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United States District Court  
Southern District of New York

7:19-cv-10860

Sherise Richardson, individually and on  
behalf of all others similarly situated,

Plaintiff,

- against -

Mars, Incorporated,

Defendant

Class Action Complaint

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

1. Mars, Incorporated (“defendant”) manufactures, distributes, markets, labels and sells ice cream products purporting to contain flavor from their natural characterizing flavor, vanilla, under their M&M's brand (“Products”).

2. The Products are available to consumers from retail and online stores of third-parties and defendant’s website and are sold in boxes containing 6 bars of 1.63 FL OZ (9.78 FL OZ).

3. The relevant front and back label representations include “Vanilla” and “vanilla reduced fat ice cream.”



4. The designation of the Product’s flavor is shown through the following images and/or statements.



I. Ice Cream Products

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. When ice cream has 1.4% or more egg yolk solids as part of its base, it is referred to as “french ice cream.”<sup>4</sup>

9. According to ice cream lore, Thomas Jefferson supposedly “invented” vanilla ice cream when he learned of vanilla during his ambassadorship to France and upon returning to Monticello, mixed this bottle with the frozen milk and cream dessert he was fond of consuming

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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> 21 C.F.R. § 135.110(f)(1).

while drafting the Declaration of Independence.<sup>5</sup>

10. President Jefferson is even said to have imported vanilla so this new frozen dairy treat could be served at his inaugural ball.

## II. Vanilla is Perennial Favorite Ice Cream Flavor

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

12. 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>6</sup>

13. 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>7</sup>

14. 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 and sprinkled with crushed nuts and topped by a maraschino cherry (“sundae”) or dunked in a cold frothy glass of root beer (“float”).<sup>8</sup>

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

15. 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

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<sup>5</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>6</sup> Press Release, IDFA, [Vanilla Reigns Supreme; Chocolate Flavors Dominate in Top Five Ice Cream Favorites Among Americans](#), July 1, 2018

<sup>7</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>8</sup> [The True Wonders of Vanilla Ice Cream](#), FrozenDessertSupplies.com.

extractable from one-unit weight of vanilla beans.”<sup>9</sup>

16. 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>10</sup>

17. 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>11</sup>

18. 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>12</sup>

19. This demand could not be met by the natural sources of vanilla, leading manufacturers to devise clever, deceptive and dangerous methods to imitate vanilla’s flavor and appearance.

20. 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>13</sup>

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<sup>9</sup> 21 C.F.R. §169.3(c).

<sup>10</sup> Daphna Havkin-Frenkel, F.C. Bellanger, Eds., Handbook of Vanilla Science and Technology, Wiley, 2018.

<sup>11</sup> Berenstein, 412; some of the earliest recorded examples of food fraud include unscrupulous Roman merchants who sweetened wine with lead.

<sup>12</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.](#)

<sup>13</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.

21. 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

22. 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>14</sup>

23. 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>15</sup>

<u>Type of Food Fraud</u>	<u>Application to Vanilla</u>
<p>➤ Addition of markers specifically tested for instead of natural component of vanilla beans</p>	<ul style="list-style-type: none"> <li>• Manipulation of the carbon isotope ratios to produce synthetic vanillin with similar carbon isotope composition to natural vanilla</li> </ul>
<p>➤ Appearance of <i>more</i> and/or higher quality of the valued ingredient</p>	<ul style="list-style-type: none"> <li>• Ground vanilla beans and/or seeds to provide visual appeal as “specks” so consumer thinks the product contains real vanilla beans, when the ground beans have been exhausted of flavor</li> <li>• Caramel to darken the color of an imitation vanilla so it more closely resembles the hue of real vanilla<sup>16</sup></li> <li>• Annatto and turmeric extracts in dairy products purporting to be flavored with vanilla, which causes the color to better</li> </ul>

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<sup>14</sup> Société Générale de Surveillance SA, (“SGS “), [Authenticity Testing of Vanilla Flavors – Alignment Between Source Material, Claims and Regulation](#), May 2019.

<sup>15</sup> Kathleen Wybourn, DNV GL, [Understanding Food Fraud and Mitigation Strategies](#), PowerPoint Presentation, Mar. 16, 2016.

<sup>16</sup> Renée Johnson, “Food fraud and economically motivated adulteration of food and food ingredients.” Congressional Research Service R43358, January 10, 2014.

- resemble the hue of rich, yellow butter
- Substitution and replacement of a high quality ingredient with alternate ingredient of lower quality
    - 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
  - Addition of less expensive substitute ingredient to mimic flavor of more valuable component
    - 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>17</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>18</sup>
  - Compounding, Diluting, Extending
    - “Spiking” or “fortification” of vanilla through addition of natural and artificial flavors including vanillin, which simulates vanilla taste but obtained from tree bark
  - Addition of fillers to give the impression there is more of the product than there actually is
    - 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,

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

<sup>18</sup> Berenstein, 423.

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
  - Ingredient List Deception<sup>19</sup>
    - “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

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

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

25. First synthesized from non-vanilla sources by German chemists in the mid-1800s, vanillin was the equivalent of steroids for vanilla flavor.

26. 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>20</sup>

27. Today, only 1-2% of vanillin in commercial use is vanillin obtained from the vanilla

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<sup>19</sup> Recent example of this would be “evaporated cane juice” as a more healthful sounding term to consumers to identify sugar.

<sup>20</sup> Katy Severson, [Imitation vs. Real Vanilla: Scientists Explain How Baking Affects Flavor](#), Huffington Post, May 21, 2019.



plant, which means that almost all vanillin has no connection to the vanilla bean.

28. 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.”).

29. 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.

30. 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).

31. 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.

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

32. 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.

33. However, the starting material, eugenol, is subjected to high heat and high pressure in conversion to vanillin, which is actually considered by the FDA to be a synthetic method.

34. These low-cost “natural vanillins” are produced by the ton in China, with little transparency or verification, before being delivered to the flavor companies for blending.

D. Vanilla “WONF” to Imitate Real Vanilla

35. The global shortage of vanilla beans has forced the flavor industry to “innovate[ing] natural vanilla solutions...to protect our existing customers.”<sup>21</sup>

36. 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.

37. 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.”

38. According to industry leaders like the head of “taste solutions” at Irish conglomerate Kerry, flavor manufacturers must “[G]et creative” and “build a compounded vanilla flavor with other natural flavors.”

39. 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>22</sup>

40. 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>23</sup>

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<sup>21</sup> Amanda Del Buono, [Ingredient Spotlight](#), Beverage Industry, Oct. 3, 2016.

<sup>22</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>23</sup> Donna Berry, [Understanding the limitations of natural flavors](#), BakingBusiness.com, Jan. 16, 2018.

41. That high level executives in the flavor industry openly boast of their stratagems to give consumers less vanilla for the same price is not unexpected, given that the trade organization for flavor companies has abandoned its “self-policing” role as a guardian for honesty and fair dealing towards consumers.

42. For example, the flavor trade group disbanded its Vanilla Committee, which was responsible for ensuring honest labeling, in favor of pocketing dues and membership fees from the largest food conglomerates.

#### IV. Ice Cream Flavor Labeling

43. 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>24</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 cream Category III contains synthetic ingredients.

44. 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>25</sup>

##### A. Early Ice Cream Flavoring Debate is “Stirring”

45. 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

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<sup>24</sup> Daphna Havkin-Frenkel and Faith C. Belanger, eds., *Handbook of Vanilla Science and Technology*, Wiley, 2018 (221).

<sup>25</sup> Melody M. Bomgardner, “[The problem with vanilla](#),” Chemical & Engineering News, Sept. 12, 2016.

flavors on ice cream products.

46. Unsurprisingly, the starting point for the debate was how to label vanilla ice cream flavored with added vanillin from clove oil, a natural source material.

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

48. In response, Congressmen E.A. Kenny of New Jersey and Virgil Chapman of Kentucky inquired of ice cream’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)

.....

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

49. 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>26</sup>

50. Even before ice cream standards were established, Congress framed the central question for ice cream flavoring as whether the flavor source was entirely derived from the characterizing flavor – i.e., raspberry for raspberry ice cream, vanilla for vanilla ice cream.

#### B. Ice Cream Flavoring Regulations

51. 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,

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<sup>26</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.

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”).

52. 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).

### **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)

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

54. 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.

55. 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.”).

56. Category II and III 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.”).

57. 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.’”).

58. 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).”).

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

59. 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.”).

60. 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>27</sup>

61. 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.

62. “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).

63. For the purposes of designating the type of ice cream on the front label, whether a

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<sup>27</sup> Compare 21 C.F.R. § 135.110(f)(2)-(5) with 21 C.F.R. § 101.22.



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

64. 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>28</sup>

65. 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”).

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

66. The front label statements of “Vanilla” and “Vanilla Reduced Fat Ice Cream” are understood by consumers to identify a product where (1) vanilla is the characterizing flavor, (2)

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<sup>28</sup> 21 C.F.R. § 135.110(f) was previously 21 C.F.R. § 135.110(e).

vanilla is contained in a sufficient amount to characterize flavor the product, (3) the flavor is derived from vanilla extract or vanilla flavoring, (4) no other flavors simulate, resemble, reinforce, or enhance flavoring from vanilla and (5) vanilla is the exclusive source of flavor.

67. The front label statements of “Vanilla” and “Vanilla Reduced Fat Ice Cream” fail to adequately inform consumers that the Products actually contain “non-vanilla flavors.”

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

68. The ingredient list reveals the reduced fat vanilla ice cream portion of the Product is flavored by the ingredient designated as “Natural Flavors.”

Ingredient List

**INGREDIENTS: REDUCED FAT ICE CREAM:** SKIM MILK, CREAM, SUGAR, CORN SYRUP, WHEY, MONO AND DIGLYCERIDES, CAROB BEAN GUM, GUAR GUM, CARRAGEENAN, ANNATTO EXTRACT (COLOR), NATURAL FLAVOR. **COATING:** SUGAR, COCONUT OIL, MILK, LACTOSE, PALM OIL, CHOCOLATE, COCOA POWDER, SOY LECITHIN, ARTIFICIAL FLAVOR. **COATED M&M'S® BRAND MINIS MILK CHOCOLATE CANDIES:** [MILK CHOCOLATE (SUGAR, CHOCOLATE, SKIM MILK, COCOA BUTTER, LACTOSE, MILKFAT, SOY LECITHIN, SALT, ARTIFICIAL AND NATURAL FLAVORS), SUGAR, COLORING (INCLUDES BLUE 1 LAKE, RED 40, YELLOW 6, YELLOW 5, BLUE 1, RED 40 LAKE, YELLOW 6 LAKE, YELLOW 5 LAKE, BLUE 2 LAKE, BLUE 2), CORN SYRUP, DEXTRIN, CORNSTARCH, CARNAUBA WAX], COCOA BUTTER.

**INGREDIENTS: REDUCED FAT ICE CREAM:** SKIM MILK, CREAM, SUGAR, CORN SYRUP, WHEY, MONO AND DIGLYCERIDES, CAROB BEAN GUM, GUAR GUM, CARRAGEENAN, ANNATTO EXTRACT (COLOR), **NATURAL FLAVOR**. **COATING:** SUGAR, COCONUT OIL, MILK, LACTOSE, PALM OIL, CHOCOLATE, COCOA POWDER, SOY LECITHIN, ARTIFICIAL FLAVOR. **COATED M&M MINIS MILK CHOCOLATE CANDIES:** [MILK CHOCOLATE (SUGAR, CHOCOLATE, SKIM MILK, COCOA BUTTER, LACTOSE, MILKFAT, SOY LECITHIN, SALT, ARTIFICIAL AND NATURAL FLAVORS), SUGAR, COLORING (INCLUDES BLUE 1 LAKE, RED 40, YELLOW 6, YELLOW 5, BLUE 1, RED 40 LAKE, YELLOW 6 LAKE, YELLOW 5 LAKE, BLUE 2 LAKE, BLUE 2), CORN SYRUP, DEXTRIN, CORNSTARCH, CARNUBA WAX], COCOA BUTTER.

69. Where a product is labeled as a type of, or containing, vanilla ice cream, without any or adequate qualification, but the ingredient list identifies “natural flavor” it means (1) the flavoring is not exclusively from vanilla, (2) the non-vanilla flavor likely contains vanillin, not disclosed as an artificial flavor when paired with real vanilla, (3) the non-vanilla flavors simulate, resemble and reinforce the vanilla flavor and (4) the use of these non-vanilla flavors allow the use of less real vanilla.

70. Had the Products flavoring derived exclusively from vanilla, the ingredient list would declare the common or usual names of one or more of the exclusively vanilla ingredients, *viz*, Vanilla Extract, Concentrated Vanilla Extract, Vanilla Flavoring and Concentrated Vanilla Flavoring, and not declare any other flavor ingredient. *See* 21 C.F.R. §§ 169.175 to 169.178.

71. The 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>29</sup>

72. 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>30</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.

73. 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.

74. 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

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<sup>29</sup> 21 C.F.R. §§ 169.175 (Vanilla extract.), 169.177 (Vanilla flavoring.); also concentrated versions of each of these.

<sup>30</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.

term, depending on criteria currently known only to defendant (i.e., components of the “natural flavor” ingredient).

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

75. Gas chromatography-mass spectrometry (“GC-MS”) and high-performance liquid chromatography (“HP-LC”) can determine the presence of flavor compounds typically associated with vanilla (“marker compounds”).

76. These four marker compounds 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%

77. Analysis of the Products by GC-MS and/or HP-LC has shown or is likely to show mismatched ratios of these vanilla marker compounds and/or the non-detection of certain marker compounds.

78. The reason for these results is that the “Natural Flavors” ingredient refers to a “blend” of vanilla extract or vanilla flavoring with non-vanilla flavors.

79. In reality, “blend” is too generous a term to describe the Product’s “Natural Flavors” because this term implies the vanilla and non-vanilla components are present in relatively equivalent amounts.

80. However, the amount of real vanilla contained in the “Natural Flavors” is *de minimis*, and at best, real vanilla does not constitute the entirety of the “Natural Flavors,” which is required to label a product vanilla ice cream.

VIII. Coloring Misleads Consumers to Expect Products Contain More Vanilla Than They Do

81. The Products contain extracts of annatto for coloring purposes, indicated on the ingredient list – “Annato Extract (Color).”

82. Annatto extracts are often used in cheddar cheese to provide a rich yellow-orange shade evocative of milkfat associated with butter, produced by dairy cattle in the United States.

83. No allegation is made with respect to how annatto and turmeric are declared or about their use, which is specifically permitted by regulation.<sup>31</sup>

84. Though added coloring is permitted in ice cream, it is not permitted if it results in a misleading impression as to the quality of the product.

85. The result of annatto is a darker color as indicated below, which is similar in appearance to color of the ice cream scoops on the front labels.



86. The darker color makes the consumer (1) less likely to question or be skeptical of the amount and type of vanilla in the Products, (2) expect the Products to be similar to other, accurately labeled vanilla ice creams and (3) expect the Products contain more vanilla than they actually do.

87. Since the annatto does modify the color of the vanilla ice cream closer to a vanilla ice cream flavored exclusively by flavor from the vanilla plant *and* because the Products lack sufficient vanilla – in amount and percent of the total flavoring – the use of annatto is misleading

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<sup>31</sup> 21 C.F.R. § 101.22(k)(3)

and used specifically to make it appear the Products have more vanilla than they actually do.

IX. Products Labeled as or with Vanilla Ice Cream Modified by Express Nutrient Content Claims<sup>32</sup>

A. Differences between “Vanilla Ice Cream” and “Vanilla Ice Cream” Modified by Express Nutrient Content Claims

i. Allowance Made for Variations in Fat, Sugar and Calories in Ice Cream

88. Until the early 1990s, any product with “ice cream” (or a standardized food) in its name had to meet requirements set in its standards of identity which required a dairy product with “not less than 10 percent milkfat, nor less than 10 percent nonfat milk solids.”<sup>33</sup>

89. Around this time, express nutrient content claims were introduced, which meant companies could make “direct statement[s] about the level (or range) of a nutrient in a food, e.g., ‘low sodium’ or ‘contains 100 calories,’” milkfat or sugar.<sup>34</sup>

90. In all other respects, the product has to maintain conformity to the standard so consumers will not expect a product to taste and/or perform in a certain way when that product departs in significant and/or material ways from what they are accustomed to receiving.

91. For example, instead of requiring ice cream to have 10% milkfat, “lowfat ice cream” could contain a maximum of 3 grams of total fat per serving (½ cup) and “nonfat ice cream” could contain less than 0.5 grams of total fat per serving.<sup>35</sup>

92. The following table contains variations of ice cream with express nutrient content claims.

Nutrient Content Claim + Ice Cream<sup>36</sup>

Difference between Modified

<sup>32</sup> 21 CFR § 130.10 – Requirements for foods named by use of a nutrient content claim and a standardized term.

<sup>33</sup> 21 C.F.R. § 135.110(a)(2).

<sup>34</sup> 21 C.F.R. § 101.13(b)(1).

<sup>35</sup> 21 C.F.R. § 130.10(a).

<sup>36</sup> 21 C.F.R. § 130.10(e) (“*Nomenclature*. The name of a substitute food that complies with all parts of this regulation is the appropriate expressed nutrient content claim and the applicable standardized term.”)

and Standardized Ice Cream

**Reduced Fat** Ice Cream

- 25% less fat than a reference product<sup>37</sup>

**Light** Ice Cream

- 50% reduction in total fat from the reference product, or one-third reduction in calories if fewer than 50% of the calories are from fat<sup>38</sup>

**No Sugar Added** Ice Cream

- No amount of sugars or ingredient that contains sugars is added during processing or packaging;
- The food does not contain an ingredient containing added sugars<sup>39</sup>

**Low Fat** Ice Cream

- Not more than 3 g of total fat per serving<sup>40</sup>

**Nonfat** or **Fat Free** Ice Cream

- Less than 0.5 g of fat per serving<sup>41</sup>

ii. Performance Characteristics

93. Modified versions of standardized foods were permitted to deviate from the standard with respect to performance characteristics like moisture content, food solids content requirements, or processing conditions.

iii. Ingredient Deviations

94. In modified foods, the ingredients were required to be those permitted by the particular standard, subject to certain exceptions.<sup>42</sup>

95. If an ingredient or component was specifically required by the standard, it could not be replaced or exchanged with a similar ingredient from another source unless the standard allows it, i.e., vegetable oil shall not replace milkfat in light sour cream).<sup>43</sup>

96. If a standard prohibited an ingredient, that ingredient could not be added in a

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<sup>37</sup> 21 C.F.R. § 101.62(b)(4)

<sup>38</sup> 21 C.F.R. § 101.56

<sup>39</sup> 21 C.F.R. § 101.60(c)(2)

<sup>40</sup> 21 C.F.R. § 101.62(b)(2)

<sup>41</sup> 21 C.F.R. § 101.62(b)(1)

<sup>42</sup> 21 C.F.R. § 130.10(d)(1).

<sup>43</sup> 21 C.F.R. § 130.10(d)(2).

modified version of the food.<sup>44</sup>

97. All ingredients required by a standard have to still be present in a significant amount in a modified version of the food, *viz.*, at least that amount that is required to achieve the technical effect of that ingredient in the food.<sup>45</sup>

**B. The Product’s Representation as a “Vanilla Reduced Fat Ice Cream” are Misleading**

98. The Product is represented as a Modified Versions of Vanilla Ice Cream, which is misleading and fails to comply with the requirements for express nutrient content claims for standardized foods.

99. Vanilla ice cream modified by an express nutrient content claim still requires that the flavor is derived exclusively from the characterizing flavor, vanilla, because vanilla is a required ingredient for adherence to the standardized food..

100. The standard for vanilla ice cream does not permit the Products to replace or substitute flavors obtained from a non-vanilla source for flavors obtained from the vanilla plant, *i.e.*, vanilla flavoring or vanilla extract. *See* 21 C.F.R. § 130.10(d)(2).<sup>46</sup>

101. Vanilla ice cream modified by an express nutrient content claim does not permit non-vanilla bean derived flavors in a Category 1 vanilla ice cream. *See* 21 C.F.R. § 130.10(d)(3).<sup>47</sup>

102. The prohibited ingredient or ingredient component in the Reduced Fat Vanilla Ice Cream Product is the non-vanilla part of the “Natural Flavor.”

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<sup>44</sup> 21 C.F.R. § 130.10(d)(3).

<sup>45</sup> 21 C.F.R. § 130.10(d)(4).

<sup>46</sup> 21 C.F.R. § 130.10(d)(2) (“An ingredient or component of an ingredient that is specifically required by the standard (*i.e.*, a mandatory ingredient) as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169 of this chapter, provides for the addition of such ingredient (*e.g.*, vegetable oil shall not replace milkfat in light sour cream); 21 C.F.R. § 135.110(f)(2)(i)

<sup>47</sup> 21 C.F.R. § 130.10(d)(3) (“An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section.”); 21 C.F.R. § 135.110(f)(2)(i)



103. Because non-vanilla flavor is not permitted by the standard in vanilla ice cream, it is by definition used in excess of levels provided for by the standard.

104. Even if non-vanilla flavors were permitted in a product labeled “vanilla ice cream,” the Product’s labels would still be misleading because the ingredient list does not identify the “Natural Flavors” with an asterisk, such as “\*Ingredient(s) not in regular vanilla light ice cream” or “\*Ingredient(s) in excess of amount permitted in regular vanilla light ice cream.”<sup>48</sup>

C. Express Nutrient Content Claim Does Not Relate to Flavoring Used in Ice Creams

105. The only authorized deviations from the standard by express nutrient content claims are those that (1) are necessary to make the nutrient content claim, (2) ensure that the food meets the performance characteristics of the traditional standardized food and (3) ensure the food is not nutritionally inferior to the traditional standardized food.

106. The allowed modifications to standardized foods relate to direct statements about the level or range of a nutrient in the food such as fat, sugar and calories, as opposed to the amount and composition of the flavoring.

107. Modification of a food by an express nutrient content claim does not provide justification or authority for deviating from the vanilla flavor requirement of a Category 1 ice cream because:

- The nutrient content claims modify the term “ice cream” by adjusting the nutrient composition of the Products;

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<sup>48</sup> 21 C.F.R. § 130.10(f)(2) (“Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement “\*Ingredient(s) not in regular \_\_\_\_” (fill in name of the traditional standardized food) or “\*Ingredient(s) in excess of amount permitted in regular \_\_\_\_” (fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.); 21 C.F.R. § 135.110(f)(2)(i).

- Vanilla ingredients are not nutrients, but flavorings;
- Vanilla extract and vanilla flavorings are insignificant sources of calories, fat, sugar and other nutrients which are subject to express nutrient content claims;
- Should a company wish to use less vanilla in an ice cream, it can easily do so by designating that product with the term “vanilla flavored” or a similar variation
- The amount, type and/or percentage of vanilla is not permitted to be adjusted on the basis of making a nutrient content claim because the amount of vanilla has no functional or technical effect on those aspects of the food which are modified by the nutrient content claim.

## X. Conclusion

108. 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.

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

110. 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.

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

112. As a result of the false and misleading labeling, the Product is sold at a premium price, approximately no less than \$5.99 per 9.78 FL OZ, excluding tax – compared to other similar products represented in a non-misleading way.

Jurisdiction and Venue

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

114. 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).

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

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

117. Plaintiff Sherise Richardson is a citizen of New York.

118. Defendant Mars, Incorporated is a Delaware corporation with a principal place of business in McLean, Fairfax County, Virginia.

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

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

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

Parties

122. Plaintiff Sherise Richardson is a citizen of Orange County, New York.

123. Defendant is a Delaware corporation with a principal place of business in McLean, Fairfax County, Virginia.

124. During the class period, plaintiff purchased one or more of the Products 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,

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

Class Allegations

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

127. 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.

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

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

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

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

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

133. 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

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

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

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

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

138. 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, to characterize the taste or flavor of the Products.

Negligent Misrepresentation

139. Plaintiff incorporates by reference all preceding paragraphs.

140. Defendant misrepresented the substantive, quality, compositional, organoleptic and/or nutritional attributes of the Products through misrepresenting the amount, quantity and/or proportion of the flavoring ingredient.

141. Defendant had a duty to disclose and/or provide non-deceptive labeling of the Product and its components and ingredients, and knew or should have known same were false or misleading.

142. 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.

143. 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.

144. 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.

145. 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.

146. Plaintiff incorporates by reference all preceding paragraphs.

147. Defendant manufactures and sells products which purport to contain sufficient amounts of the highlighted ingredient, vanilla, to characterize the taste or flavor of the Products, which is desired by consumers.

148. 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 presence or absence of the aforementioned ingredient.

149. Defendant had a duty to disclose and/or provide a non-deceptive description and identification of the Product and its ingredients.

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

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

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

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

would have.

Fraud

154. Plaintiff incorporates by references all preceding paragraphs.

155. Defendant's purpose was to sell a product 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.

156. Defendant's fraudulent intent is evinced by its failure to accurately indicate the Products contained less of the desired ingredient.

157. 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

158. Plaintiff incorporates by reference all preceding paragraphs.

159. Defendant obtained benefits and monies because the Product 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 23, 2019

Respectfully submitted,

Sheehan & Associates, P.C.

/s/Spencer Sheehan

Spencer Sheehan

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*-and-*

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*mreese@reesellp.com*



7:19-cv-10860  
United States District Court  
Southern District of New York

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Sherise Richardson, individually and on behalf of all others similarly situated,

Plaintiff

- against -

Mars, Incorporated,

Defendant

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Class Action 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 23, 2019

/s/ Spencer Sheehan  
Spencer Sheehan

# EXHIBIT “A”



Food and Drug Administration

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*  
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”



10

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

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,

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

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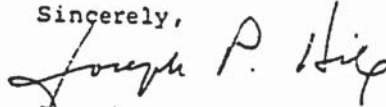
\*/ "...[S]ection [401]...has no relation to, no connection with, the adulteration provisions of the Act." Bruce's Juices v. United States, 194 F.2d 935, 936 (5th Cir. 1952), citing United States v. 36 Drums of Pop'n Oil, 164 F.2d 150 (5th Cir. 1947).

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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”



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:

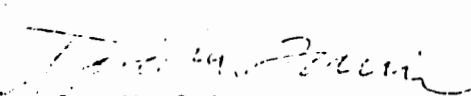
This is in reply to your letter of July 31, 1979 concerning the use of vanilla-vanillin and natural non-vanilla derived flavorings in category II Vanilla Flavored Ice Cream.

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: [Mars' M&M's Ice Cream Bars Contain Less Real Vanilla Than Represented on Packaging, Case Says](#)

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