A Brief History of Fruit and Vegetable Juice Regulation in the United States

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A BRIEF HISTORY OF FRUIT AND VEGETABLE JUICE REGULATION IN THE UNITED STATES

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Class of 2011

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Submitted in satisfaction of the course requirement
INTRODUCTION

Fruit and vegetable juices have a long history of regulation in the United States. Early in the late 19th and early 20th centuries, juices were often indirectly regulated by import tariffs, which taxed juice products in different ways. Most domestic juices were sold fresh, and there was little need for further regulation until the invention of refrigeration. The first national regulations came in the form of informal standards of identity for each juice. In 1938, Congress amended the Federal Food, Drug, and Cosmetic Act to grant the Food and Drug Administration (“FDA”) authority to “promulgate definitions and standards of identity for any food product in order to ‘promote honesty and fair dealing in the interest of consumers.’”¹ In addition to these standards of identity, the 1938 amendments created a series of mandatory labeling requirements for all foods. While these requirements were helpful, they did not require juice manufacturers to reveal the percentages of juice in their beverages. This became problematic when juice manufacturers were successful in distilling juice essences — concentrated flavor that made diluted juices taste similar to 100 percent juice.² Although percentage-labeling requirements were adopted for orange juice in 1977, special interests in the beverage lobby prevented their expansion to other juices for over a decade. In 1990, however, Congress adopted percentage-labeling requirements for fruit and vegetable juice as part of the Federal Food, Drug, and Cosmetic Act. This system is still the framework by which fruit and vegetable juice is regulated in the United States.

This Paper traces the history of fruit and vegetable juice regulation. Part I discusses the use of tariffs and standards of identity from the early 1900s until the 1970s. Part II traces the history of labeling regulation for both 100 percent juices and diluted juice beverages — focusing on the 1974 diluted juice proposal that was stalled for nearly fifteen years. Part III briefly describes the current label-focused approach adopted by the Federal Food, Drug, and Cosmetic Act. Part IV concludes.

I. HISTORY OF JUICE REGULATION

A. Import Tariffs

In the late–18th century, import tariffs played a large role in the regulation of fruit juices. While these tariffs did not affect the domestic fruit juice industry, the definitions adopted during this time had long-lasting effects. The McKinley Tariff Act of 1890, for example, increased the import taxes “from 38 percent to 49.5 percent” for various foreign goods in an attempt to protect U.S. industries. In order to determine whether something was taxed at a certain rate, the McKinley Tariff carefully defined the requirements for various juices — drawing a clear line based on the level of alcohol in the juice. If the juice contained less than 18% alcohol it was taxed at sixty cents per gallon, while juice containing more than 18% alcohol was taxed at $2.50 per proof gallon. This provision

4 See Tariff Act of 1890, 26 Stat. 567, sec. 1, para. 339. A proof gallon is “one liquid gallon of spirits that is 50% alcohol at 60 degrees F.” Frequently Asked Questions, TTB Form 5110.40, available at http://www.ttb.gov/forms_tutorials/f511040/faq_instructions.html. This new distinction based on alcohol percentage replaced the old tariff of 20%, regardless of the juice makeup. See The McKinley Bill as Enacted by the Fifty-First Congress: Complete Text of the Bill, Showing the Old and New Rates 19 (1890).
was adopted with cherry and prune juice in mind, but applied to “other fruit juice, not specially provided for.”

Despite the clear language of the McKinley Tariff, litigation soon arose over the meaning of “cherry juice.” In *Smith v. Rheinstrom*, the defendant was a company that imported from Germany fourteen casks of an article labeled “cherry juice.” Unlike standard cherry juice at the time, however, this cherry juice had been subjected “to heat in a vacuum, and eliminating the watery parts, reducing five gallons of the natural cherry juice to one gallon of the product, and adding 17 per cent. of alcohol.” This process created a “syrup-like” liquid that was different from cherry juice in both texture and color. Because this article consisted of cherry juice with less than 17 percent alcohol, it fell within the textual requirements of “cherry juice” in the McKinley Tariff. The U.S. Circuit Court of Appeals for the Sixth Circuit, however, held that the article did not satisfy the definition of cherry juice as it was known when the McKinley Tariff was passed. The court found that cherry juice carried a “well-known commercial meaning” at the time of enactment — “natural juice of the cherry obtained by expression, with sufficient alcohol added to keep it from fermentation.” The concentrated cherry juice’s “difference in color, weight, strength as a flavoring ingredient, and cost” caused it to fall outside of the McKinley Tariff’s definition of cherry juice.

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6 *See* 65 F. 984, 984 (6th Cir. 1895).
7 *Id.* at 985.
8 *See id.* The article also sold for substantially more money. While regular cherry juice was sold at 30 cents per gallon, this condensed juice sold for $1.10 per gallon. *Id.*
9 *See id.*
10 *Id.* (emphasis added).
11 *Id.*
The “commercial meaning” test in *Rheinstrom* presented one of the earliest fruit or vegetable juice regulations in the United States. When later courts attempted to define a juice, they typically looked to the definition established in commerce at the time of enactment to determine whether juice that was somehow modified or contained too much alcohol was subject to higher tariffs.\(^\text{12}\)

**B. Standards of Identity**

Around the same time tariffs were cementing the commercial meaning of some fruit and vegetable juices, the FDA was maintaining “informal food standards, both as guidance for its own regulatory action against economic adulteration and to assist state and local officials.”\(^\text{13}\) These standards of identity began before the Pure Food and Drug Act of 1906 was even enacted and were officially authorized nearly thirty years later by section 401 of the Federal Food, Drug, and Cosmetic Act.\(^\text{14}\) The purpose of the standards was to “ensure that consumers received good food value for their dollar.”\(^\text{15}\) By 1970 they were so widespread that some have estimated nearly fifty percent of all American foods were subject to a standard of identity promulgated by the FDA.\(^\text{16}\)

\(^{12}\) See, e.g., Voigh v. Mihalovitch, 125 F. 78 (S.D. Ohio 1899) (holding that cherries preserved in liquid containing ten percent alcohol did not satisfy the commercial meaning test in *Rheinstrom*); United States v. Rich, 176 F. 732, 733 (2d Cir. 1910) (finding that imported fruit juice with “some of the water removed by evaporation” was not concentrated fruit juice under the 1897 Tariff Act).

\(^{13}\) Peter Barton Hutt, *A Brief History of FDA Regulation Relating to the Nutrient Content of Food*, in *NUTRITION LABELING HANDBOOK* 4 (Ralph Shapiro ed., 1995).

\(^{14}\) See HUTT, supra note 1, at 93. It has been argued that “[o]ne of the greatest weaknesses of the 1906 Act was its failure to provide for mandatory standards of identity and quality for food, which would have the force of law in prosecutions for adulteration and misbranding.” Note, *Development in the Law: The Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 659 (1954).

\(^{15}\) HAMILTON, supra note 2, at 32.

\(^{16}\) See HUTT, supra note 1, at 93.
Early standards of identity adopted a “recipe” approach, “under which every permitted ingredient was specifically listed in the standard.” This approach was seen as inadequate because “functional food ingredients” such as “preservatives, emulsifiers, thickeners,” and sweeteners could not be used in connection with a food or beverage until they had been approved by the FDA; however, this is the approach the FDA attempted to use in its early regulation of fruit and vegetable juices.

Despite widespread adoption of standards of identity in other areas, the juice industry went largely unregulated for the first half of the 20th century. The explanation for this is a practical one — before the widespread adoption of refrigeration, juice products were required to be made fresh. It was also much more difficult, if not impossible, for juice manufacturers to manipulate juices in deceptive ways. This changed, however, as technology advanced in consumer homes and juice manufacturing plants. The FDA first proposed a general standard of identity for fruit juices on August 13, 1964. The proposal specified standards of identity for various beverages made from

17 Id.
18 The FDA eventually abandoned the recipe approach in favor of allowing any functional ingredients that were “safe and suitable.” See HUTT, supra note 1, at 96. This allowed manufacturers to use functional ingredients as soon as they were approved for safe use; manufacturers no longer had to wait for the further step of having the ingredient added to the recipe for a given food. According to the FDA, a “safe and suitable” ingredient: “(1) Performs an appropriate function in the food in which it is used. (2) Is used at a level no higher than necessary to achieve its intended purpose in that food. [and] (3) Is not a food additive or color additive . . . .” 21 U.S.C. § 130.3(d).
19 Id.
20 See Diluted Fruit Juice Beverages, 29 Fed. Reg. 11,621 (proposed Aug. 13, 1964) (to be codified at 21 C.F.R. pt. 27) [hereinafter 1964 Proposal]. Standards of identity for “diluted citrus fruit juice beverages” were proposed by Sunkist Growers; the FDA Commissioner proposed the other standards. Id. It is worth noting, however, that this was simply the first time that a standard of identity was proposed that would broadly apply to fruit juices — the FDA has previously expressed interest in adopted standards of identity for pineapple-grapefruit juice in 1960. See Canned Pineapple-Grapefruit Juice
orange, grapefruit, lime, and lemon, and then proposed percentage-juice requirements for other diluted fruit juices.\textsuperscript{21} These standards of identity all define fruit juices based on the percentage of the “equivalent natural strength” juice they contain. The 1964 proposal served as the foundation for other proposed standards of identity over the next fifteen years. While the history of these standards is interesting, and introduces some of the controversies that later delayed the 1974 percentage-juice labeling proposal, it is worth noting at the outset that no standards of identity were ever actually enacted for these juices.

1. Orange Juice

Orange juice was the first juice discussed in the 1964 proposal. These proposals were designed to solve the problems of having “a number of diluted orange juice beverages that bore misleading and noninformative names such as ‘orange drink’ or ‘orange juice beverage.’”\textsuperscript{22} At least one survey of orange juice products in the 1960s and early 1970s found “substantial consumer confusion about the amount of orange juice contained in the various beverages,” with consumers “perceiving many diluted orange juice beverages to be 100 percent orange juice or to contain substantially more orange juice than was actually present.”\textsuperscript{23} Additionally, many consumers mistakenly thought

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\textsuperscript{21} See id. at 11,621–25.
\textsuperscript{22} Common or Usual Names for Nonstandardized Foods; Diluted Fruit or Vegetable Juice Beverages, 49 Fed. Reg. 22,831 (proposed June 1, 1984) (to be codified at 21 C.F.R. pt. 102) [hereinafter June 84 Proposal].
\textsuperscript{23} Id. at 22,831–32.
that some orange-flavored beverages contained orange juice when they actually contained none at all.\textsuperscript{24}

The 1964 proposal begins by defining four different standards of identity for orange juice beverages proposed by Sunkist growers. The isolation of orange essence and refined orange oil motivated these detailed juice categories, because manufacturers could produce a beverage that tasted like orange juice without containing much natural juice.\textsuperscript{25} With one exception, explained below, these beverages all contain the same recipe — any combination of natural, concentrated, or reconstituted orange juice, orange oils, water, sweeteners, and “acidifying ingredients.”\textsuperscript{26} First, “orange nectar” is defined as any mixture that contains no less than 50 percent orange juice.\textsuperscript{27} Second, “orange/juice-drink” could contain no less than 30 percent orange juice.\textsuperscript{28} Third, “orangeade” was a beverage with the same ingredients that contained no less than 15 percent orange juice.\textsuperscript{29} Finally, “orange drink” only needed to contain 6 percent orange juice and could also modify the recipe with specified optional ingredients, so long as they

\textsuperscript{24} See id. at 22,832.
\textsuperscript{25} See HAMILTON, supra note 2, at 86.
\textsuperscript{26} See 1964 Proposal, supra note 20, at 11,621–26. The full language of the standard states:

\textit{It is prepared by mixing orange juice, orange juice for manufacturing, concentrated orange juice, concentrated orange juice for manufacturing, reconstituted orange juice, or any combination of these juice ingredients with orange oil and/or concentrated orange oil and/or orange essence, water, one or more nutritive sweeteners, and one or more of the acidifying ingredients citric acid, other edible orangic acids, lemon juice, or concentrated lemon juice.}

\textit{Id.} at 11,621.
\textsuperscript{27} Id. Natural strength orange juice is defined as having a Brix level of 11.8 degrees.
\textsuperscript{28} Id.
\textsuperscript{29} Id. at 11,622.
were “not used in a manner to cause the finished drink to simulate or imitate orange juice.”

These standards of identity evolved over the years. In their final (unadopted) form, there were three separate categories of orange juice beverages. First, “orange juice drink” was defined as a beverage that “contains less than 70 percent but not less than 35 percent equivalent single strength orange juice.” Second, “orange drink” was a beverage that contained between 10 and 35 percent equivalent single strength orange juice. Finally, similar standards were established for “orange flavored drink,” which contained between 0 and 10 percent orange juice. Unfortunately, differences arose “between representatives of the two major orange-producing areas of the United States . . . [over] names, minimum orange juice requirements, and added color and other ingredients used.” As a result, no standards of identity for orange juice were ever adopted.

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30 Id. The optional ingredients included “coloring, ascorbic acid, butter salts, emulsifying and stabilizing substances, and weighting oils.” Id.
31 Notably, in 1968 there were proposals that established three categories of orange juice beverages, with minimum percentages of orange juice associated with each one. See Diluted Fruit Juice Beverages; Order Establishing Identity Standards for Diluted Orange Juice Beverages, 33 Fed. Reg. 6865 (proposed May 7, 1968) (to be codified at 21 C.F.R. pt. 27). These were replaced by percentage ranges in the final 1972 proposal. Diluted Orange Juice Beverages, 37 Fed. Reg. 5224, 5227 (Mar. 11, 1972) (to be codified at 21 C.F.R. pt. 27). Like the other forms of orange juice beverages, the regulations for “orange juice drink” also contained definitions for orange juice drink made of concentrated and powered orange juice drink. See id. at 5228.
32 See id. at 5228.
33 See id. at 5229.
34 See id. at 5229.
36 See id. at 6969 (permanently staying the 1972 proposal for standards of identity for diluted orange juice beverages).
2. Pineapple-Grapefruit

In 1960, three manufacturers of pineapple-grapefruit juice proposed a standard of identity for pineapple-grapefruit juice. This was one of the earliest such proposals received by the FDA, and ultimately led to a final rule being issued in 1968. Under this final rule, the recipe for pineapple-grapefruit juice called for some mixture of the two juices in pure or concentrated form, water, and optional sweetening ingredients. The final beverage was required to have some combination of pineapple and grapefruit juices that was not less than 50 percent of the total beverage. Although published in the Federal Register, this standard of identity was indefinitely stayed in 1968 and formally revoked in 1982.

3. Grapefruit

In addition to pineapple-grapefruit standards of identity, the FDA attempted to establish similar standards for other grapefruit beverages. In the 1964 proposal, for example, the recipe for grapefruit beverages combined any form of natural, concentrated, or reconstituted grapefruit juice with “grapefruit oil and/or grapefruit essence, water, one

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37 See Pineapple-Grapefruit Proposal, supra note 20, at 3987. The three manufacturers were California Packing Corporation, Hawaiian Pineapple Company, and Gerber Products Company. Id.
39 See id. The optional sweetening ingredients included “[s]ugar, invert sugar sirup, dextrose, corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup.” Id.
40 See id. (“[t]he adjusted weight of the combination of these fruit juice ingredients shall be not less than 50 percent of the weight of the finished food . . .”).
or mote nutritive sweeteners, and one or more of the acidifying ingredients . . .”

Using this recipe, any beverage containing at least 30 percent “natural strength grapefruit juice (10.8˚ Brix basis)” was labeled as “grapefruit juice-drink” or “juice-drink grapefruit.”

Grapefruit beverages containing not less than six percent natural strength grapefruit juice were named “grapefruit drink,” and any beverages with less than six percent grapefruit juice were called “grapefruit flavored drink.”

It is unclear what happened to this proposal, but it was no longer present when many of the other juice standards of identity were adopted in 1982.

4. Lemon

Many different standards were set for lemon beverages in the original 1964 proposal. Two of these beverages used the same recipe as orange and grapefruit juices, with lemon juice substituted. “Lemon drink” was defined as any beverage containing not less than six percent lemon juice, while “lemon flavored drink” contained less than six percent lemon juice.

Additionally, two standards were proposed for lemonade and pink lemonade that followed a similar recipe but made the inclusion of lemon oils or essence optional. Lemonade was required to have at least 12.3 percent lemon juice. Pink lemonade was required to contain at least 12.3 percent of some fruit juice, which included “any suitable fruit or vegetable juice or concentrate thereof, to color the product pink.”

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42 1964 Proposal, supra note 20, at 11,622.
43 Id.
44 See id. at 11,622–23.
45 See id. at 11,623.
48 Id.
Lemon drink and lemon flavored drink were ultimately dropped from consideration, but standards of identity were adopted for lemonade and colored lemonade in 1968.\footnote{See Diluted Fruit Juice Beverages; Order Establishing Identity Standards for Lemonade, Colored Lemonade, and Limeade, 33 Fed. Reg. 6864 (May 7, 1968) (to be codified at 21 C.F.R. pt. 27) [hereinafter Lemon/Lime Standard].} After receiving relatively few comments on the original lemonade proposals, the FDA decided these standards of identity would “promote honesty and fair dealing in the interests of consumers . . .”\footnote{Id.} The requirements for colored lemonade were identical to lemonade, except “it is colored with a safe and suitable color.”\footnote{Id.} Like all other adopted juice standards of identity, these were indefinitely stayed and ultimately revoked in 1982.\footnote{See 1982 Revocation, supra note 41, at 34,131.}

5. Lime

Similar to other juices, the 1964 proposal established a recipe for lime beverages that consisted of any combination of natural or concentrated lime juice, water, and “one or more nutritive sweeteners.”\footnote{1964 Proposal, supra note 20, at 11,624. This recipe also included the optional ingredients of “cold-pressed lime oil, concentrated lime oil, lime essence, and buffer salts.” Id. The 1964 proposal also sought to establish standards of identity for “lemon and limeaid,” “lemon and lime drink,” “lemon and lime flavored drink,” “fruit lemon drink,” and “fruit flavored lemon drink,” which all consisted of mixtures of both lemon and lime juices, or lemon and other fruit juices in various percentages. See id. at 11,624–25.} Limeade was the name given to any beverage that contained at least 12.3 percent lime juice. Additionally, beverages with at least six percent lime juice were called “lime drink,” and those will less than six percent lime juice were named “lime flavored drink.”\footnote{Id.} Lime drink and lime flavored drink were never adopted, but a standard of identity for limeade was adopted in 1968. This definition of
limeaid referenced the standard established at the same time for lemonade, and adopted a recipe that was essentially the same as the recipe listed above. After resistance from the juice industry, these standards were stayed months after their adoption, and revoked in 1982.

6. Other Juices and the Cranberry Controversy

The 1964 proposal distinguished all other fruit juices on the basis of their percentage of fruit juice. “Fifty percent fruit juice drinks” were required to have “not less than 50 percent of fruit juice, calculated to a single strength basis.” Additionally, blended fruit juice drinks were required to use “fruit juice ingredient[s] . . . in a quantity at least sufficient to impart its characteristics to the blend . . . .” Beverages that contain between 30 and 50 percent fruit juice were labeled as “thirty percent fruitades,” while beverages with between 10 and 30 percent fruit juice were named “ten percent fruit drinks.”

This rule was met with opposition by the cranberry industry. They claimed that the fifty percent juice requirement was “too high for a juice drink prepared from cranberries because cranberry juice is characteristically so acidic and astringent that a beverage containing 50 percent single strength cranberry juice is not as palatable as one

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55 See Lemon/Lime Standard, supra 49, at 6865 (“Limeade is the beverage food that conforms to the compositional requirements prescribed by § 27.99 for lemonade, except that instead of using lemon juice ingredients . . . [the] ingredients [are] derived from mature limes . . .”).
56 1964 Proposal, supra note 20, at 11,625.
57 Id.
58 Id. at 11,626.
Further, a cranberry beverage containing 25 percent juice would be labeled a “ten percent fruit drink” under the 1964 proposal. Because cranberry cocktails with 25 percent juice had “been accepted by consumers as a ‘quality’ drink for many years,” the FDA proposed a new standard of identity for cranberry juice cocktails with four basic requirements. First, the juice must be prepared using single strength or concentrated cranberry juice, or both. Second, water and “one or more nutritive sweetening ingredients” can be added to the cocktail as long as the filtered beverage contains at least “25 percent by volume of equivalent single strength cranberry juice.” Third, the Brix level of the cranberry cocktail must be between fourteen and sixteen degrees Brix. Finally, the acid content of the cocktail must be “not less than 0.55 gram per 100 milliliters.”

The FDA determined that these standards served the interests of consumers, and adopted a final rule that left the proposed standard essentially unmodified. Cranberry juice manufacturers were unhappy with the adopted standards of identity, however, and filed requests for a public hearing. Their principle complaints revolved around: “(1) the labeling of the beverages, (2) the lack of provision for adding color, and (3) the minimum

60 Id.
61 Id. The proposed regulation also required the cranberry juice cocktail be sealed in containers to prevent spoilage, list the ingredients in order of predominance on the label, and use the name “Cranberry juice cocktail—a juice drink.” Id. Similar standards were included for “[a]rtificially sweetened cranberry juice cocktail.” See id.
percentage of equivalent single strength juice required.” 63 The stay was never lifted, and the standards of identity were revoked after the FDA adopted the new labeling requirements that are the subject of Part II.

II. LABELING REQUIREMENTS

A. Orange Juice

After the FDA failed to adopt a standard of identity for orange juice, 64 it adopted regulations for the naming of diluted orange juice beverages. 65 These naming standards were necessary because labels at the time were largely uninformative and consumers had “no way to make a value comparison of the beverages at the time of purchase.” 66

According to the final regulation, diluted orange juice beverages were required to contain three major components: (1) a descriptive name that complied with section 102.1(a); 67 (2) a declaration of the percentage of juice contained in the beverage “expressed as a multiple of five not greater than the actual percentage of juice present”; 68 and (3) a percentage of orange juice with an “equivalent single strength of 11.8 percent orange juice soluble solids.” 69 These requirements were a resounding success, “stimulat[ing] competition between diluted orange products and [result[ing] in informed purchases by

64 These standards of identity were first proposed in 1964, but were permanently stayed in 1973. See 1973 Final Rule, supra note 35, at 6968.
65 See id. at 6969.
66 Id. at 6968.
67 See id. at 6969.
68 See id. The percentage of juice could be expressed using the word “percent” or the symbol “%.” Id. Additionally, beverages containing less than five percent orange juice could use the phrase “less than 5%” on their labels. Id.
69 Id.
consumers.” This regulation was used as a baseline for the FDA’s attempt to regulate other diluted fruit or vegetable juices for the next fifteen years, and remained in effect until Congress passed the NLEA in 1990.

**B. 1974 Proposal**

In 1974, the FDA proposed a new regulation to establish labeling requirements for diluted fruit or vegetable juices other than diluted orange juice. A final rule was issued in June 1980, with the 1974 proposal largely unchanged. From 1980 to 1990, however, juice manufacturers repeatedly delayed implementation of the regulations and the 1974 proposal was never enacted.

1. **Adopted Regulations**

After the FDA adopted common or usual names for orange juice in 1973, it attempted to extend similar requirements to other juices. The FDA was motivated by the observation that “most labels on diluted juice products . . . show[] that consumers are not being informed in regard to the amount of juice present,” despite the percentage of juice being “the major factor determining the price and consumer acceptance of the product.” The 1974 proposal applied to all noncarbonated beverages “containing less than 100 percent and more than 0 percent fruit or vegetable juice(s),” with the exception of orange juice. These beverages were required to comply with the existing descriptive name

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70 *June 84 Proposal, supra* note 22, at 22,832.
71 This regulation, codified at 21 C.F.R. § 102.32, was reviewed by the FDA in 1984 and was upheld without amendment. *See id.* ("the agency is not amending or repealing §§ 102.30 and 102.32").
73 *Id.* The existing orange juice regulations were not affected by these proposals.
regulations\textsuperscript{74} and also list “the percentage of each juice contained in the product . . . . declared in 5 percent increments . . . not greater than the actual percentage of juice in the product.”\textsuperscript{75} If a beverage contained 54 percent apple juice, therefore, it must contain a statement on the label that states “50 percent apple juice.” If a beverage contains between zero and five percent juice, however, it must be labeled as “‘less than 5’ percent.”\textsuperscript{76}

The 1974 proposal calculated the percentage of juice in a beverage “on the basis of the soluble solids content of the single strength (undiluted) juice used to prepare the diluted juice(s).”\textsuperscript{77} This suggestion was unpopular with juice manufacturers because it failed to “specifically define or give average figures for the soluble solids content of each single-strength juice which might be diluted.”\textsuperscript{78} The FDA recognized the need for these averages, but felt that waiting for them to be established “would deprive the consumer of valuable information about these beverages for an undefined period of time.”\textsuperscript{79} Throughout the history of FDA juice regulation, however, the average soluble solids content values were never established for any juice other than orange juice.\textsuperscript{80}

\textsuperscript{74} See 21 C.F.R. § 102.1(a).
\textsuperscript{75} 1974 Proposal, supra note 72, at 20,908.
\textsuperscript{76} Id.
\textsuperscript{77} Id.
\textsuperscript{78} Diluted Fruit or Vegetable Juice Beverages; Common or Usual Names for Nonstandardized Foods, 45 Fed. Reg. 39,247 (June 10, 1980) (to be codified at 21 C.F.R. pt. 102) [hereinafter June 1980 Final Rule].
\textsuperscript{79} Id.
\textsuperscript{80} See Diluted Fruit or Vegetable Juice Beverages Other Than Diluted Orange Juice Beverages, 52 Fed. Reg. 26,690 (proposed July 16, 1987) (to be codified at 21 C.F.R. pt. 102) [hereinafter 1987 Proposal] (“To date, no information or data have been developed to establish average soluble solids content values for individual, single strength juices other than orange juice”).
Many of the affected parties filed comments criticizing other aspects of the 1974 proposal. The FDA considered these objections, but ultimately rejected the vast majority of them. Multiple-juice producers, for example, claimed the percentage declaration requirement for individual juices was unnecessary, could disclose trade secrets, and might result in overcrowding on labels. These concerns were not outweighed by the benefit of having “the consumer . . . know how much of that juice(s) is present.” Additionally, the manufacturers of diluted juice beverages made from high-acid juices complained that the 1974 proposal ignored their history of basing juice content on “the citric acid content per unit volume in combination with the Brix-acid ratio rather than total soluble solids.” The FDA acknowledged this departure from custom, but held that the interests in label uniformity to prevent customer confusion outweighed the unsupported Brix-acid ratio test.

2. Effective Date Stayed Until 1982 and then 1984

In December 1980, the FDA heard a petition for reconsideration of the 1974 proposal by the National Food Processors Association (“NFPA”). NFPA argued that the requiring both total juice and individual juice percentages was “redundant and would create unnecessary label overcrowding, reduce formulation flexibility, compel disclosure of trade secrets, and result in misleading declarations of individual juice percentage.” The FDA rejected these claims, finding that “[t]he consumer has a right to know the

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82 Id.
83 Id. at 39,249.
84 Id.
86 Id. at 80,498.
approximate amount of each of the identified juices in the drinks.” The effective date of the 1974 proposal was extended one year, however, to allow NFPA (and other manufacturers) to exhaust their current inventory of labels. This delay was seen as beneficial to consumers because “costly destruction of existing label inventories . . . would result in higher costs . . . and therefore would not be in their best interest.”

In March 1982 — mere months before the 1974 proposal would become effective — the FDA postponed the effective date of the regulation for two years. Under the “Regulatory Flexibility Act, Executive Order 12291, and the Paperwork Reduction Act of 1980, the FDA was required to review certain regulations, including the ones “concerning diluted orange juice beverages . . . and noncarbonated beverage products containing no fruit or vegetable juice.” The FDA believed the 1974 proposal was substantially similar to these regulations and decided to review all three regulations together. Allowing the 1974 proposal to become effective during this review period would cause manufacturers to “incur substantial compliance costs that may later be found unnecessary should the review process result in a decision to revoke or modify the regulations.” The FDA therefore postponed the effective date of the 1974 proposal until July 1, 1984.

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87 Id.
88 The effective date for compliance was extended from July 1, 1981 to July 1, 1982. See id. at 80,497.
89 Id. at 80,498.
90 Common or Usual Names for Nonstandardized Foods; Diluted Fruit or Vegetable Beverages; Proposed Extension of Effective Date, 47 Fed. Reg. 13,003 (proposed Mar. 26, 1982) (to be codified at 21 C.F.R. pt. 102).
91 Id.
92 Id. The FDA noted that firms that had already changed their labeling to comply with the 1974 proposal could continue to use those new labels. See id. Despite the postponement, the FDA officially revoked the proposed standards of identity for
3. Amendments

In early 1984, the FDA released its review of the three regulations discussed above. The Agency found that the two orange juice regulations had “resulted in informed purchases by consumers,” and left them in tact without repeal or amendment. It proposed minor amendments to the 1974 proposal, however, to satisfy the concerns raised by “manufacturers of multiple juices and high-acid juices.” The FDA focused on two complaints lodged by multiple-juices beverage producers: (1) the name required by the regulation might be too long, and (2) the percentage declaration might be misleading because “the rounded off percent declarations of the individual juices could be significantly different from the actual total percentage of juices present.” In order to allow for shorter product names, the 1974 proposal was amended to give manufacturers an option between “declaring either the percentage of individual juice content or the percentage of total juice content.” Additionally, the FDA responded to the rounding concerns by requiring the juice declaration to be expressed “as a whole number not greater than the actual percent contained in the beverage,” rather than rounding down to the nearest five percent.

Manufacturers of high-acid juices such as cranberry juice, on the other hand, argued that percentage declaration requirements were misleading because these juices cranberry juice cocktail, artificially sweetened cranberry juice cocktail, lemonade, and colored lemonade in August 1982. See 1982 Revocation, supra note 41, at 34,131.

93 June 84 Proposal, supra note 22, at 22,832.
94 Id. See also Part II.C.1, supra.
95 June 84 Proposal, supra note 22, at 22,832.
96 Id.
97 Id. This amendment also satisfied concerns by the lemonade industry that their product — traditionally 13 percent juice — would be misleadingly expressed as 10 percent until the old percentage formulation. See id. at 22,833.
were never served in their non-diluted forms. Because of the high acid content of cranberry juice, it must be heavily diluted in order for customers to enjoy its taste. Requiring manufacturers to label cranberry juice cocktails with the low juice percentage that is standard for these beverages might lead consumers to think they are purchasing an inferior cranberry juice product. 98 Recognizing that this problem may lead to confusion — the exact problem the 1974 proposal was designed to eliminate — the FDA proposed to exempt diluted cranberry juice from the 1974 proposal. Additionally, beverage manufacturers were invited to propose similar exemptions for other high-acid fruits. 99

After proposing these amendments, the FDA also suggested extending the effective date of the 1974 proposal until a new final rule could be issued to incorporate the changes. None of these proposals were implemented, however, and the process reached a stalemate for over three years. 100

4. Revocation

In July 1987, the FDA suggested revoking both the 1974 proposal and its 1984 proposed amendments to “allow voluntary percentage labeling of these diluted juice beverages at the discretion of the manufacturer and according to the demands of the marketplace.” 101 The FDA acknowledged the troubled history behind the 1974 proposal and the controversy it sparked among juice producers. Because of these controversies, the Agency revisited the necessity of juice percentage regulations. The FDA found that, although there was ample evidence supporting similar regulation in the orange juice

98 See id. at 22,832.
99 See id.
100 See 1987 Proposal, supra note 80, at 26,690.
101 Id. at 26,691.
industry, there were no “significant consumer awareness problems concerning the value
of [other] diluted juice beverages during the past 6 years since the [1974 proposal] was
stayed.” Some manufacturers believed accurate percentage labeling was beneficial to
consumers, but there were no reported complaints from customers of manufacturers who
did not report juice percentages. According to the FDA, the 1974 proposals were
therefore “neither necessary not practicable at this time.”

After the proposed revocation of the 1974 proposal, the FDA invited comments
from the public for a two-month period. This comments period was ultimately
extended until the end of the year, and then reopened briefly the following January
against the wishes of several U.S. senators. Nothing came of these comments and the
1974 proposal lay dormant indefinitely.

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102 Id.
103 See id.
104 Id.
105 See id. Comments were originally due by September 14, 1987.
106 See Diluted Fruit or Vegetable Juice Beverages Other Than Diluted Orange Juice Beverages; Extension of Comment Period, 52 Fed. Reg. 36,046 (Sept. 25, 1987) (to be codified at 21 C.F.R. pt. 102) (extending comments for 90 days to allow the National Juice Products Association to “formulate appropriate recommendations . . . [after] their mid-year meeting in October,” and for the Center for Science in the Public Interest (“CSPI”) to “obtain and compile . . . data regarding consumer complaints and awareness problems concerning the value of diluted juice beverages”).
107 See Diluted Fruit or Vegetable Juice Beverages Other Than Diluted Orange Juice Beverages; Reopening of Comment Period, 53 Fed. Reg. 1795 (Jan. 22, 1988) (to be codified at 21 C.F.R. pt. 102) (extending comments for 45 days past the previous December 13, 1987 deadline at the request of CSPI). According to the FDA, “several members of the U.S. Senate request[ed] that the comment period not be extended further.” Id.
5. NFPA Proposal

In early 1989, the NFPA proposed new regulations to replace the 1974 proposal.\(^\text{108}\) One year later, in January 1990, the FDA requested comments on the NFPA proposal.\(^\text{109}\) This new proposal endorsed expressing the juice percentage “as a whole number not greater than the actual percentage,” rather than the five percent increments contained in the unamended 1974 proposal. Additionally, the proposal allowed multiple-juice beverages to only declare the total percentage of juice contained in the beverage, “rather than as part of the statement of identity on the principal display panel.”\(^\text{110}\) These requirements were both suggested, but not adopted, in the 1984 amendments to the 1974 proposal.\(^\text{111}\) Most importantly, however, the NFPA proposal placed the required percentage juice declaration to be on the information panel “rather than as part of the statement of identity on the principal display panel.”\(^\text{112}\)

The FDA expressed concern with some aspects of the NFPA proposal. It was concerned, for example, “about accurately representing the contents of multiple juice products and diluted multiple juice products that contain minor amounts of the characterizing juice . . . ”\(^\text{113}\) If the percentage juice declaration was moved to the information panel on the back of the label, it might “impl[y] that the characterizing juice

\(^{\text{108}}\) See Juice and Diluted Juice Beverages; Common or Usual Name for Nonstandardized Foods, 55 Fed. Reg. 3266 (proposed Jan. 31, 1990) [hereinafter NFPA Proposal] (“FDA has now received a citizen petition from NFPA dated January 19, 1989 . . . requesting that the agency revoke the current common or usual name regulation for diluted fruit or vegetable juice beverages other than diluted orange juice beverages . . . .”).

\(^{\text{109}}\) Id.

\(^{\text{110}}\) Id. at 3267.

\(^{\text{111}}\) See June 84 Proposal, supra note 22, at 22,832.

\(^{\text{112}}\) NFPA Proposal, supra note 108, at 3267.

\(^{\text{113}}\) Id. at 3268.
is either the only juice or the major juice present in the product when it is not.”\(^{114}\) The
FDA requested comments on methods for solving this problem.\(^{115}\) Additionally, the FDA
was concerned with the NFPA’s lack of regulation for modified juices. Modification of
juices was a growing problem in the juice industry, and ranged from “relatively minor
changes, such as altering the acidity to improve the taste, to major modifications that
remove virtually all flavors and colors, and result[] essentially in sugar water.”\(^{116}\) These
modifications were especially worrisome when they removed nutritious components of a
juice and replaced them with sugars. The FDA therefore sought comments on how
modified juices should be named as part of beverages, and whether they should count in
calculating the juice percentage in a beverage.\(^{117}\) Finally, because of the many
unresolved issues involving diluted juice beverages, the FDA requested comments “on
the entire issue of the common or usual name regulation for diluted juice
beverages . . . “\(^{118}\)

After being reopened for 30 days at the request of the numerous juice

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\(^{114}\) *Id.* For litigation that was sparked by similar concerns, see, e.g., POM Wonderful LLC v. The Coca Cola Co., 727 F. Supp. 2d 849 (C.D. Cal. 2010) (finding pomegranate-blueberry flavored 100% juice blend that contained mostly apple and pear juice was not false advertising).

\(^{115}\) *Id.* (“FDA is seeking comments on how to accurately represent, through identity statements and vignettes, diluted juice blend products with one or more characterizing juices . . . “).

\(^{116}\) *Id.* (“FDA has been concerned for the last several years about modified juices, including decharacterized or stripped juices”). The FDA illustrated this problem succinctly:

> For example, consumers would be economically deceived if deflavored, decolored, acid-reduced grape juice was used in a product, such as raspberry-flavored juice beverage, that was labeled with respect to the percentage of juice and to ingredient content as though the decharacterized grape juice was an unaltered juice.

\(^{117}\) *Id.*

\(^{118}\) *Id.* at 3269.
producers, this comment period finally ended on July 5, 1990. Then, nearly thirty years after the FDA’s first proposal for naming diluted juice beverages other than diluted orange juice, Congress preempted this area with the Nutrition Labeling and Education Act of 1990.

III. THE MODERN APPROACH

Congress “settled the question of whether, and where, a declaration of the percentage of juice in a fruit or vegetable juice beverage must be included on the product’s label” with the Nutrition Labeling and Education Act of 1990 (“NLEA”), which amended section 403 of the Federal Food, Drug, and Cosmetic Act. The requirements set forth in this Act have remained essentially unchanged since 1990.

A. Labeling Requirements

1. Juice Percentage

The Federal Food, Drug, and Cosmetic Act currently requires beverages with fruit or vegetable juices to have “a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food.” This labeling requirement applies broadly to almost any beverage containing or resembling fruit juice. The regulations are applicable, for example, to “any food that

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119 See Juice and Diluted Juice Beverages; Common or Usual Name for Nonstandardized Foods, 55 Fed Reg. 22,845 (June 4, 1990). The groups requesting additional time for comments included “Processed Apples Institute, Inc., the National Juice Products Association, Dole Packaged Foods Co., Florida Citrus Processors Association, the Florida Department of Citrus, and the NFPA.” Id.
120 See Unified Agenda, 56 Fed. Reg. 17,293, 17,298 (Apr. 22, 1991) (stating that the FDA must propose a new diluted fruit or vegetable juice regulation to conform with the NLEA).
121 21 U.S.C. § 343(i).
122 The FDA later clarified that the NLEA did not just apply to diluted juices, but also 100 percent juices. See Food Labeling; Declaration of Ingredients; Common or Usual
purports to be a beverage that contains any fruit or vegetable juice,” products with labels “bear[ing] any vignette . . . or other pictorial representation of any fruit or vegetable,” and products “contain[ing] color and flavor that gives the beverage the appearance and taste of containing a fruit or vegetable juice.”\textsuperscript{123} It doesn’t matter if your product contains no fruit or vegetable juice whatsoever — if a product in any way represents itself as containing juice products it must have a percent juice declaration.\textsuperscript{124} The NLEA, therefore, led to the revocation of previous FDA regulations on “products whose label or labeling represents, suggests, or implies that they contain juice.”\textsuperscript{125}

The percentage juice declaration can be satisfied in many different ways, depending on the makeup of the fruit or vegetable juices in the beverage. Assuming the beverage actually contains some amount of fruit or vegetable juice, there are three possible options. All of these percentage labeling requirements require the percentage to be “expressed as a whole number not greater than the actual percentage of the juice in the beverage.”\textsuperscript{126} First, the label can specify the amount of a given juice that the beverage contains — e.g., “Contains 75 % pear juice.”\textsuperscript{127} It is worth noting that if a juice has been

\textsuperscript{123} 21 C.F.R. § 101.30(a).
\textsuperscript{124} \textit{See id.} (“The beverage may be carbonated or noncarbonated, concentrated, full-strength, diluted, or contain no juice”). Additionally, a beverage with less than 100 percent juice cannot use percentage declarations to describe characteristics of the beverage — e.g., “‘100 percent natural’ or ‘100 percent pure.’” 21 C.F.R. § 101.30(l).
\textsuperscript{125} Food Labeling; Declaration of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages, 56 Fed. Reg. 30,452, 30,453 (proposed July 2, 1991) (to be codified at 21 C.F.R. pts. 101 and 102) [hereinafter \textit{1991 Proposal}]. 21 C.F.R. § 102.30 was finally revoked in 1993. \textit{See 1993 Final Rule, supra} note 122, at 2897.
\textsuperscript{126} \textit{See, e.g., id.} at 2925.
\textsuperscript{127} \textit{See 21 C.F.R.} § 101.30(b)(1).
modified to the point that it is unrecognizable or contains less than the normal nutrient range for that juice, it “shall not be included in the total percentage juice declaration”\textsuperscript{128} and that fruit or vegetable “may not be depicted on the label.”\textsuperscript{129} Second, the label can state the total percentage of juice contained in the beverage without specifying the fruit or vegetable juices at issue — e.g., “Contains 100% juice.”\textsuperscript{130} This was one of the most contested requirements facing the FDA — because it allows manufacturers of juice blends to advertise a high percentage of juice without divulging the specific percentage of each fruit or vegetable — but a narrow reading of the NLEA led to this statutory conclusion.\textsuperscript{131} Additionally, “[i]f the beverage contains 100 percent juice and also contains non-juice ingredients that do not result in a diminution of the juice soluble solids . . . it must be accompanied by the phrase ‘with added _____,’ the blank filled in with a term such as ‘ingredient(s),’ ‘preservative,’ or ‘sweetener,’ as appropriate . . . .”\textsuperscript{132}

If a company’s product contains added sugar and the company represents the product as 100 percent juice without an additional declaration, it may be liable for false advertising.

\textsuperscript{128} 21 C.F.R. § 101.30(k).
\textsuperscript{129} 21 C.F.R. § 102.33(f).
\textsuperscript{130} See 21 C.F.R. § 101.30(k).
\textsuperscript{131} Initially, after the NLEA, the FDA interpreted the “such fruit” language of section 403(i) as requiring “the declaration of the percentage of each represented juice” on a beverage label. \textit{1991 Proposal, supra} note 125, at 30,456. This was seen as a good way to combat the problem that arose when “the name or the vignette on the label suggests that the expensive juice, such as raspberry, is present in a substantial quantity, and that, therefore, the beverage is of good value, when in fact there is only a small amount of the juice present.” \textit{Id.} at 30,455. In 1993, however, the FDA changed its mind and adopted a narrow reading of the statute. Because other sections of the NLEA clearly specify requirements for “each such ingredient,” the FDA concluded that “had the intent of Congress been to require percent individual juice declaration, it clearly knew how to do so.” \textit{1993 Final Rule, supra} note 122, at 2900. Absent legislative history to the contrary, the NLEA was read to require declaration of percent of total juice but not declaration of percent of individual juices in a multiple-juice beverage.” \textit{Id.}
\textsuperscript{132} 21 C.F.R. § 101.30(b)(3).
under the Latham Act. If a beverage is only flavored to resemble fruit or vegetable juice (artificially or by using minor amounts of juice), different sets of labeling regulations apply. These products only need a statement on their label that “us[es] terms such as ‘flavor’, ‘flavored’, or ‘flavoring’ with a fruit or vegetable name . . . .” There are three important exceptions, however, when the label must affirmatively state that the beverage contains no juice: (1) when the label contains the word “juice”; (2) when there is “[a]n explicit vignette depicting the fruit or vegetable from which the flavor derives”; or (3) when the beverage contains a “[s]pecific physical resemblance to a juice or distinctive juice characteristic . . . .”

2. Diluted Multiple-Juice Beverages and Single-Strength Juice Blends

If a beverage contains multiple juices, whether in diluted or 100 percent juice form, additional labeling requirements apply. First, each juice must be listed in the ingredient statement “in descending order of predominance by volume . . . .” Second, if a beverage contains juice that is not specifically named or implied, the “common or usual name for the product shall indicate that the represented juice is not the only juice

133 This is true even if the adulteration with unknown to the company. See POM Wonderful LLC v. Purely Juice, Inc., 362 Fed. Appx. 577, 579–80 (9th Cir. 2009) (affirming the lower court’s finding of false advertising when a product claiming to be 100% pomegranate juice contained additional sugar that was added to the concentrate by a foreign entity).
134 21 C.F.R. § 101.30(b)(2).
135 21 C.F.R. § 101.30(b)(3).
136 21 C.F.R. § 101.30(c)(1)–(3); see also 21 C.F.R. § 101.30(d) (“the label shall declare ‘contains zero (0) percent (or %) juice’ . . . . [or] ‘contains no fruit juice’”).
137 21 C.F.R. § 102.33(b).
present (e.g., ‘Apple blend; apple juice in a blend of two other fruit juices.’).” Third, manufacturers cannot include a small amount of cranberry juice in a beverage, for example, and then call the product a cranberry juice blend. If the named juice is not the most predominant by volume, the beverage label must “[i]ndicate that the named juice is present as a flavor or flavoring” and “[i]nclude the amount of the named juice, declared in a 5-percent range.” For example, a pomegranate-raspberry juice blend with minor amounts of pomegranate might read, “pomegranate juice drink 3 to 8 percent pomegranate juice.”

3. Other

In addition to labeling requirements presented above, fruit and vegetable juices are subject to other important regulations. If any of the juices in a beverage are made from concentrate, for example, the label must clearly indicate this. Juices with artificial coloring, flavoring, or chemical preservatives must also expressly state this on the label. Finally, juice beverages must comply with the same nutritional labeling requirements as all other consumable foods.

B. Brix Levels

1. Uses

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138 21 C.F.R. § 102.33(c).
139 21 C.F.R. § 102.33(d)(1)–(2).
140 See 21 C.F.R. § 102.33(g)(1). The label can include the term “from concentrate” or “reconstituted.” Id.
141 See 21 U.S.C. § 343(k). This provision only applies to the extent compliance is practical. It seems likely, however, that compliance would never be a problem for the vegetable or fruit juice industry.
142 See 21 U.S.C. § 343(q); 21 C.F.R. § 102.5 (providing “General principles” for the naming of foods).
The FDA determines whether juice from concentrate is 100 percent juice by measuring its Brix level. Each degree Brix represents “1 gram of sugar per 100 grams of . . . juice.” The higher the Brix level, therefore, the higher the level of sucrose in the unconcentrated juice.

When Congress adopted new juice labeling requirements, it specified the minimum Brix levels for fifty-three fruit and vegetable juices. 100 percent strawberry juice, for example, must have a minimum Brix level of 8.0 degrees, while 100 percent pomegranate juice has a minimum Brix level of 16.0 degrees. If a beverage from concentrate that is labeled 100 percent juice does not meet this minimum Brix level, the FDA does not consider it 100 percent juice. It is worth noting, however, that unconcentrated juice “directly expressed from a fruit or vegetable” is considered 100 percent juice, regardless of its Brix level.

2. Labeling

If juice concentrate is added to 100 percent juice to raise the Brix level, the beverage label does not need to contain the statement “from concentrate.” If water is

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143 21 C.F.R. § 101.30(h)(1) (“the [FDA] will calculate the labeled percentage of juice from concentrate . . . using the minimum Brix levels listed below”).


145 See 21 C.F.R. 101.30(h)(1). Fruits and vegetables without Brix values in this table are to “be calculated on the basis of the soluble solids content of the single-strength (unconcentrated) juice used to produce concentrated juice.” 21 C.F.R. 101.30(h)(2).

147 Id.

148 21 C.F.R. 101.30(i).
added to 100 percent juice to lower the Brix level, however, the beverage must be labeled as “from concentrate” or “reconstituted.”\textsuperscript{149}

\textit{C. Implementation of NLEA}

The percent juice labeling requirements established in the NLEA were set to become effective on May 8, 1993. The FDA pushed this date back one year, however, when it became clear that package and label suppliers could not provide a sufficient number of new labels before this date.\textsuperscript{150} This delay also allowed juice producers “to coordinate these label changes with other label changes, such as mandatory nutrition labeling . . . .”\textsuperscript{151} The legislation, and its related FDA regulations, took effect on May 8, 1994.\textsuperscript{152}

\textbf{IV. CONCLUSION}

This Paper shows that the regulation of fruit and vegetable juices was a slow process, resulting in decades of back-and-forth between the FDA and juice manufacturers. While these proposed standards of identity and label requirements teased out the various problems with juice regulation, it ultimately took congressional action to reach some sort of solution. And the solution was imperfect — two decades later; there is still widespread confusion about the health benefits of various juice blends. Manufacturers increasingly entice consumers with images of super-fruits such as pomegranate and açaí — known for their antioxidants and other nutritious qualities — in

\textsuperscript{149} See 21 C.F.R. § 102.33(g)(2).
\textsuperscript{150} See Food Labeling; Declaration of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages, 58 Fed. Reg. 49,190, 49,191 (Sept. 22, 1993) (to be codified at 21 C.F.R. pt. 101).
\textsuperscript{151} \textit{Id.} The FDA predicted that this one-year exemption would save the juice producers $51 million in compliance costs.
\textsuperscript{152} See 21 C.F.R. § 101.30(m).
fruit juice blends they actually contain minor amounts of these expensive juices. The
FDA has known about this problem for years, but it has received relatively little
regulatory attention since the adoption of the NLEA. With consumers being more health
conscious than ever before, perhaps the time has come to revisit some of these unresolved
issues from the 1974 proposal.