading Because They are Labeled and Named Similar to Other Products

128. Competitor brands to defendant's Products are labeled as or containing vanilla bean ice cream, and are not misleading because they only contain flavoring derived from vanilla beans.

A. Vanilla Bean Ice Cream Product of Competitor and Defendant

129. The following is an example of a Vanilla Bean Ice Cream of defendant and a competitor.

Competitor Product

Madagascar Vanilla Bean Ice Cream



Product

Vanilla Bean Ice Cream



INGREDIENTS: CREAM, MILK, CANE SUGAR, SKIM MILK, EGGS, VANILLA BEAN, VANILLA EXTRACT, CAROB BEAN GUM, GUAR GUM.

**INGREDIENTS:** CREAM, MILK, CANE SUGAR, SKIM MILK, EGGS, VANILLA BEAN, VANILLA EXTRACT, CAROB BEAN GUM, GUAR GUM.

INGREDIENTS: MILK, CREAM, SKIM MILK, SUGAR, EGG YOLKS, CONTAINS 2% OR LESS OF GROUND VANILLA BEANS, VANILLA EXTRACT, NATURAL FLAVORS, CAROB BEAN GUM, TARA GUM, GUAR GUM, CARRAGEENAN.

**INGREDIENTS:** MILK, CREAM, SKIM MILK, SUGAR, EGG YOLKS, CONTAINS 2% OR LESS OF GROUND VANILLA BEANS, VANILLA EXTRACT, NATURAL FLAVORS, CAROB BEAN GUM, TARA GUM, GUAR GUM, CARRAGEENAN.

130. The competitor product lists only “Vanilla Bean” and “Vanilla Extract” on its ingredient list.

131. The competitor product does not need to include “Natural Flavors” because the flavoring comes only from real, unexhausted vanilla beans and vanilla extract.

132. The competitor product’s listing of vanilla beans as an ingredient and in the name of their products is truthful and non-misleading because that product does not declare “natural flavors” and the manufacturer’s transparent business practices has removed any doubt about its authenticity in disclosing its methods for including non-exhausted vanilla beans.

## IX. Conclusion

133. The flavor houses and the failure of the flavor industry to engage in its prior role of self-policing industry are culpable for the above-referenced consumer deception.

134. This self-policing role was discarded at approximately the same time the flavor trade group disbanded its vanilla sub-group, tasked exclusively with preventing the consumer fraud described here.

135. Even though the flavor industry and flavor companies do not manufacture the Product, they supply its most valuable and important component – the flavoring.

136. The proportion of the characterizing component, vanilla – from vanilla beans and vanilla extract or vanilla flavoring – have a material bearing on price or consumer acceptance of the Products because they are more expensive and desired by consumers.

137. The Products are misleading because they do not contain the amount, type and percentage of vanilla beans and vanilla extract or vanilla flavoring as a component of the flavoring in the ice cream, which is required and consistent with consumer expectations.

138. Had plaintiff and class members known the truth about the Products, they would not have bought the Product or would have paid less for it.

139. The Product contains other representations which are misleading and deceptive.

140. As a result of the false and misleading labeling, the Product is sold at a premium price, approximately no less than \$5.99 per 473 ML, excluding tax – compared to other similar products represented in a non-misleading way.

#### Jurisdiction and Venue

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

142. 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).

143. Upon information and belief, the aggregate amount in controversy is more than \$5,000,000.00, exclusive of interests and costs.

144. This is a reasonable assumption because defendant’s Product is sold in thousands of stores across all 50 states.

145. Plaintiff Lorenzo Benites is a citizen of New York.

146. Defendant 7-Eleven, Inc. is a Texas corporation with a principal place of business in Irving, Dallas County, Texas.

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

148. Venue is proper because plaintiff and many class members reside in this District and defendant does business in this District and State.

149. A substantial part of events and omissions giving rise to the claims occurred in this District.

#### Parties

150. Plaintiff Lorenzo Benites is a citizen of Queens County, New York.

151. Defendant is a Texas corporation with a principal place of business in Irving, Dallas County, Texas.

152. During the class period, plaintiff purchased one or more of the Product identified herein, in his district and/or state, for personal use, consumption or application based on the above representations, for no less than the price indicated, *supra*, excluding tax,

153. Plaintiff would consider purchasing the Product again if there were assurances that the Products' representations were no longer misleading.

#### Class Allegations

154. The classes will consist of all consumers in all 50 states with sub-classes for the individual states and nationwide classes.

155. Common questions of law or fact predominate and include whether the representations were likely to deceive reasonable consumers and if plaintiff and class members are entitled to damages.

156. Plaintiff's claims and basis for relief are typical to other members because all were subjected to the same representations.

157. Plaintiff is adequate representative because his or her interests do not conflict with other members.

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

159. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest.

160. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to adequately and fairly protect class members' interests.

161. Plaintiff seeks class-wide injunctive relief because the practices continue.

New York General Business Law ("GBL") §§ 349 & 350  
and Consumer Protection Statutes of Other States and Territories

162. Plaintiff asserts causes of action under the consumer protection statutes of New York, General Business Law ("GBL") §§ 349 & 350.

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

164. Plaintiff and class members desired to purchase products which were as described by defendant and expected by reasonable consumers, given the product type.

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

166. Defendant's conduct was misleading, deceptive, unlawful, fraudulent, and unfair because it gives the impression to consumers the Products contain sufficient amounts of the highlighted ingredient, vanilla beans, to characterize the taste or flavor of the Products.

Negligent Misrepresentation

167. Plaintiff incorporates by reference all preceding paragraphs.

168. Defendant misrepresented the substantive, quality, compositional, organoleptic and/or nutritional attributes of the Products through misrepresenting the characterizing properties of the flavoring ingredient, vanilla beans.

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

170. 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 or service type.

171. The representations took advantage of consumers' (1) cognitive shortcuts made at the point-of-sale and (2) trust placed in defendant, a well-known and respected brand in this sector.

172. Plaintiff and class members reasonably and justifiably relied on these negligent misrepresentations and omissions, which served to induce and did induce, the purchase of the Products.

173. Plaintiff and class members would not have purchased the Products 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.

174. Plaintiff incorporates by reference all preceding paragraphs.

175. Defendant manufactures and sells products which contain the identified characterizing ingredients and/or flavors, in amounts sufficient to independently characterize the Products, which are desired by consumers and does not contain flavor from other ingredients.

176. The Products warranted to Plaintiff and class members that they possessed

substantive, functional, nutritional, qualitative, compositional, organoleptic, sensory, physical and other attributes which they did not due to the flavoring not consisting entirely of vanilla from vanilla beans and vanilla extract or vanilla flavoring.

177. Defendant had a duty to disclose and/or provide a non-deceptive description and identification of the Products.

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

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

180. The Products did not conform to their affirmations of fact and promises due to defendant's actions and were not merchantable.

181. Plaintiff and class members relied on defendant's claims, paying more than they would have.

#### Fraud

182. Plaintiff incorporates by references all preceding paragraphs.

183. Defendant's purpose was to sell products which purported to contain valuable and desired characterizing ingredients and/or flavors, and represent the Products were exclusively flavored by the designated ingredients and contained sufficient independent amounts of same.

184. Defendant's fraudulent intent is evinced by its failure to accurately indicate the Products contained non-vanilla flavoring in place of actual, non-exhausted vanilla bean component in the Products.

185. Plaintiff and class members observed and relied on defendant's claims, causing them to pay more than they would have, entitling them to damages.

Unjust Enrichment

186. Plaintiff incorporates by reference all preceding paragraphs.

187. Defendant obtained benefits and monies because the Products were not as represented and expected, to the detriment and impoverishment of Plaintiff and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

**WHEREFORE**, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying Plaintiff as representative and 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 and/or refrain from the challenged representations, restitution and disgorgement for members of the State Subclasses pursuant to the consumer protection laws of their States;
4. Awarding monetary damages and interest, including treble and punitive damages, pursuant to the common law and consumer protection law claims, and other statutory claims;
5. Awarding costs and expenses, including reasonable fees for plaintiff's attorneys and experts; and
6. Other and further relief as the Court deems just and proper.

Dated: November 20, 2019

Respectfully submitted,

Sheehan & Associates, P.C.

/s/Spencer Sheehan

Spencer Sheehan

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*-and-*

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1:19-cv-06551  
United States District Court  
Eastern District of New York

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Lorenzo Benites, individually and on behalf of all others similarly situated,

Plaintiff

- against -

7-Eleven, Inc.,

Defendant

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Complaint

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Sheehan & Associates, P.C.  
505 Northern Blvd., #311  
Great Neck, NY 11021  
Tel: (516) 303-0552  
Fax: (516) 234-7800

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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: November 20, 2019

/s/ Spencer Sheehan  
Spencer Sheehan

# EXHIBIT “A”



## Food and Drug Administration

20

MAY 31 1979

Mr. Glenn P. Witte  
International Association of  
Ice Cream Manufacturers  
910 Seventeenth Street, N.W.  
Washington, D.C. 20006

Dear Mr. Witte:

This is in reply to your letter of May 11, 1979 concerning the labeling of ice cream containing naturally derived non-vanilla bean flavoring compounds to enhance, simulate and/or intensify flavor derived from vanilla bean.

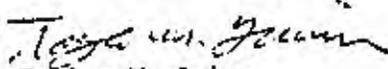
The federal standard for ice cream 21 CFR 135.110, has, since its promulgation in the early 1960's, provided for a system for designating characterizing flavors in ice cream which has come to be referred to as the "3 category flavor labeling". The system recognizes three distinct types of ice cream, based on the use of natural and various combinations of natural and artificial flavors that characterize this food. The designation of a characterizing flavor for category I ice cream is based on the premise that only natural flavor derived from the product whose flavor is simulated may be used. The flavor designation for category II ice cream is on the basis that the product contains both natural and artificial flavor, but the natural flavor predominates, whereas in category III the artificial flavor predominates.

The definition and standard of identity as it pertains to the designation of flavors in the identity statement for ice cream was established long before the development of the general flavor regulations published under 21 CFR 101.22. Consequently, the labeling requirements for the declaration of flavors in the name of ice cream are specifically provided for by the standard. The general flavor regulations are not applicable to this standardized food.

While the requirements for flavor designation for category I ice cream are not all inclusive as written, the historical and current interpretation I believe is that the flavor agent for vanilla ice cream (a category I product) is limited to vanilla bean and/or flavor derived from vanilla beans.

It is our understanding that there are available in the market place, natural flavoring compounds that resemble, simulate and/or enhance vanilla flavor but are not derived from vanilla bean. These flavor compounds would not comply with the intent of the flavor provisions of Category I ice cream. However, they would qualify for category II labeling (vanilla flavored ice cream) provided that the flavor derived from vanilla beans predominates.

Sincerely yours,

  
Taylor M. Quinn  
Associate Director  
for Compliance  
Bureau of Foods

# EXHIBIT “B”



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
WASHINGTON, D.C. 20204

October 30, 1979

Mr. Daniel P. Thompson  
Bonner, Thompson, O'Connell & Gaynes  
900 Seventeenth Street, N.W.  
Washington, D.C. 20006

Dear Mr. Thompson:

During our conference with you and Mr. Anthony Filandro, Vice President of Virginia Dare Extract Company, Inc., of Brooklyn, New York, on October 19, 1979 you raised a question concerning category II vanilla flavor in ice cream. You requested that we reply to your question in writing.

The ice cream standard under 21 CFR 135.110(e)(5)(i) states that an artificial flavor simulating the characterizing flavor shall be deemed to predominate in the case of vanilla beans or vanilla extract used in combination with vanillin, if the amount of vanillin used is greater than one ounce per unit of vanilla constituent as that term is defined in §169.3(c). Consequently, an ice cream manufacturer could not call his product "vanilla flavored ice cream" (Category II) if the flavor consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source (which simulates, resembles, or reinforces the vanilla flavor) is added to the product. The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream. Ice cream made from such a product would come under category III and have to be labeled as "artificial vanilla".

We hope this adequately answers the question you raised at our meeting.

Sincerely yours,

*R. E. Newberry*  
R. E. Newberry  
Assistant to the Director  
Division of Regulatory Guidance  
Bureau of Foods

# EXHIBIT “C”



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
WASHINGTON, D.C. 20204  
April 10, 1979

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Mr. David B. Daugherty, President  
Zink & Triest Company, Inc.  
P.O. Box 321  
Montgomeryville, Pa. 18938

Dear Mr. Daugherty:

This is in reply to your letter of 3/16/79 concerning the use of a flavor blend (other natural flavors) in category I ice cream.

The definition and standard of identity for ice cream (21 CFR 135.110) as it pertains to the designation of flavors in the identity statement for this food was established long before the development of the general flavor regulations published under 21 CFR 101.22. Consequently, the labeling requirements for the declaration of flavors in the name of ice cream are specifically provided for by the standard and is separate and apart from the general flavor regulations. Therefore, the standard for ice cream does not provide for the label designation of "With other flavors" (WONF).

A product identified as "Vanilla Ice Cream" is subject to the category I ice cream requirements and, therefore, must contain only the characterizing flavor derived from vanilla beans.

We hope this information is helpful.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "J. L. Summers".

J. L. Summers  
Assistant to the Director  
Division of Regulatory Guidance  
Bureau of Foods

## EXHIBIT “D”



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

FEB -9 1983

Daniel R. Thompson, Attorney at Law  
Bonner, Thompson, O'Connell, Gaynes & Middlekauff  
900 Seventeenth Street, N.W.  
Washington, D.C. 20006

Stephen A. Weitzman, Attorney at Law  
Weitzman & Rogal  
1320 Nineteenth Street, N.W.  
Washington, D.C. 20036

Re: Labeling of Ice Cream Products  
Flavored with Vanilla Docket  
No. 80A-0209

Dear Sirs:

On May 16, 1980, the Flavor and Extract Manufacturers' Association (FEMA) filed a request for an advisory opinion regarding the labeling of ice cream products flavored with vanilla. FEMA presented a letter from a Bureau of Foods employee (the Newberry letter) and requested that the agency confer advisory opinion status on the letter's interpretation of the labeling requirements in the ice cream regulation (21 CFR 135.110). I signed an advisory opinion granting this request on February 12, 1981.

The ice cream regulation establishes a three-tiered system of labeling that is based on the amount of the natural characterizing flavor a product contains, and on whether, if the product contains both a natural characterizing flavor and an artificial flavor that simulates it, the natural characterizing flavor predominates. Under this system, natural vanilla flavor predominates, and ice cream can be labeled as "vanilla flavored," when the product contains one ounce of vanillin per unit of vanilla constituent. The advisory opinion sets forth FDA's view that when any flavor from a non-vanilla bean source that simulates vanilla is added to such a product, the natural flavor no longer predominates, and the product can no longer be labeled "vanilla flavored."

On February 23, 1981, David Michael & Co. (the objector) wrote to Secretary Schweiker and objected to this advisory opinion. On February 27, 1981, the agency stayed the opinion

*Ice cream,*

*Labeling -*

*Vanilla Flavoring*

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to consider the objection and to provide the objector with an opportunity to submit additional material.

I have now fully considered the issues raised by the advisory opinion and by the objection. I have carefully reviewed the extensive memoranda submitted by both the objector and FEMA, the attachments to these memoranda, and the written comments of the International Association of Ice Cream Manufacturers (IAICM). I have also met with representatives of the objector, IAICM, and FEMA.

As a result of my deliberations, for the reasons discussed below, I have decided to reaffirm the February 12, 1981 advisory opinion.

I. The Advisory Opinion Is An Interpretative Rule And Therefore Not Subject to Section 701(e) of the Food, Drug, and Cosmetic Act or to the Administrative Procedure Act

The objector contends that the advisory opinion effectively amends 21 CFR 135.110(e)(2)(ii) to prohibit the use of non-characterizing natural ingredients in "vanilla flavored" ice cream. Objector's April 6, 1981 submission, p. 35. The objector argues that the opinion thus was improperly issued because a standard of identity established under section 401 of the Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 341, can only be amended after compliance with section 701(e) of that statute, 21 U.S.C. 371(e).

The objector is incorrect for two reasons. First, as will be discussed in more detail below, the advisory opinion deals only with the effect on ice cream labeling of the use of flavoring ingredients that simulate the characterizing flavor. It has no bearing on the labeling of ice cream that contains flavors that do not simulate the characterizing flavor.

Second, and more importantly, under the test established in Gibson Wine Co. v. Snyder, 194 F.2d 329 (D.C. Cir. 1952), the advisory opinion is an interpretative rule. In Gibson Wine Co., *supra*, 194 F.2d at 331, the court stated:

Generally speaking, it seems to be established that "regulations," "substantive rules" or "legislative rules" are those which create law, usually implementary to an existing law; whereas interpretative rules are statements as to what

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the administrative officer thinks the statute or regulation means.

See also Cabais v. Egger, 690 F.2d 234, 238 (D.C. Cir. 1982). The February 12, 1981 advisory opinion presents the agency's view on how 21 CFR 135.110(e)(5)(i) requires a manufacturer to label a product that contains flavor consisting of one ounce of vanillin per unit of vanilla constituent plus any amount of a flavor from a non-vanilla source that simulates vanilla. It does not make any change in 21 CFR 135.110(e)(5)(i).

In the preamble to FDA's proposed procedural regulations (40 FR 40682 (September 3, 1975)), the agency anticipated the situation presented here and specifically stated that whether the labeling of a product is consistent with the agency's regulations would be an appropriate subject for an advisory opinion. 40 FR 40695. Thus, the February 21, 1981 advisory opinion is an interpretative rule and is not subject to the provisions of 21 U.S.C. 371(e). (As an interpretative rule, the advisory opinion is also exempt from the provisions of the Administrative Procedure Act (APA). 5 U.S.C. 553(b)(B).)

The cases cited by the objector in its April 16, 1981 submission (pp. 29-34) are not to the contrary. Both Guardian Federal Savings & Loan v. Federal Savings & Loan Insurance Corp., 589 F.2d 658, 644 (D.C. Cir. 1978) and Chamber of Commerce of United States v. OSHA, 636 F.2d 464, 469 (D.C. Cir. 1980) utilize the test enunciated in Gibson Wine Co. v. Snyder, *supra*. Noel v. Chapman, 508 F.2d 1023 (2d Cir.), *cert. denied* 425 U.S. 824 (1975) and Parco v. Norris, 426 F.Supp. 976 (E.D. Pa. 1977) are not relevant. They relate to the distinction between general statements of policy and substantive rules and not to the distinction between interpretative and substantive rules. Finally, even if an agency action has substantial impact, it is still not subject to notice and comment rulemaking if, like the February 12, 1981 advisory opinion, it is otherwise expressly exempt under the APA. Cabais v. Egger, *supra*, 690 F.2d at 237.

Therefore, the February 12, 1981 opinion is not a substantive regulation and can properly be issued as an advisory opinion by FDA.

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## II. The Advisory Opinion Was Issued In Accordance With Appropriate Procedures

The objector has charged that even if the February 12, 1981 advisory opinion is an advisory opinion, it was issued in contravention of FDA's procedures on advisory opinions, the President's moratorium on regulations, and Executive Order 12291. Again, I find that I do not agree with the objector.

Section 10.85(a)(1) of FDA's regulations (21 CFR 10.85(a)(1)) enunciates the agency's policy of granting a request for an advisory opinion whenever feasible. In 1981, the agency found that it could issue an advisory opinion in response to FEMA's request. I find no basis upon which to conclude that this decision was inconsistent with 21 CFR 10.85.

Because the request for the advisory opinion seeks the agency's interpretation of an FDA regulation, the request presents a policy issue of broad application and not one applicable only to a particular product. Because FDA has long experience in administering the ice cream standard of identity, even though this matter is complex (see page 41 of the objector's April 6, 1981 submission), the agency had adequate information upon which to issue an informed advisory opinion in 1981. In addition, now that the agency has had the benefit of the comments of the objector, FEMA, and IAICM, there can be no question about the adequacy of the information underlying my decision to reinstate the advisory opinion. Finally, because there apparently is some confusion about the agency's interpretation of 21 CFR 135.110, it is in the public interest to issue this advisory opinion. Therefore, I find no basis in 21 CFR 10.85 for not reinstating the February 12, 1981 advisory opinion.

However, I agree with the objector that FEMA's request for an advisory opinion was not adequate under 21 CFR 10.85(b). A person who requests an advisory opinion from FDA has an obligation to provide a full statement of all facts and legal points relevant to the request. The requestor is not free, as FEMA did, to make assumptions about what information is or is not known to the agency. In addition, FEMA inaccurately described the Newberry letter in its request. The request states that the Newberry letter "...answers the question: What is the legal name of an ice cream product, the flavor of which 'consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source....'" "Request for an Advisory

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Opinion," dated May 16, 1980, from John G. Adams, past President of FEMA, p. 1. In fact, the Newberry letter was qualified and dealt only with those flavors from non-vanilla bean sources that "simulate, resemble, or reinforce" the vanilla flavor. FEMA's inaccurate description of the Newberry letter undoubtedly contributed to the confusion surrounding this proceeding.

In many cases, FDA would consider denying, under 21 CFR 10.85(a)(2)(i), a request like that submitted by FEMA because it presents insufficient information. The agency has committed itself to granting an advisory opinion when feasible (21 CFR 10.85(a)(1)); however, and in the circumstances presented here, for the reasons I have discussed, it is feasible to respond to FEMA's request.

The advisory opinion did not violate the President's moratorium or Executive Order 12291. Both of these directives applied only to regulations required to be promulgated by informal notice and comment rulemaking under the APA. As I explained previously, this advisory opinion is not the subject of notice and comment rulemaking. In fact, on February 10, 1981, Secretary Schweiker issued a memorandum to officials in the Department of Health and Human Services in which he stated that the President's directive does not apply to policy-setting actions outside the scope of the APA's informal rulemaking process. Among the examples he gave were interpretative rulings. As stated above, FDA's advisory opinions are interpretative rulings.

The objector also contends that FDA should have complied with the Regulatory Flexibility Act (RFA) in issuing the advisory opinion. By its terms, the RFA applies only to rules issued by notice and comment rulemaking, and, thus, this statute too does not apply to the advisory opinion.

### III. The Advisory Opinion Is Correct And Is Consistent With Longstanding FDA Policy

After carefully considering all the information submitted on the appropriateness of the February 12, 1981 advisory opinion, I have concluded that that opinion is correct, and that it is consistent with the prior statements made by FDA. Therefore, I am reinstating this advisory opinion. However, before explaining the basis on which I reached these conclusions, I will address a preliminary matter that was debated in the comments on the advisory opinion. My determination on this preliminary matter establishes the foundation on which my other conclusions rest.

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## A. The Relationship Between §§135.110 and 101.22

The objection and the other comments FDA received on the advisory opinion contained a significant amount of discussion on the relationship between the ice cream regulation (21 CFR 135.110) and the general flavoring regulations (21 CFR 101.22). For example, the objector accused the agency of selectively borrowing from the general flavoring regulations in reaching its advisory opinion. See, e.g., Objector's April 3, 1981 submission, p. 41. After carefully considering this issue, I agree with the statement made by Taylor Quinn, Associate Director for Compliance of the Bureau of Foods, in his letter of May 31, 1979, to Glenn P. Witte of IAICM: "The general flavor regulations are not applicable to this standardized food [ice cream]."

The regulatory scheme under the general flavor declaration requirements of 21 CFR 101.22 is significantly different from the three-category labeling scheme in the ice cream regulation for declaring the characterizing flavor in ice cream. For example, under the general flavor regulations, if a food contains any artificial flavor that simulates, resembles, or reinforces the characterizing flavor, the food must be labeled "artificially flavored." 21 CFR 101.22(i)(2). In contrast, under the ice cream regulation, if the food contains both a natural characterizing flavor and an artificial flavor simulating it, the food need not be labeled as artificial unless the artificial flavor predominates (although when the natural flavor predominates, the presence of the artificial flavor must be indicated on the label). 21 CFR 135.110(e)(2)(ii). At the time FDA adopted the general flavor regulations, the agency considered revising the ice cream regulation to make it consistent with the general flavoring regulations. 38 FR 33284, 33287 (December 3, 1973). See also 38 FR 27144, 27145 (July 25, 1975). However, the agency ultimately decided to retain the three-category labeling scheme in the ice cream regulation. 42 FR 19127, 19131 (April 12, 1977). Because of the differences between the two regulations, the general flavoring regulations have no relevance to this matter.

However, the fact that the general flavoring regulations themselves are not relevant does not mean that all of the information contained in preambles to Federal Register notices on those regulations is also irrelevant. Not only is a preamble to a regulation an advisory opinion, 21 CFR 10.85(d)(1), but there is also a significant agency interest in being consistent among its regulations, at least in such matters as terminology. Therefore, a discussion in the pre-

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amble to the general flavoring regulations about the meaning of a term that is used in the ice cream regulation as well as in the general flavoring regulations is applicable to both regulations.

One example of such a discussion is comment 17 to the December 3, 1973 final rule on the general flavor regulations. The paragraph explaining the subject of that comment states:

17. Questions have arisen as to how the characterizing flavor is to be determined, and as to how it will be determined whether added flavor "simulates" a characterizing natural flavor or otherwise characterizes the product.

Because the ice cream regulation also uses both "characterizing flavor" and "simulating," the discussion in comment 17 would obviously be relevant in interpreting the ice cream regulation as well as the general flavoring regulation.

On the other hand, because of the differences between the ice cream regulation and the general flavoring regulations, some agency discussions of one of these regulations will not be applicable to the other. For example, the Newberry letter concerns a product that contains a flavor consisting of one ounce of vanillin per unit of vanilla plus an additional amount of flavor from a non-vanilla bean source that simulates vanilla. Although such a product would be labeled as "artificially flavored" under both the general flavoring regulations and the ice cream regulations, the reasons for doing so would be completely different under §101.22 (the product contains artificial flavor, vanillin) than under §135.110 (the natural characterizing flavor does not predominate under the facts specified). Because the Newberry letter concerns only the application of the ice cream regulation, contrary to the claims of the objector (see Objector's submission of August 31, 1981, p. 8), it would not be relevant in interpreting 21 CFR 101.22.

B. The Advisory Opinion Correctly Interprets 21 CFR 135.110

Perhaps the best way to analyze the February 12, 1981 advisory opinion is to look at the portion of the Newberry letter that is quoted in the opinion on a sentence-by-sentence basis. There is no controversy about the first sentence, which merely restates the contents of 21 CFR 135.110(e)(5)(i), or about the last sentence, which simply follows from the two that precede it. The real concern is

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over the middle two sentences. Thus, a closer analysis of these statements in the advisory opinion is necessary.

1. "Consequently, an ice cream manufacturer could not call his product 'vanilla flavored ice cream' (Category II) if the flavor consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source (which simulated, resembles, or reinforces the vanilla flavor) is added to the product."

This sentence states that if any amount of flavor that simulates vanilla, the natural characterizing flavor, is added to the balance of vanilla and vanillin at which the vanilla is deemed to predominate, natural vanilla will no longer predominate. This statement is consistent with both 21 CFR 135.110 and the prior statements of the agency.

- a. The use of the words "simulates, resembles, or reinforces" in this sentence, rather than the word "simulates" alone, is consistent with the agency's longstanding interpretation of the latter term. As explained above, it is appropriate to use the December 3, 1973 preamble in interpreting the ice cream regulation. In that preamble, in response to questions about how to determine "whether added flavor 'simulates' a characterizing natural flavor," the agency states that the test is not solely whether the flavor simulates or is chemically identical to the characterizing flavor, but also whether it resembles, reinforces, or extends it. 38 FR 33286. Thus, it was appropriate to incorporate "resembles" and "reinforces" into this sentence of the advisory opinion.

- b. It is clear from the context in which the Newberry letter was written that the subject of the letter was a flavor that simulates the characterizing flavor. The Newberry letter was written after a meeting between Anthony Filandro of Virginia Dare Extract Co. and Daniel R. Thompson, counsel to FEMA, and Taylor Quinn, James Summers, and R. E. Newberry of FDA. The memorandum of this meeting indicates that Messers Filandro and Thompson inquired about the effect of "adding a natural flavor from a non-vanilla bean source which simulates, resembles, and reinforces the vanilla flavor." The Newberry letter, by its own terms, was intended to respond to this inquiry. Thus, the Newberry letter was not intended to set forth the effect of adding a non-characterizing flavor to a mixture of vanillin and vanilla constituent.

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c. The Newberry letter is correct under 21 CFR 135.110(e). Because that section makes no provision for any natural flavors other than natural characterizing flavors, FDA must treat all natural flavors that simulate the characterizing flavor as artificial flavors when deciding what name should appear on the principal display panel. Thus, the addition of a flavor that simulates vanilla to ice cream that contains one ounce of vanillin per unit of vanilla constituent would mean that the balance at which the natural characterizing flavor -- vanilla -- predominates would no longer obtain. In such circumstances, the artificial flavor -- including natural flavors simulating vanilla -- will be deemed to predominate.

d. This sentence of the advisory opinion is consistent with prior statements made by the agency. On May 31, 1979, in response to a letter from Glenn P. Witte of the IAICM, Mr. Quinn wrote:

It is our understanding that there are available in the market place, natural flavoring compounds that resemble, simulate and/or enhance vanilla flavor but are not derived from vanilla bean. These flavor compounds would not comply with the intent of the flavor provisions of Category I ice cream. However, they would qualify for category II labeling (vanilla flavored ice cream) provided that the flavor derived from vanilla beans predominates.

See also Letter of August 22, 1979, from Mr. Quinn to Kenneth B. Basa, National Food Ingredients Company, which contains a statement to the same effect.

Both the advisory opinion and the Quinn letter to Witte reflect the fact that 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. The Quinn letter states that these natural flavor compounds can be used with natural vanilla flavors to make "vanilla flavored" ice cream, so long as the natural vanilla flavor predominates. The advisory opinion does not say that these compounds cannot be used to make such a product. What the advisory opinion does say is that if a natural flavor compound that simulates vanilla is added to vanilla flavored ice cream that is formulated at the point of predominance of the natural characterizing flavor (one ounce of vanillin per unit of vanilla constituent), the addition of this compound will mean that the natural characterizing

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flavor no longer predominates. There is nothing in the Quinn letter to the contrary.

2. "The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream."

- a. The objector claims that the test embodied in this sentence establishes a minimum amount of natural vanilla flavored ice cream, and that the sentence consequently is inconsistent with 21 CFR 135.110. Objector's submission of August 31, 1981, p. 51. The objector misapprehends the meaning of this sentence. The sentence is not about how much vanilla must be in a product to call it "vanilla flavored" but about how to determine whether a flavor simulates the characterizing flavor. The agency first established this test in its response to comment 17 in the December 3, 1973 preamble. There FDA said that a flavor that extends the characterizing flavor, that is, makes it appear that more of the characterizing flavor is present than is actually the case, simulates the characterizing flavor. 38 FR 33286. Thus, a flavor that permits less of the characterizing flavor to be used than would otherwise be the case simulates that flavor.

The objector argues that comment 17 establishes taste as the only test for determining whether an added flavor simulates a characterizing natural flavor. Objector's submission of April 6, 1981, p. 54. In support of this contention, the objector cites the following language from comment 17:

...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....

Id. In so arguing, however, the objector ignores the fact that the portion of comment 17 that he quotes speaks of the "principal test." Implicit in the use of these words is the fact that there are other criteria besides taste that are to be applied in deciding whether a flavor simulates the characterizing flavor. One of those tests is whether the flavor

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extends the characterizing natural flavor. Thus, under comment 17, if an ice cream manufacturer added a small amount of a natural flavor not derived from the vanilla bean to his mix to permit the use of a smaller amount of vanilla-vanillin flavor, the natural flavor would simulate the characterizing flavor.

Therefore, the objector's claim that this sentence of the advisory opinion is inconsistent with 21 CFR 135.110 and with comment 17 in the December 3, 1973 preamble is without merit.

b. The objector contends that the test established in this sentence of the advisory opinion for determining whether a non-vanilla flavor simulates vanilla violates the principles established in United States v. 88 Cases, ... Birely's Orange Beverage, 187 F.2d 967 (3d Cir.), cert. denied 342 U.S. 861 (1951). Objector's February 23, 1981 submission, p. 8 and Objector's August 31, 1981 submission, p. 48. FDA finds this claim to be groundless.

The Birely's case turned on the question of whether there was any danger of confusing the product at issue with something else that is defined, familiar, and superior. 187 F.2d at 972. In Birely's, the court found that such a danger did not exist because there was no standard for diluted orange drinks like that made by the claimant, and because there was no danger that an ordinary consumer would confuse the claimant's product with undiluted orange juice. . . . at 973. Here, however, there is such a danger. Contrary to the claims of the objector (see Objector's submission of August 31, 1981, p. 51), FDA has established a standard for what can be called "vanilla flavored ice cream." The advisory opinion is intended to prevent consumer confusion by preventing the application of this name to products that do not meet the standard. Thus, the situation here is clearly distinguishable from that in the Birely's case.

For this reason, and because, as FEMA has pointed out, FEMA's submission of June 29, 1981, p. 18, this case involved application of section 401 of the FD&C Act, while Birely's involves application of section 402, and the two sections

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have no relation to one another,\*/ the principles enunciated in Birely's are not applicable to the immediate case

C. The Consumer Preference For Natural Flavors Is Irrelevant To This Matter.

The objector contends that the February 12, 1981 advisory opinion ignores the demonstrated consumer preference for natural products and for products that contain natural additives. Objector's April 6, 1981 Submission, p. 50. This contention may well be true, but it is irrelevant to a decision in this matter.

For ice cream, the name that appears on the principal display panel is determined by the factors set forth in 21 CFR 135.110(e). Under the labeling scheme established in that provision, whether a flavor is natural is significant only when that flavor is the characterizing flavor, in this case, vanilla. Any flavor, whether natural or not, that is used in ice cream to simulate the characterizing vanilla flavor is treated as an artificial flavor, unless it is derived from vanilla beans. If the objector wishes to change this scheme to reflect the claimed consumer interest in natural flavors, it is free to petition the agency to amend the regulation. For now, however, the advisory opinion must, as it does, reflect the regulation that is currently in effect.

IV. Conclusion

For the foregoing reasons, I find that the February 12, 1981 advisory opinion is consistent with 21 CFR 135.110 and with the prior statements made by FDA. Therefore, I am lifting the stay on the advisory opinion and reinstating this advisory opinion.

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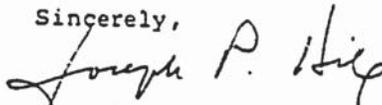
\*/ "...[S]ection [401]...has no relation to, no connection with, the adulteration provisions of the Act." Bruce's Juices v. United States, 194 F.2d 935, 936 (5th Cir. 1952), citing United States v. 36 Drums of Pop'n Oil, 164 F.2d 150 (5th Cir. 1947).

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On behalf of FDA, I would like to thank those who submitted comments and who met with me for their interest and contribution to the decisionmaking process in this matter.

Sincerely,



Joseph P. Hile  
Associate Commissioner for  
Regulatory Affairs

cc: John F. Speer, Jr., President  
International Association of  
Ice Cream Manufacturers  
910 Seventeenth Street, N.W.  
Washington, D.C. 20006

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# EXHIBIT “E”



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

AUG 22 1979

Mr. Kenneth B. Basa  
National Food Ingredient Company  
4830 S. Christiana Avenue  
Chicago, Ill. 60632

Dear Mr. Basa:

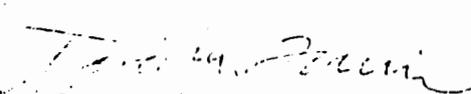
This is in reply to your letter of July 31, 1979 concerning the use of vanilla-vanillin and natural non-vanilla derived flavorings in category II Vanilla Flavored Ice Cream.

We will respond to your questions in the order in which they appear in your letter.

1. Natural flavors not derived from vanilla beans may be used in combination with the standardized items included under 21 CFR 169 (vanilla-vanillin extract or vanilla-vanillin flavoring) for category II vanilla flavored ice cream provided that the flavoring contributed by or derived from the vanilla beans predominates.
2. The combination of vanilla-vanillin extract or vanilla-vanillin flavoring with natural flavors not derived from vanilla beans as provided above may be marketed in a single package. However, such a combination should in no way imply or suggest that this combination is one of the standardized flavors covered under 21 CFR 169.
3. The labeling for the above combination flavoring should identify what the combination is, e.g. "Vanilla-Vanillin Extract and \_\_\_\_\_" (the blank to be filled with the names of the particular flavors used) or "Vanilla-Vanillin Extract with other natural flavors". The ingredient statement should declare the standardized flavoring by its specific common or usual name with a parenthetical listing of the optional ingredients required to be declared by the particular standard, and each ingredient of the natural non-vanilla flavoring should be declared by its specific common or usual names.

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

Sincerely yours,

  
Taylor H. Quinn  
Associate Director  
for Compliance  
Bureau of Foods

# ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [7-Eleven's 'Vanilla Bean Ice Cream' Is Not Exclusively Flavored with Vanilla, Class Action Claims](#)

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