

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 102

[Docket No. 80N-0140]

RIN 0095-AC48

Food Labeling; Declaration of Ingredients; Common or Usual Name For Nonstandardized Foods; Diluted Juice Beverages

AGENCY: Food and Drug Administration HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food labeling regulations to establish requirements for the declaration of the percentage of juice in foods that purport to be beverages containing fruit or vegetable juice. The agency is also revising the existing common or usual name regulation for diluted fruit or vegetable juice beverages. FDA is also revoking the common or usual name regulations for noncarbonated beverage products that contain no fruit or vegetable juice and for diluted orange juice beverages. This final rule responds to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and is part of FDA's ongoing rulemaking on juices and juice beverages.

EFFECTIVE DATE: May 8, 1993, except that amendments to part 102 become effective May 8, 1994.

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 2, 1991 (56 FR 30452), FDA proposed requirements for the declaration of the percentage of juice in foods that purport to be beverages containing fruit or vegetable juice (hereinafter referred to as the July 2, 1991, proposal). There had been a longstanding controversy over percentage juice declaration in diluted fruit and vegetable juice beverages. The 1990 amendments (Pub. L. 101-535) 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 products label. Section 7 of the 1990 amendments amends section 403(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(i)) to

require, that "if the food purports to be a beverage containing vegetable or fruit juice, it bear a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food." In the preamble to the July 2, 1991, proposal, FDA discussed questions remaining about the exact meaning and the implementation of this provision (56 FR 30452 at 30453). The agency proposed to add new § 101.30 to establish requirements for the percentage declaration, and to delete the similar provision from the existing common or usual name regulation for diluted fruit or vegetable juice beverages in § 102.33 (21 CFR 102.33)). The agency also proposed to make revisions to the requirements in § 102.33 pertaining to the product name. FDA also proposed to revoke the common or usual name regulations for noncarbonated beverage products containing no fruit or vegetable juice in § 102.30 (21 CFR 102.30) and for diluted orange juice beverages in § 102.32 (21 CFR 102.32). Because these products would be covered under proposed § 101.30 and the revised § 102.33, the agency tentatively found that separate regulations for these products are no longer needed. In addition, the agency withdrew its July 16, 1987, proposal to revoke the existing regulations on common or usual names for diluted fruit or vegetable juice beverages (52 FR 26690).

The agency received over 200 responses to the July 2, 1991, proposal from a wide range of sources, including consumers, consumer organizations, professional associations, State and local government agencies, manufacturers, and trade associations. Each of the responses contained one or more comments. Several comments addressed issues outside the scope of the July 2, 1991, proposal and will not be discussed here. A number of comments suggested modification of various provisions of the July 2, 1991, proposal. A summary of the relevant issues raised in the comments and the agency's responses follow.

II. Percentage Juice Labeling

A. Applicability (Covered Products)

Section 403 (i) of the act requires that the label of any food that purports to be a beverage containing fruit or vegetable juice bear a percent juice declaration on the information panel. In the July 2, 1991, proposal, FDA described this requirement for percentage juice declaration as applying to full-strength juices and to various other standardized

and nonstandardized fruit and vegetable beverages. The scope of the proposed regulation included waters, carbonated and noncarbonated beverages containing juice, juice nectars, diluted juices, wine coolers containing juice, and any beverage that contains no juice but whose labeling, color, or flavor represents, suggests, or implies that fruit or vegetable juice may be present.

1. One comment stated that the agency should not determine for consumers when a beverage purports or does not purport to contain juice. The comment stated that consumers will come to recognize the presence or absence of juice in a beverage by the presence or absence of a percent juice declaration.

The agency points out that the statute requires percentage declaration of fruit or vegetable juice on the label of a food if it "purports" to be a beverage containing vegetable or fruit juice. The agency is therefore obliged to base its requirements on whether or not the product purports to contain juice. FDA is applying its longstanding policy on whether a food purports to contain an ingredient, i.e., a food purports to contain an ingredient if it conveys, implies, or professes outwardly that it contains that ingredient; or the food has the appearance of being, intending, or claiming to contain that ingredient. The term "purports" is used in its ordinary sense, and includes what the food is accepted as by the average consumer under ordinary conditions of purchase as well as what it appears or is represented to be by labeling or other means. (*United States v. 306 Cases Containing Sandford Tomato Catsup with Preservative*, 55 F. Supp. 725, 727 (E.D.N.Y. 1944); *United States v. 30 Cases, More or Less, labeled in part: "Leader Brand Strawberry Fruit Spread"*, 93 F. Supp. 764 (S.D. Iowa 1950). Accordingly, a beverage purports to contain juice if it states or implies on the label that it contains juice or has the appearance of being juice or containing juice. New § 101.30(a) applies this policy for beverages.

2. Several comments said that FDA should be able to use extra-label sources of information, such as advertisements and store promotions as well as the beverage label, in determining whether percent juice declaration requirements apply. Several comments stated that percent juice declaration requirements should apply to carbonated soft drinks if a manufacturer uses advertising to represent that the firm's beverage contains juice. On the other hand, one comment opposed the use of extra-label sources of information to determine whether a product purports to contain

juice because there is no precedent for it.

The agency agrees that advertisements in the form of store promotions or other extra label information stating or implying that the particular beverage contains juice result in the advertised beverage purporting to contain juice, and therefore percentage juice declaration is required. While FDA is not attempting to regulate advertising or claims made in advertising, contrary to the second comment, statements made in advertising have long affected the labeling of food products. FDA has given similar significance to advertising in the regulations on nutrition labeling (§ 101.9 (21 CFR 101.9)) and on the characterizing flavor labeling requirements (§ 101.22 (21 CFR 101.22)). In both of these instances, an advertising claim for a nutrition or flavor characteristic of a food invokes the requirement for nutrition labeling or flavor characterization labeling on the basis that the consumer who wants the food because of its particular nutrient content or flavor is entitled to examine a label that reveals facts material in light of the representations made, including those made in advertising, at the time of purchase. Similarly, FDA concludes that once a juice content claim is made for a beverage, the consumer who wants the product because of claims about its juice content is entitled to examine a label that provides juice content information at the time of purchase. Therefore, the agency is providing in new § 101.30(a) that advertising is a means by which a beverage purports to contain juice.

3. One comment expressed the belief that the requirement in the 1990 amendments for percent declaration of juice content does not apply to full-strength juice (including 100 percent juice prepared from concentrate). It stated that the 1990 amendments mandated this information for beverages that contain fruit or vegetable juices and not those that are 100 percent fruit or vegetable juice.

The agency disagrees with this interpretation of the statute. The statute states, “* * * if the food purports to be a beverage containing vegetable or fruit juice * * *,” A single-strength juice product may contain a single juice as its only ingredient. A beverage that is a single-strength juice made from concentrate and water contains 100 percent juice. Likewise, a beverage that is a blend of more than one single-strength juice may contain 100 percent juice. The agency believes that using the interpretation in the comment would result in inconsistent requirements, e.g., the second and third types of products described above would bear percentage

juice declarations, while the beverage consisting of one single-strength juice as its only ingredient would not.

The legislative history for this provision is not helpful in determining congressional intent. It states only: “Section 7(2) would require statements as to the percentage of fruit or vegetable juice contained in products sold as such juice,” (136 Congressional Record—H5842 (July 30, 1990)). Thus, FDA finds no basis to conclude that Congress intended such an inconsistent outcome and therefore concludes that the interpretation of the statute in the comment is incorrect. Accordingly, the agency finds that beverages that contain only a single-strength juice are subject to the percentage juice declaration requirements.

4. A number of comments requested that juice flavored waters and seltzers be exempted from the requirement for declaration of percent of juice. They stated that the juice ingredient in these beverages is present in minor amounts (usually less than 2 percent) for flavoring, and that the beverages are not considered by consumers to be sources of juice. They stated further that naming the juice used as a flavor in the ingredient list should not be considered as purporting to be a beverage that contains juice. Several of the comments stated that a product should not have to declare percent of juice if the label states that it is flavored with the fruit juice» e.g., “—————flavored drink” or “A-B drink with a touch of lemon.” The comments explained that the term “flavored” used with the common or usual name of the beverage informs the consumer that the juice is present in minor amounts for flavoring or taste, and that the beverage does not contain a significant amount of fruit or vegetable juice.

The agency agrees with the comments that a beverage flavored with a small amount of juice may not “purport to be a beverage containing juice” as that phrase is meant in the 1990 amendments. FDA believes that declaration of juice content provides information essential to the consumer in determining the nature of the product and reveals facts material in light of any representation made that the beverage contains juice. The agency considers that where a beverage contains a small amount of juice (usually less than percent) for flavoring purposes, the label makes clear that the juice is present for flavoring, the word “juice” is not used on the label except in the ingredient list, the beverage is not represented as containing a significant amount of juice. In such a case, information on the amount of juice present would not be

essential to describe the nature of the product. The agency concludes that such a product does not purport to contain juice within the meaning of the statute, and that therefore declaration of percent of juice is not required.

However, the label statement describing the flavor role of the small amount of juice must include the term “flavor” or “flavored” or otherwise indicate that the amount of juice is small and not use the word “juice.” When a beverage contains a fruit or vegetable juice but does not use a form of the word “flavor” or otherwise indicate that the amount of juice is small, e.g., “lemon iced tea” or “lemon drink,” the combination of the name of the fruit in the name of the product and declaration of the juice in the ingredient list implies that the beverage not only derives its flavor from the juice, but that it contains the juice. Thus, the product would purport to contain juice. In addition, use of the word “juice” in the flavor designation or elsewhere on the label, except in the ingredient list, would convey a similar impression. The statute requires the declaration of the percent of the juice in such circumstances.

In addition, the overall impression of the label, packaging, and physical characteristics of the beverage taken together may give the consumer the impression that the beverage contains juice and not just minor amounts of juice for flavor. For example, vignettes, such as one depicting juice flowing or oozing from a fruit or vegetable, or the physical characteristics of juice, such as the presence of pulp, would give the impression that the beverage contains juice. As described in new § 101.30(a), beverages bearing such representations purport to contain juice and are therefore required to bear the percent juice declaration.

Accordingly, the agency is including in the final regulation as new § 101.30(c) (proposed § 101.30(c) and (d) are deleted in response to comment 10 of this document) an exemption from percentage juice declaration for juice flavored beverages such as waters or seltzers provided that the beverage is labeled with a juice flavor description using the term “flavor,” “flavored,” or “flavoring” or otherwise makes clear that the juice is present in a small amount. To be exempt, the products advertising, label, and labeling must not bear: (1) The term “juice” on the label other than in the ingredient statement, e.g., “seltzer water flavored with raspberry” or “seltzer water with a touch of raspberry,” (2) a vignette, e.g., depicting juice exuding from a fruit or vegetable; or (3) specific resemblance to

a juice, e.g., via distinctive juice characteristic such as pulp.

5. In the preamble to the July 2, 1991, proposal, FDA tentatively concluded that wine coolers and similar beverages containing less than 7 percent alcohol by volume that purport to contain unfermented fruit or vegetable juice are covered by proposed § 101.30 and are required to bear a percentage juice declaration (56 FR 30452 at 30454). While several comments supported this position, others objected, stating that wine coolers do not purport to contain juice but are juice flavored wine. The comments stated that many brands of wine coolers and some sangrias currently sold in the United States contain natural and artificial juice flavors rather than juice or pulp and are labeled in compliance with § 101.22, indicating that they contain flavors rather than juice. One of the comments stated that brands representing approximately 93 percent of all wine coolers sold in the United States are manufactured with fruit flavors rather than fruit juice. Several comments stated that wine coolers, including sangrias, should be treated in the same fashion as juice flavored soft drinks because consumers purchase wine coolers as alternatives to other alcoholic beverages, the same as soda drinkers who drink cherry cola when they want a change from regular cola.

The agency points out that wine coolers that do not contain unfermented juice are not covered by this regulation unless they purport to contain juice by means of advertising, labeling statements, vignettes, or physical characteristics. Thus, if a wine cooler does not contain any juice, has labeling that makes clear that it contains flavors rather than juice, and does not bear a vignette that implies fruit juice content, it is not subject to new § 101.30. In addition, FDA advises that noncarbonated beverages that purport to contain juice but do not, in fact, contain any juice were required by § 102.30 to state that they contain no juice. FDA concludes that this new regulation does not appreciably change the requirements for juice content declaration for the wine coolers referred to in these comments. Accordingly, no change in the regulation or its applicability is warranted by these comments.

6. Several comments stated that requiring percentage juice declaration on wine coolers is unfair because the same requirement does not apply to most other alcoholic beverages including spirits-based and malt-based coolers, which compete directly against wine coolers.

The agency advises that the labels of alcoholic beverages (those that contain 7 percent or more alcohol by volume and malt beverages) are regulated in accordance with the Federal Alcohol Administration Act (27 U.S.C. 205) administered by the Bureau of Alcohol, Tobacco and Firearms and are controlled differently from wine coolers. The labeling of wine coolers, like other beverages that contain less than 7 percent alcohol by volume, are regulated under the act. To the extent that these statutes differ, the products are regulated differently in other labeling aspects as well as in declaration of percentage juice content. It is not up to FDA, but to Congress, to decide that the same requirements must apply to wine coolers, other alcoholic beverages, and malt based beverages.

7. Some comments agreed with the agency proposal that traditional carbonated fruit-flavored soft drinks (sodas) have a substantial history of marketing as products with fruit flavor and are recognized as containing only fruit flavor and not necessarily fruit juice. These comments recommended that carbonated fruit flavored soft drinks be exempted from percentage juice declaration. However, several other comments said that the percent juice declaration regulation should apply if a soft drink manufacturer uses labeling to represent that a carbonated beverage does contain juice, such as vignettes depicting juice dripping from a fruit.

These comments are consistent with the preamble to the July 2, 1991, proposal, in which FDA stated that the label and labeling of soft drinks (sodas) generally do not give the impression through words or explicit vignettes that these beverages contain juice (56 FR 30452 at 30454). FDA therefore concludes that if a soft drink (soda) does not represent or suggest in the name, labeling statement, or ingredient statement that it contains fruit or vegetable juice, there is no basis to find that it purports to contain juice. Accordingly, for clarity the agency is adding a statement to that effect to the regulation in § 101.30(a). However, FDA also concludes that, as discussed in the preamble to the July 2, 1991, proposal, a soft drink (soda) that contains ingredients, such as pulp, that give the impression that it contains juice or that bears an explicit vignette that gives the impression of juice content, purports to contain juice (56 FR 30452 at 30454). Such a product would be required under § 101.30(d) to declare juice content. In addition, those soft drinks that do contain juice usually make that fact known. These products purport to contain juice and are subject to the

percentage juice declaration requirement.

8. In the July 2, 1991, proposal, FDA also addressed requests for exemption from percentage declaration for bulk juice concentrates for institutional use. The agency stated that it was not proposing to exempt these bulk concentrates because of a lack of information substantiating the need or value of such an exemption. Some comments requested exemption from percent juice declaration for bulk juice concentrates for institutional use because they claimed this information is provided to consumers in other ways by the institution, and the institution specifies the juice content of the product in contracts and purchasing agreements.

Because these comments provided no additional information to support their assertions, the agency still does not have information that demonstrates a need for an exemption from percentage juice declaration for bulk juice concentrates for institutional use. Therefore, FDA is not including such an exemption in this final rule.

However, those requesting an exemption from percentage juice declaration for bulk juice concentrates for institutional use may petition for such an exemption under § 10.30 (21 CFR 10.30), providing the agency with information such as actual contracts or purchasing agreements specifying juice content and verifiable instances and examples of the percentage juice content presentation provided to consumers served the juice derived from the bulk juice concentrates by specific institutions, as well as data demonstrating the extent of use of these products by institutions.

9. Some comments requested exemption from percent juice declaration for bulk concentrates intended for further processing because consumers would not see the labeling, and manufacturers require bulk concentrate that meets their specifications from their suppliers.

The agency advises that bulk concentrates for further processing are covered by the exemptions provided in § 101.100(d) (21 CFR 101.100(d)). That regulation specifies criteria for exemption from labeling requirements including those of section 403(i) of the act. Therefore, there is no need to grant a new exemption.

B. What Percentage Must be Declared

Section 403(i) of the act, as modified by section 7(2) of the 1990 amendments, requires that if a food purports to be a beverage containing fruit or vegetable juice, it must bear a statement of * * * *

the total percent of such fruit or vegetable juice contained in the food * * ." In the July 2, 1991, proposal, FDA tentatively concluded that this statement could be read two ways, one to require declaration of percent of total juice and the other to require declaration of percent of each juice represented to be in the beverage. The agency found that under either reading a material fact would not be disclosed. Reading section 403(i) of the act together with section 201(n) of the act (21 U.S.C. 321(n)) and section 403 (a) of the act, FDA proposed to require declaration of both the percent of total juice and the percent of each juice represented to be in a multiple-juice beverage.

10. Many comments opposed the requirement for declaration of percent of individual juices in multiple-juice beverages. They cited the following reasons for their opposition: (1) The statutory language of the 1990 amendments does not require declaration, of percent, of individual juice in multiple-juice beverages; (2) proprietary formula information would be revealed by a 1-percent increment declaration of individual juices; (3) variable (least cost) juice blend formulation driven by fluctuations in cost or availability of individual juices would be eliminated with the proposed 1-percent increment label declaration requirement as labels would, have to be changed to reflect formulation changes; (4) the requirement is unenforceable with current analytical methodology; (5) there are no data or information that demonstrate consumer interest in or benefit from the requirement; and (6) label clutter on the information panel would be increased.

In contrast, other comments supported the proposed requirement for individual juice percentage declaration, stating: (1) The 1990 amendments clearly require a total percent juice declaration, and it does not follow that Congress did not intend for the consumer to be fully apprised of the identity and amount of the juices that make up the declared total amount of juice: (2) some juice beverages have misleading labels in that high cost/value or intense flavor juices are given greatest label prominence but are present in minor amounts; (3) some manufacturers misrepresent the juice content of their beverage through the use of added pulp, clouding agents, and thickening agents which mislead consumers into believing that these beverages have more juice than is actually present; (4) more precise, direct information on relative amounts of specific juices in multiple-juice beverages is needed by consumers

to make in-store purchasing decisions; (5) among multiple-juice beverages with the same total juice percentage, a juice's order of predominance in the ingredient statement does not directly translate to its percentage in the beverage; and (6) enforcement actions by Federal, State, and local consumer protection agencies will be needed less often because the percent of individual juice declaration will remove possible ambiguity as to whether a product label may be misleading to the consumer.

The agency has reconsidered its interpretation of the amendment to section 403(i) of the act in light of the arguments presented in the comments. The agency notes the contrast in language in section 403(i)(2) of the act, which, on the one hand, requires the declaration of the common or usual name of "each such ingredient" when a product is fabricated from two or more ingredients but only the declaration of the total juice percentage of "such" fruit or vegetable juice contained in the food, not "each" fruit or vegetable juice contained in the food. Thus, had the intent of Congress been to require percent individual juice declaration, it clearly knew how to do so. Based on the face of the law, it is reasonable to expect that Congress would have used the word "each" in place of, or preceding, the word "such" in the phrase "such fruit or vegetable juice," as it did in the phrase "each such ingredient." Without relevant legislative history on the provision, FDA now finds that the better reading of section 7 of the 1990 amendments is that it requires declaration of percent of total juice but not declaration of percent of individual juices in a multiple-juice beverage.

Nor is it clear that the percent of each individual juice represented on the label is a material fact under section 201 (n) of the act for all multiple-juice beverages. In the July 2, 1991, proposal, FDA stated that if the label of a beverage declared the presence of one or more juices by representation (i.e., word or vignette) and declared the total percentage of juice in the product, but did not declare the percentage of each individual represented juice, the label would be misleading (56 FR 30452 at 30456). The agency tentatively found that such a label would create an impression that overstates the amount of the represented juices in the beverage if not all the juice in the beverage is supplied by the represented juices.

While beverage labels clearly are misleading if they misrepresent the contribution of one or more individual juices to the total amount of juice, the agency acknowledges that not all multiple-juice beverage labels that bear

representations of individual juices misrepresent the contribution of the individual juices to the total. For example, a vignette that depicts all the fruits or vegetables in the product may not misrepresent an individual juice contribution. In addition, declaration as a part of the product name of all juices present (in descending order by volume of single-strength juice) would generally not be misleading.

Accordingly, FDA is not including in the final regulation the requirements in proposed § 101.30(c) and (d) for the declaration of the percent of juice for all juices in multiple-juice beverages that are declared in the label or labeling, by word, vignette, or other means, other than inclusion in the statement of ingredients, to be present in the beverage. The agency is also deleting proposed § 101.30(e), which provided for optional declaration of percent of individual juices not represented on the label. Instead, the agency has included in the final regulation on the common or usual name of such beverages, provisions for adequately descriptive names that will inform the consumer of the nature of the product. As discussed in detail in Section III. of this document, for beverages where one or more but not all the juices are named and the named juice is not the predominant juice, the agency is providing two alternatives for describing the contribution of the named juice. The label must either state that the beverage is flavored by the named juice (e.g., "raspberry flavored juice drink") or declare the content of the named juice in a 5 percent range (e.g., "raspberry juice drink 2 to 7 percent raspberry juice"). The agency believes that this approach will adequately deal with the kinds of misleading labeling discussed in the comments from consumer groups.

Because FDA is deleting the requirement for declaration of percent of individual juice content in multiple juice beverages, a number of comments are no longer relevant. Such comments include those regarding which juices should be included in the percent of individual juice declaration and the impracticability of declaring individual juices in 1-percent increments. The agency is not addressing these comments because the concerns they express are moot. In addition, allegations that this regulation would result in a compensable taking of private property are no longer relevant. These allegations were based on the contention that a requirement for declaration of percent of individual juices would be a mandatory disclosure of proprietary information and would thereby constitute a taking. Because the

requirement in question has been deleted, there is no need for FDA to address the issue.

11. No comments objected to the requirement that the declaration of percent of total juice be in 1-percent increments. However, several comments pointed out that the regulation should provide for beverages that contain less than 1 percent juice. They stated that to have a "0 percent juice" declaration on a product with juice declared in the ingredient list would be confusing to the consumer. One comment suggested that FDA provide for a statement such as "less than 1 percent juice" instead of requiring "0 percent juice" for those products that contain juice at a volume of less than 1 percent.

The agency agrees that a declaration of juice content of less than 1 percent may be appropriate if it accurately describes the amount of juice in the product. Therefore, FDA is revising the provisions in new § 101.30(b) for percentage juice declaration to allow for this declaration.

C. How Declarations Should Be Made—Placement and Prominence

Section 403(i)(2) of the act requires "a statement with appropriate prominence cm the information panel" of the percentage of juice. The agency proposed requirements that it believed would provide appropriate prominence for the percentage juice declaration and still allow room for other required information. The agency proposed in § 101.30(g) that if the beverage is sold in a package that has an information panel, the percentage juice declaration is to be prominently placed near the top of the information panel, with no other printed label material appearing above it. Additionally, the agency proposed to require that the declaration be in easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the product name, and in lines generally parallel to the base on which the package rests.

The agency also proposed in § 101.30(h) that the percentage juice declaration may also be placed on the principal display panel if the declaration is consistent with that presented on the information panel. Further, the agency proposed in § 101.30(i) that if the beverage package does not include an information panel, the percentage juice declaration must be placed on the principal display panel: (1) In type size not less than that required for the declaration of net quantity of contents statement, (2) located near the name of the food, and

(3) in lines generally parallel to the base on which the package rests. (Paragraph designations of new § 101.30 have been changed to paragraphs (e), (f), and (g), respectively, as a result of changes discussed in response to comment 10 of this document.)

12. Some comments suggested that the total juice content should be required to be placed at the top of the principal display panel with the common or usual name. They stated that otherwise the declaration of total juice would not have appropriate conspicuousness or prominence, because many consumers do not routinely, or cannot easily, read fine print, i.e., one-sixteenth of an inch minimum height, on the information panel.

The agency advises that the act requires that the percent juice declaration be on the information panel. The comments did not provide a legal basis on which the agency could require an additional declaration on the principal display panel. However, as provided in new § 101.300(f), the agency is permitting percent total juice on the principal display panel as an optional declaration.

13. Several comments stated that in addition to the percent juice declaration on the information panel, percent juice declaration should be allowed on the principal display panel.

As stated in response to the previous comment, the agency does not object to the additional declaration of percent juice content on the principal display panel, provided that it is consistent with the declaration on the information panel. This additional declaration is provided for in new § 101.30(f).

14. Although no comments objected to the requirement that a total percent juice declaration appear on the principal display panel in the absence of an information panel, some comments objected to the requirement that placement of the percent juice declaration on the principal display panel be near the name of the food. These comments asserted that there is no compelling reason for such placement and that there should be more flexibility in the location of the declaration.

The agency disagrees with the comments. Consumer use of the percent juice content declaration will be facilitated if it is in a consistent prominent location on the food label. The comments did not recommend alternative placement criteria.

Currently, some juice beverage labels bear percent juice statements such as "100 percent juice" or "100 percent juice blend" on the principal display

panel near the name of the juice product. Because of the longstanding industry tradition of marketing food products bearing percentage claims near the name of the food on the principal display panel, and because of agency regulations providing for such percentage declarations in association with the common or usual names of nonstandardized foods (§ 102.5(b) (21 CFR 102.5(b))), consumers have become accustomed to seeing such percent juice information, when it appears on the principal display panel, near the name of the food. Therefore, the agency concludes that the proposed requirement for placement of the percent juice declaration on the principal display panel near the name of the food, if there is no information panel, provides appropriate prominence as required by the statute. This requirement is set forth below as new § 101.30(g).

15. Several comments objected to the proposed requirement that the percent juice declaration be near the top of the information panel with no printed information appearing above it. These comments wanted more flexibility to use available label space efficiently and to minimize label clutter that they said would result from declaration of percent juice statements near the top of the information panel. The comments stated that the 1990 amendments did not mandate that the percentage juice declaration be the most prominent or conspicuous item on the information panel. Finally, the comments said that the July 2, 1991, proposal gives the declaration more prominence than health and safety statements such as those required for saccharin section 403(o) and (p) of the act (codified at 21 CFR 100.130(d)(2), 101.11, 105.66(b) and 180.37) or phenylalanine (21 CFR 172.804(e)(2)), and other statements concerning storage, preparation, recycling, and deposit information. The comments requested that they have, at a minimum, the option of placing such information as the brand name, product name, product logos, and the universal product code (UPC) above the percentage juice declaration.

The suggestion in the comments that required information on the information panel is not more important than optional information, and should have equal but not greater prominence, is contrary to existing regulatory requirements that have not been changed by the 1990 amendments. The agency is not requiring that the percent juice declaration be the most prominent and conspicuous item on the information panel by virtue of its placement near the top of the

information panel. FDA considered that the same regulations that currently apply to labeling information appearing on the information panel. (§ 101.2 (21 CFR 101.2)) will also apply to the total percent juice declaration and did not wish to unduly disrupt the customary sequence of required information on the information panel, i.e., nutrition information, ingredient statement, and name and place of business of the distributor (§ 101.2(b)). Further, because the percentage juice declaration is now required information, the agency believes it must be at least as prominent as other required information to have the "appropriate prominence" required by the statute (21 CFR 101.2(c) and 101.15).

Consistent with these considerations, the agency finds that placing optional information such as storage instructions and recipes, which need not appear on the information panel at all, above the total percentage declaration, and consequently above all other required information on the information panel, will not give the percentage declaration "appropriate prominence." The comments did not provide any examples or information to substantiate a need for additional flexibility, and the agency is not convinced by the comments' assertions that the prominence and placement of the required total percent juice declaration is unreasonably restrictive.

However, having considered all the comments on this issue, the agency concludes that since the product name or brand name or logo often appear at the top of the information panel, they may continue to appear above the percentage juice declaration on the information panel. However, any additional printed material, other than product name or brand name or logo that appears above the percentage juice declaration will render the percent juice declaration so inconspicuous that the "appropriate prominence" required by the 1990 amendments will not be provided. Consistent with past agency practice, foods whose labeling omits or fails to prominently or conspicuously convey required information, and instead utilizes available label space to give prominence and conspicuousness to nonmandatory information, will be subject to legal action.

Finally, FDA considers the UPC to be a sufficiently distinctive label feature that it does not affect the prominence and conspicuousness of other information on the label. The agency has therefore not seen a need to regulate its location on the label in relation to required information. Consequently, the final regulation does not prohibit the

UPC from appearing above the percentage declaration on the information panel.

Accordingly, the agency is revising the regulation in new § 101.30(e)(1) to include the words "except the brand name, product name, logo, or universal product code" after the word "statement."

16. Several comments objected to the requirement that the percent total juice declaration be not less than the largest type on the information panel except that used for the product name because it gave the percent declaration undue prominence. These comments asserted that the type size requirements should not be any greater than for other required information, i.e., a minimum one-sixteenth of an inch in height unless exempted pursuant to § 101.2(f). Additionally, the comments asserted that type size requirements should relate only to type size of the required information on the information panel and not to the brand name, product name, UPC, or any other nonmandatory information on the information panel. One comment suggested a minimum 3/32 of an inch type size instead of the proposed one-sixteenth of an inch on large containers such as half-gallon cartons, so that the print size would be more proportional to other printed material on the carton.

In the July 2, 1991, proposal, the agency attempted to strike a balance between "appropriate prominence" for the percent juice declaration and that of other required information and of nonmandatory information on the information panel. The agency believes that the total percentage juice declaration should be at least as prominent as any other information on the same panel, whether required or not. However, because the agency also recognized that manufacturers may desire to place the product name prominently on the information panel, it proposed to exclude the name from consideration relative to the type size for the total percent juice declaration. Consistent with the decision above to permit brand name, product name, logo, or UPC to be located above the percent juice declaration, the exclusion from type size comparison should also apply to the brand name and the logo. The agency also did not intend to include the UPC among the label information on which type size for the percent juice declaration is based. As stated above, it considers that the UPC is sufficiently distinctive in appearance that it does not interfere with the prominence or conspicuousness of other label information.

In meeting the mandate of the 1990 amendments for appropriate prominence of the percentage juice declaration, FDA did not wish to deviate unnecessarily from existing type size requirements or to establish new type size requirements such as the requested 3/32 of an inch type size for large containers. The comment requesting larger minimum type size for large containers did not provide information to substantiate a need for larger type or to demonstrate that the 3/32-inch type size would be appropriate to meet such a need. Therefore, FDA is retaining the one-sixteenth of an inch minimum type size provision in the final rule.

To summarize, the type size requirement of not less than the largest type on the information panel with the exception of product or brand name, the logo, and the UPC ensures a certain proportionality of type size for required and nonmandatory statements. This proportionality of type size both provides for "appropriate prominence" of the percentage juice declaration and helps to curb instances of inappropriate prominence of nonmandatory information over required information on the information panel.

Therefore, the agency is requiring in new § 101.30(e)(2) that the declaration of percentage juice be prominently placed on the information panel, appearing in easily legible boldface type, in distinct contrast to other printed or graphic matter, in a height not less than the largest type on the information panel except for that used for the brand name, product name, logo, or UPC.

17. Some comments objected to the requirement in proposed § 101.30(g)(2) that the percentage juice declaration on the information panel be in lines generally parallel to the base upon which the package rests. They stated that the requirement limits the flexibility of beverage manufacturers in placement of the required declaration and other required information on the information panel. Several other comments suggested that the percent juice declaration be in lines generally parallel to other required information, whether or not this information is also parallel to the base on which the package rests.

The agency advises that placing required information on the principal display panel in lines other than generally parallel to the base upon which the package rests requires the consumer to unnecessarily manipulate the package to read the required information, making it less likely to be read. Consistent with this fact,

statements of identity and net quantity of contents are required to appear on the principal display panel in lines generally parallel to the base upon which a package rests (§ 101.3(d) and 101.105(f) (21 CFR 101.3(d) and 101.105(f)), respectively).

However, the agency agrees with the comments that requiring that the percent juice declaration be on the information panel in lines generally parallel to the base is not justified because other mandatory information on the information panel is not required to be in lines generally parallel to the base of the package. The regulations in § 101.2 do not include specific orientation requirements for mandatory declarations such as the ingredient statement, nutrition labeling, or name and place of business of the manufacturer, packer, or distributor.

Accordingly, FDA concludes that because it does not have substantial justification for this additional orientational requirement and in light of objections from comments, the proposed requirement should be withdrawn. Therefore, FDA has deleted the phrase "and in lines generally parallel to the base on which the package rests" from proposed § 101.30(g)(2) (redesignated as new § 101.30(e)(2) in this final rule).

The agency, however, is persuaded by the suggestion in the comments that the percent juice declaration should be in lines generally parallel to other required information, whether or not this information is also parallel to the base on which the package rests. Because existing § 101.2(e) provides that all information appearing on the information panel pursuant to this section must appear in one place without intervening material, it is reasonable that the percent juice declaration should be in lines generally parallel with this information, so that the consumer will not have to manipulate the package to read all the required information. This orientational requirement will ensure that appropriate prominence of the percent juice declaration is maintained. Therefore, the agency has inserted the phrase "in lines generally parallel to other required information" after the word "panel" in new § 101.30(e).

D. Associated label Statements

In the July 2, 1991, proposal, FDA discussed declarations that use a percentage (usually 100) to describe a term other than juice, such as "100 percent pure" or "100 percent natural" (56 FR 30452 at 30457). The agency stated that these declarations have a great potential to mislead the consumer into believing that the product is 100

percent juice. FDA advised that such statements should not be used. In addition, the agency requested comments as to whether FDA should adopt regulations specifically providing that declarations such as "100 percent pure" or "100 percent natural" or "100 percent" to describe a term other than juice are misleading, particularly when used on the principal display panel of diluted juice beverages.

18. Several comments stated that the terms "pure" and "natural" are ambiguous and tend to mislead consumers about the nature of a product. These comments stated that at times, the terms "pure" and "natural" mislead a consumer into believing that the product consists entirely of juice. A number of comments stated that using the term "100 percent" with the terms "pure" and "natural" exaggerates and exacerbates the already ambiguous and misleading nature of the terms "pure" and "natural" on diluted juice beverages. These comments said that consumers are consistently confused and misled by such statements into believing that the beverages are all juice with no additional ingredients or are full-strength (100 percent) juice. These comments stated that the use of these phrases should be restricted by FDA because most juice beverages are not 100 percent juice, or they are processed, i.e., reconstituted with water and ingredients other than juice such as sweeteners, preservatives, flavors, colors, pulp, and thickening and clouding agents to restore the juice to its original expressed juice state, to compensate for seasonal or regional variations, or to create a unique juice based beverage.

Opposing comments stated that the terms "pure" and "natural" can be used in some contexts in which they would not be misleading. These comments argued that consumers read the terms "pure" and "natural" to mean that the product is made of natural ingredients such as fruit juices, water, natural sweeteners, and flavors. They recommended that labels bearing the terms "pure" and "natural" be evaluated on a case-by-case basis.

Several comments were of the opinion that use of a percentage to describe an undefined attribute on products required to bear a percent juice declaration could potentially be misleading to consumers. They stated that therefore, any use of "100 percent" on the label in conjunction with an undefined term should be prohibited, unless the product is a full-strength (100 percent) juice product. However, these comments stated that this policy should not restrict use of a percentage

declaration that is clearly defined as not being related to juice content, i.e., "contains 100 percent of U.S. Recommended Daily Allowance (U.S. RDA) for Vitamin C."

The agency advises that while there is no specific prohibition against the use of the terms "pure" and "natural," it has discouraged the use of these terms because they are ambiguous and may be misleading. For example, "orange juice," "pure orange juice," and "100 percent pure orange juice" are identical foods, but "pure" as applied to the food implies that other identical products are "impure" or "not pure" if they do not bear the same term on their label. The term "natural" is similarly ambiguous when applied to any food except flavors and flavorings.

The agency concludes that this rulemaking is not the appropriate vehicle to consider whether terms such as "pure" and "natural" should be permitted on juice product labels. The comments presented opinions on the word "pure," but they did not provide sufficient information on which to base a regulation. The term "natural" is included in another agency rulemaking. In the **Federal Register** of November 27, 1991 (56 FR 60421 at 60466), FDA published a proposal entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" that included, among other things, a discussion of various aspects of defining the term "natural." A final rule based on that proposal is published elsewhere in this issue of the **Federal Register**. In that rulemaking, however, the agency decided not to define the term "natural."

However, FDA also concludes that the use of a percentage, particularly 100 percent, in conjunction with terms other than "juice," such as "pure" and "natural," on a beverage that is not full-strength juice can be misleading, particularly where the 100 percent figure appears near the name of the product, but not in close proximity to a prominent declaration of the percentage of juice. On the other hand, FDA with those comments that stated that statements clearly unrelated to juice content, e.g., "provides 100 percent of U.S. RDA of vitamin C," are not misleading.

Therefore, to clarify these matters, under sections 403(a) and 701(a) of the act (21 U.S.C. 371(a)), the agency is including in the final regulation a prohibition on the use of "100 percent" or any other percentage unrelated to juice content that could be misunderstood to represent the percent of juice in the beverage. This provision in the final regulation, designated new

§ 101.30(l), states: "A beverage required to bear a percentage juice declaration on its label shall not bear any other percentage declaration that describes the juice content of the beverage in its label or in its labeling (e.g., "100 percent natural" or "100 percent pure"). However, the label or labeling may bear percentage statements clearly unrelated to juice content (e.g., "provides 100 percent of U.S. RDA of vitamin C").

E. Calculation of Percentage Juice

1. Juice From Concentrate

The agency proposed that in enforcing the act and in ensuring that percentage juice declarations are truthful and not misleading, it would calculate the percentage juice from concentrate in a juice or juice beverage using the minimum Brix levels that were listed in proposed § 101.30(j)(1). (Because of revisions to the final regulation proposed § 101.30(j) is redesignated as new § 101.30(h)). In the July 2, 1991, proposal, the agency strongly recommended that manufacturers use this method in calculating the percentage juice from concentrate. The agency also advised that if the July 2, 1991, proposal were adopted, while manufacturers may use any appropriate alternate method, they should ensure that this alternate method produces similar results.

In the preamble to the July 2, 1991, proposal, FDA listed proposed minimum Brix values for a number of fruit and vegetable juice products and minimum anhydrous citric acid contents for two fruit juices, based primarily on data from the National Juice Products Association (NJPA) in December of 1989 and May of 1990 (56 FR 30452 at 30466).

FDA received comments on 13 of the 51 proposed minimum Brix values for 100 percent juice and comments regarding minimum Brix values for two other juice products not listed in the proposed regulation. Most comments claimed that one or more of the 13 values were too high and offered information or data to support their claims. Several comments simply objected to the proposed Brix values as being too high without suggesting more appropriate values. Brix data in the comments were provided in several forms: Individual values, ranges of values, monthly or yearly averages, and mean values with designated standard deviations. A presentation of the data submitted, and the agency's review and conclusions, follow.

a. Evaluation of Brix data in comments.

FDA acknowledges that much of the Brix data in agency files is old and may be out of date. The Brix data used in establishing the fruit or fruit juice content in the standards of identity for fruit butter and fruit jelly (§§ 150.110 and 150.140 (21 CFR 150.110 and 150.140)) were obtained from authentic fruit samples collected before 1940. Although the data were used for many years without question for fruit butters and fruit jelly, when these data were incorporated in the standard of identity for canned nectars, FDA received an objection that questioned the applicability of the single-strength juice values to canned nectars and suggested that they be reevaluated in light of current commercial practice in the manufacture of nectars. Thus, the standard for canned nectars (§146.113 (21 CFR 146.113)) was stayed in 1968 (33 FR 10713, July 27, 1968).

Differences in juice composition that result from factors such as horticultural practices, processing operations, and geographical origin, as well as the use of new varieties of certain species, may account for differences in Brix values obtained on juice products prior to 1940 and values obtained for fruit juices currently produced under current good manufacturing practice. In reviewing the data submitted in comments, FDA has consulted published references on juice composition, e.g., U.S. Department of Agriculture (USDA) Food Composition Tables (Handbook 8-9: Fruits and Fruit Products and Handbook 8-11: Vegetables and Vegetable Products) (Refs. 5 and 6). FDA has also reviewed Brix data in files that were used in support of existing standards of identity and data contained in published articles on juice research and composition. In instances where there are established values in standards of identity that appear to be too high compared to newer information, and the data submitted in support of lower values seem reasonable in light of this newer information, FDA has adopted a lower value in new § 101.30(h)(1). Where FDA has adopted a lower Brix value for 100 percent juice than is currently listed for the fruit juice in an existing standard of identity, FDA intends to consider revision of the standard of identity at a later date to make it consistent with the Brix value that the agency is adopting in this regulation.

b. Use of Brix data.

19. Several comments supported FDA's proposal to calculate the labeled percentage of juice from concentrate in a reconstituted juice or in a diluted juice beverage based on the minimum Brix standards. One comment expressed the opinion that the Brix concept represents

the most workable method for accurately and consistently calculating the percentage of juice. A comment from the Government of Canada also expressed support for specifying minimum Brix values for use in calculating the percentage of juice included in diluted juice leverages and reconstituted juices. However, the comment stated that it does not support the proposed Brix values because they would effectively exclude Canadian products from the U.S. market. Other comments in the letter from the Government of Canada on specific juices are discussed below. One comment opposed the proposed method of calculating the percentage of juice based on minimum Brix values, established by regulation, instead of requiring the percentage of juice to be calculated in terms of the actual soluble solids content of the original juice. The comment maintained that use of the table of fixed Brix values in proposed § 101.30(j)(1) (redesignated as new § 101.30(h)(1)), which, the comment contended, contains values well below the Brix of sound ripe fruit, gives food processors a license to overstate the quantity of juice in their products.

FDA recognizes that when a minimum Brix value based on the mean or a range of values for a particular fruit or vegetable juice is established by regulation, there will always be some juices that will have Brix values above the minimum, and some juices that will be below the minimum because of natural variations in the source fruits and vegetables. The agency also acknowledges that, in some instances, producers of lower Brix juices will have to use more juice to meet the minimum soluble solids requirements for reconstituted full-strength juice. However, use of standardized Brix levels in preparing and labeling blended juice products and diluted juice products from concentrates will ensure that consumers obtain products with a reliably determined minimum juice soluble solids content. As a result consumers will be able to make meaningful value comparisons between brands of such products based on the labeled juice content. Use of actual Brix levels of the original juice used to manufacture the concentrates could lead to variations in the levels of soluble solids on labels of products that bear the same percentage juice declaration. Therefore, FDA is not modifying its proposed use of standardized minimum Brix levels to determine the percent juice in juice products made from

concentrate, as requested by the comment.

c. Approaches other than use of Brix.

20. One comment proposed an alternative to Brix calculation for percentage juice in the case of orange juice and other citrus juices that have been modified by the removal of the naturally occurring sugars that are then replaced partially or wholly by intense sweetening agents. The proposed method would use citric acid content or the ascorbic acid content consistent with FDA's proposal for lemon juice and lime juice.

The comment provided guide values of 8.0 grams per liter citric acid and 200 milligrams per liter ascorbic acid for orange juice as an alternative for the determination of percentage juice for orange juice with sugars removed and referenced methods for determination of the citric acid and ascorbic acid content ("RSK-Values, The Complete Manual, Guide Values and Ranges of Specific Numbers, Including the Revised Methods of Analysis," Verband der deutschen Fruchtsaftindustrie e.V., Bonn, 1987). However, the comment did not include any data to correlate and verify these values and methods as they apply to an "artificially sweetened, sugars-reduced orange juice."

The agency is not incorporating the suggested alternative method for determining the percentage of "juice" contributed by modified juices in which the native sugars have been removed and have been replaced wholly or partially by intense sweetening agents. As discussed in section II. F. of this document, these products are not considered to be juice. Under new § 101.30(h)(1), FDA is establishing minimum Brix values for fruit and vegetable juices based on the soluble solids content (i.e., primarily sugars content of the juice), with the exception of lemon juice and lime juice that are defined by citric acid content, for use in percent juice labeling. Therefore, such modified juices cannot be included in the percent juice calculation or depicted as juice in the vignette on a beverage. The description of the modification (e.g., "sugar-reduced orange juice") as part of the common or usual name of the product makes clear that the change in the product is such that it no longer purports to be juice. The product may substitute for juice, but it is not juice. Although the suggested alternative methodology may be useful for validating claims about modified juice products, the agency is not aware of acceptable methodology to confirm the content of any modified juice products, e.g., "reduced sugars" or "sugars removed" juice products.

d. Meaning of Brix standards.

21. One comment stated that from the proposed single-strength Brix standards it is not clear whether the standards are intended to represent mean values, or whether they are minimum values. In some instances, e.g., in normalizing compositional data of juice concentrates, the comment stated, it may be appropriate to use mean values. In other instances, minimum values may be more appropriate, e.g., regulations for 100 percent fruit juice made from concentrate.

The agency advises that the Brix values set out in new § 101.30(h)(1) are minimum values that are based on average values for the respective juice products. As stated in the preamble to the July 2, 1991, proposal, the purpose of establishing these Brix values for 100 percent juice is to provide a "minimum" acceptable level for determining whether a juice should be considered to be full-strength (56 FR 30452 at 30459).

e. How Brix values are set.

22. One comment stated that it is desirable to take a statistical approach in revising or establishing the Brix values. The comment stated that in some instances, it may be appropriate to use "mean" values, e.g., normalizing compositional data of juice concentrates; and in other instances, minimum values may be more appropriate, e.g., in establishing minimum Brix requirements to define 100 percent fruit juice from concentrate. The comment added that where minimum Brix values are appropriate, the minimum value could be one standard deviation below the mean if 66 percent confidence limits were applied, or two standard deviations if 95 percent confidence limits were thought to be more appropriate. For some juices, e.g., orange juice and apple juice, the comment maintained that there should be adequate data bases available for such statistical applications. For many commodities, the data will need to be developed. The comment also maintained that there needs to be agreement on the sample protocol for developing such data bases.

FDA agrees that a statistical approach should be used to establish the minimum Brix values when adequate data bases are available. However, because of the limited amount of data available to FDA for most juice products for which minimum values were proposed, a statistical approach could not be used. Where comments supplied Brix data in statistical terms, means and standard deviations, FDA used these data in evaluating the proposed Brix values and in some instances has

incorporated these values in new § 101.30(h)(1). In other instances, FDA has adopted the Brix values established in the standards of identity for fruit products because they represent consensus values that are acceptable to both consumers and food processors.

Although the comment stated that there should be adequate data bases for orange juice and apple juice for statistical calculation to determine the minimum Brix value, no data bases for these juices were provided in the comment.

FDA agrees that a statistical analysis could be used to establish a Brix value for the single-strength juices. However, in the case of orange juice, the proposed Brix value of 11.8° for orange juice from concentrate is consistent with the Brix value established in the standard of identity for orange juice from concentrate (§ 146.145 (21 CFR 146.145)). In the absence of new data or information that demonstrates that the established Brix value is no longer representative of the soluble solids content of orange juice used to make frozen concentrated orange juice in this country, the agency has no reasonable basis to revise the Brix value for orange juice in new § 101.30(h)(1). A discussion on information received in comments on apple juice follows.

Because the Brix values represent minimum values, food processors are free to pack to higher soluble solids contents to meet consumers expectations when making juice products from concentrate, FDA points out, however, that should food processors use higher levels of soluble solids than is required by new § 101.30(h)(1) in reconstituting a juice to single-strength (100 percent juice) to meet consumer expectations for a sweeter juice, for example, FDA still considers the product to be 100 percent juice and not a higher percentage, such as 110 percent juice, when the additional soluble solids are the result of added juice.

23. Several of the comments cited the German RSK Brix values in support of the modifications that they suggested in the minimum Brix values listed in the July 2, 1991, proposal. One comment requested that these values be considered in establishing U.S. standards so as to achieve worldwide uniformity.

FDA agrees with the comment that the use of the German RSK Brix values may serve as useful guidelines in establishing Brix values in this country. The RSK values (termed *Richwerte* und *Schwankungsbreiten bestimmter Kennzahlen* or RSK-WERTE) are used by the German fruit juice industry as

reference points or guidelines for specified constituents in fruit juices. They assist food processors in determining whether fruit juices have been produced lawfully without adulteration. Factors influencing juice composition, such as growing region, variety, and production year, are considered in their establishment. Soluble solids content (Brix value) is one of the quality parameters defined by the RSK-WERTE guidelines. Other parameters include density, titratable acidity, sugars, acids, and amino acids. Mean values, standard values, ranges, and commentary are provided for each parameter.

A standard RSK value is usually a "minimum" or a "maximum" value, with data seldom falling above or below this value. In other words, the standard Brix value would be the minimum value in the range of values and not the mean or average Brix value. The mean RSK Brix value is not the arithmetic mean value but the value around which most of the values of industrially manufactured juice products congregate. RSK Brix values cited by the agency in this document are from "Adulteration of Fruit Juice Beverages," edited by S. Nagy, et al. (Ref. 7).

24. Several comments stated that the Brix calculation is only valid for juices to which sweeteners have not been added, and that other methods should be used to test for adulteration.

The agency agrees that the Brix calculation is only valid for juices to which sweeteners have not been added. Further, the Brix calculation to determine the percent juice content can only be used before sweeteners are added to the juice beverage in instances where the beverage is not 100 percent juice. The agency does not use Brix measurements by themselves to test for adulteration. Brix measurements can be used in conjunction with the results of other analytical methodologies and inspectional observations to support charges of product adulteration.

25. Other comments stated that the percent juice declaration should be calculated on weight/weight basis utilizing reference Brix levels because that is the manner in which the concentrates are sold.

The agency disagrees with these comments. The purpose of the regulation was not to prescribe how concentrates should be sold but to ensure that when reconstituted juice or juice from concentrate is used to produce a single-strength juice or a multiple-juice beverage, there is a standardized criterion for determining the percentage juice in the finished product. The standardized criterion

allows consumers to make price and value comparisons across the range of juice beverages. Because the juice beverages are sold on a single-strength volume basis to the consumer, and percentage juice declaration is based on this standardized criterion, it would be inappropriate to utilize a weight/weight basis.

26. One comment requested that manufacturers be allowed to reconstitute concentrated juice back to the Brix in original expressed juice if the Brix of the expressed juice is known, and records are kept for the purpose of percent juice calculation and declaration. For example, expressed apple juice with a Brix value of 9.0° could be reconstituted and declared as 100 percent apple juice even though the Brix value provided by proposed § 101.30(j)(1) for 100 percent apple juice from concentrate is 12.5°.

The agency made an exception to the use of Brix values in calculating percentage juice for expressed juices because these juices have a naturally occurring range of Brix beyond the control of the manufacturer. Similarly, in consideration of existing industry conditions, the agency's decision to use Brix value for calculation of percent juice from concentrate was derived from the industry practice of commingling juice concentrates whose original Brix is unknown.

The agency differentiated between percent juice calculation for expressed juices and juice concentrates on the basis of industry practice and out of fairness to the expressed juice segment of the industry, which is subject to the vagaries of nature. While the agency does not object to reconstituting of concentrated expressed juice to the Brix level of the original juice if that Brix value level is known, the agency finds that once a juice has been concentrated, for the purpose of percent juice calculation and subsequent percent juice declaration, the Brix value as prescribed in the regulation must be used. Use of the same minimum Brix value level in labeling juice content for a specific juice from concentrate will enhance consumer comparisons between competing brands of that juice.

Therefore, the agency is denying the comments request to reconstitute juice to its original Brix as expressed juice and declare it as 100 percent juice from concentrate although it does not have the minimum Brix value as prescribed in the regulation. This policy is consistent with Brix value requirements established in standards of identity for juice products made from concentrate.

f. Provisions to revise Brix values.

27. Many comments urged FDA to establish a mechanism to amend the table of Brix values because it may be necessary to include juices in the table that are not included now, and revised brix values may be needed in response to changes in technology, new crop varieties, and other matters.

The agency agrees that periodic amendments to the Brix value table will be necessary. However, the agency believes that adequate provisions exist in the regulation for citizen petitions. (§ 10.30). Therefore, the agency is not proposing any additional mechanisms to amend the Brix value table as adequate provisions already exist.

g. Individual juices.

28. Many comments submitted information to revise 1 or more of 13 proposed Brix values for various juicer such as apple, apricot, carrot, celery, cherry, grape, guava, lemon, orange, passion fruit, peach, pear, and raspberry (red). One comment submitted data to establish a Brix value for pomegranate juice.

i. Apple juice.

In the preamble to the July 2, 1991, proposal, FDA specifically requested comment on the proposed Brix value for apple juice, 12.5°, which the agency selected using values in the lower portion of the range of Brix values available to the agency (56 FR 30452 at 30459). NJPA had suggested that FDA adopt a Brix value of 11.0° for apple juice, based on USDA standards for grades (7 CFR 52.301 through 52.301) for U.S. Grade A apple juice.

Several comments contended that the proposed Brix value of 12.5° for apple juice is too high and urged FDA to adopt a Brix value of 11.0° as originally submitted by NJPA in comments to the agency in December 1989 and May 1990. In a comment on the July 2, 1991, proposal, NJPA stated that its suggested Brix value of 11.0° for apple juice reflects a consensus not only of NJPA's member companies but also of members of the National Food Processors Association (NFPA), with which NJPA coordinated the adoption of its December 1989 voluntary percent juice labeling policy. NJPA also pointed out that much of the concentrated apple juice used by its members is imported from foreign countries, and that any Brix value established should take into consideration the Brix value of juice produced in these countries. It noted that over 35 percent of all imported apple juice products during 1990 came from Argentina, and that the majority of the remainder came from European Community (EC) countries. According to the comment, there is no enforceable minimum Brix value requirement for

single-strength apple juice in Argentina but, in Germany and EC countries, the minimum Brix value for single-strength apple juice is 11.18°. The comment also noted that the Codex Alimentarius Commission has recommended a Brix value of 10.0° for reconstituted apple juice.

NJPA stated that Brix data from a major U.S. processor for juice expressed from apples grown in the State of Washington reflects an average Brix value of 11.58°, with a monthly range of 10.38° to 12.62° Brix (n=51) for two processing seasons (1989 to 1990 and 1990 to 1991). It claimed that similar data obtained from Michigan for the period November 1986 through November 1990 showed that monthly average Brix values ranged from 9.6° to 13.09°. The mean of the monthly Brix averages in Michigan for the 4-year period was 11.47°, with a standard deviation of 0.876°. The comment pointed out that the average Brix would have met FDA's proposed Brix value of 12.5° in only 6 months of the 4-year period, while the suggested Brix value of 11.0° would have been met in 26 months during the 4-year period. According to the comment, average monthly Brix values obtained from New York, for the period January 1987 through July 1991, ranged from a low of 9.5° to a high of 11.8°. The comment noted that, generally, juice from apples grown in the northwestern region of the United States has a higher average Brix and a lower acid content than juice produced from apples grown in the midwestern and eastern regions.

A comment from one firm noted that production records from their Austrian supplier showed that the Brix value of Austrian apple juice ranges from about 10° to 12° over the apple juice processing season. Another of the firm's suppliers provided information on apple juice from Germany, showing that in September the Brix value range of apple juice is from 9.8° to 11.0°, in October 10.5° to 11.5° and in November 11.5° to 12.3°. It noted that most of the apple juice from Germany is processed during September and October. The comment recommended that FDA establish a minimum Brix value of 11.0° for apple juice. To establish a higher value, the comment added, would be to establish an artificially high Brix level that would impose an unfair trade barrier.

A comment suggested a minimum Brix value of 10.5° for apple juice. The comment noted that minimum Brix level for U.S. Grade B apple juice is set at 10.56 in the USDA standards for grades for apple juice. (7 CFR 52.308). The comment maintained that the

proposed Brix value of 12.5° would effectively exclude Canadian products from the U.S. market.

Other comments supported a Brix value of 11.5° for apple juice. One comment recommended a minimum Brix of 11.5° for apple juice reconstituted from apple concentrate based on available data including records collected at 21 apple processing facilities, operated by 13 companies. According to the comment, the average Brix level reported by 17 of 21 plants fell in the range of 11.1° to 11.8°, with 11 of the plants reporting data in the 11.3° to 11.7° Brix range. Thus, the comment concluded, a Brix value of 11.5° is more representative of the Brix level of expressed apple juice than is the Brix value of 12.5° proposed by FDA.

Several comments contended that increasing the Brix value of apple juice to 12.5° would result in a Brix higher than normal for the expressed juices commonly used and would force food processors to produce a product that is incompatible with consumer expectations. They maintained that apple juice at a Brix of 12.5° is too sweet, especially in the Northeastern region where the taste preference for apple juice is a tart product (lower Brix/acid ratio). One comment stated that the proposed higher Brix value level of 12.5° would result in a 9 percent increase in soluble solids content over that of the currently marketed apple juice which contains from 11.0 to 11.5 soluble solids. It estimated that the increase would cost consumers of reconstituted juice products approximately \$25 million annually. It further contended that the cost of some single-strength apple juice that contains added apple juice concentrate to achieve a preferred flavor profile would be increased as well if a Brix value of 12.5° is adopted. Another comment stated, that changing the Brix from 11° to 12.5° would increase the ingredient cost by 14 percent and would further serve to put the product out of reach of many mothers who have been using apple juice for their babies.

After reviewing the data on the soluble solids content of apple juice submitted in the comments on the July 2, 1991, proposal, FDA has reconsidered its position regarding the proposed Brix value of 12.5° for 100 percent apple juice from concentrate. Data provided by industry in comments showed that mean Brix values for individual lots of apple juice range from 8.9° to 13.4°, with summary mean values (averaged monthly and yearly mean values) ranging from 11.0° to 11.58. NJPA pointed out that the minimum RSK Brix of apple juice is 11.18° and

recommended that FDA adopt a minimum value of 11.0°. The agency notes, however, that the RSK mean Brix value for apple juice is 12.08°. With respect to the comment that requested that FDA adopt the minimum Brix of 10.5° for U.S. Grade B apple juice, FDA believes that this value is too low and does not reflect average Brix values of apples produced and processed in this country, as evidenced in the comments cited above.

In response to the comment requesting adoption of the USDA U.S. Grade A Brix value of 11.0° for apple juice, FDA points out that the USDA lowered the Brix value of U.S. Grade A apple juice from 11.5° to 11.0° in response to a request from the Proceed Apple Institute (47 FR 5875, February 6 1982). At that time, USDA stated that the change was being made to include differences in growing conditions in various parts of the country, increased use of more varieties of apples in the manufacture of canned apple juice, consumer preference for a less product, and differences in processing techniques. However, comments summarized in the USDA rule noted that northwest apples have a Brix average of 12.5° or higher, to which USDA responded that the Brix requirements provided for in their standards for grades are minimum standards for each grade. It also stated that lowering the Brix by one-half of a degree will accommodate apple processors using varieties that have lower soluble solids compared with other varieties processed in other parts of the country.

FDA points out that the USDA standard (7 CFR 52.308), referenced by the comments, applies to canned single-strength apple juice, in which no more than one-fourth of the juice may have been concentrated. In the case of the USDA standard in 7 CFR 52.6221 et seq., for frozen concentrated apple juice, the minimum Brix value for a concentrate that is to be diluted 1 plus 1 is 22.9°. Such a product on dilution would have a Brix value of approximately 11.45°.

FDA acknowledges that there are differences in Brix values of apples depending on geographical growing regions, and that consumers may have developed certain preferences based on these regional differences. However, FDA believes that it should set the minimum Brix for apple juice at a level that is toward the middle of the range of Brix values for apple juice in order not to penalize producers of freshly expressed apple juice, which may have a higher solids content, to the benefit of those producers who sell reconstituted

or diluted apple juice products. It would also be fairer to consumers because they would be assured of getting reconstituted juices that more closely resembled the juice from which it was made. Consumers who prefer a less sweet juice can dilute the juice farther by adding water. However, consumers who find that a reconstituted juice tastes weak because of a lower apple juice soluble solids content cannot rectify this condition by adding more apple juice solids.

Although most of the apple juice may be sold at Brix levels ranging from 11.0° to 11.5°, according to industry-based standards established by USDA, the agency believes that in establishing a minimum value for reconstituted apple juice or diluted apple juice, the minimum should reflect the average Brix value of expressed apple juice. Thus, consideration must be given to the higher Brix apple juice produced in the northwestern areas of the United States as well as to the lower Brix value juices produced in the midwestern and eastern areas. As noted in the July 2, 1991, proposal, a study by Mattick and Moyer (Ref. 2) of the Brix of 93 authentic apple samples collected from many different areas of the country and representing many apple varieties demonstrated average Brix values of 12.60°, 12.80°, 12.83°, and 12.74° (56 FR 30452 at 30459). The German RSK value noted in the comment provides for a range of Brix values from 11.18° to 14.01° with a mean Brix value of 12.08°. In view of these higher values, FDA believes that the minimum Brix value of 11.0° suggested by several comments from industry is too low, and that a minimum Brix value of 11.5° for apple juice is more appropriate because it takes into account the apples with the higher Brix values. Further, it is consistent with the Brix of reconstituted apple juice made in compliance with the USDA standard for grades for frozen concentrated apple juice. It also represents a value on the low side of the mean Brix value established for German apple juice, as well.

Accordingly, FDA has revised the minimum Brix value for apple juice by reducing it from 12.5° to 11.5°.

ii. Apricot juice.

FDA proposed a minimum Brix value of 14.0°, based on the data submitted by NJPA. According to NJPA, this value was derived from the USDA File code 147-A-2 (March 1988). Inspection of 50 percent Juice Drinks and Juice Drink Products under the Child Nutrition Labeling Program (Food and Nutrition Service).

One comment from a fruit and vegetable processing and marketing

cooperative stated that their analyses of apricot juice over the period 1986 to 1990 showed an average Brix of 11.7° with a standard deviation of 0.8°. This average value was derived from a total of 502 measurements. The comment stated that it believed that the data were adequate because they include five different growing seasons, several varieties, and various weather conditions and cultural practices.

FDA notes that a National Canners Association report on the Brix values of authentic samples of apricots, as reported by Nelson and Tressler (Ref. 10), lists the Brix values of whole Blenheim apricots and Tilton apricots as ranging from 10.7° to 17.1°, with means of 14.1° for Blenheim apricots (n=6) and 12.6° for Tilton apricots (n=6). In this same reference, the Brix value of whole apricot pulp was 11.5°, and apricot nectar was 14.3° (n=6 in both cases). Thus, the Brix value of apricot juice appears to be dependent on the source of the extracted juice used in the analysis. Based on these data, FDA finds that the suggested Brix value of 11.7°, as provided in the comment, is reasonable. Use of the lower Brix value would permit use of an important variety, Tilton, which has a much lower Brix value than the proposed Brix value, 14.3°, from the canned nectars standard. In addition, the lower value would be representative of the Brix values currently encountered in industry as cited in the comment. Therefore, FDA is incorporating the Brix value of 11.7°, as suggested by the comment, in new § 101.30(h)(1) in place of the proposed Brix value of 14.3°. Because this amendment is based primarily on a single submission, FDA requests comments and data submitted in the form of a petition to amend this regulation if data are available that would support a different and more appropriate value.

iii. Carrot juice.

FDA proposed a minimum Brix value of 11.0° for carrot juice based on the NJPA Brix value submitted in December 1989. Subsequently, in May 1990, NJPA submitted a lower Brix value of 9.0° for carrot juice, based on data from NFPA. NJPA did not provide any justification as to why this value was more appropriate than the earlier submission. Thus, FDA published the Brix value of 11.0° because it was based on Government data rather than solely on industry practice. FDA specifically sought comments on the appropriateness of the proposed value and also requested justification for any suggested lower number.

Several comments were received on the Brix value of carrot juice that

claimed that the proposed Brix level of 11.0° was too high. One comment provided 31 average Brix values (one average for each date of measurement) for the carrot juice produced during the period January 31, 1991, through June 12, 1991. The overall average Brix level from these data is 7.0° with a range of 5.4° to 8.0°.

Later, a trade association provided additional information concerning average Brix levels for carrot juice in a memorandum, dated January 22, 1992. This information consisted of the following: (1) An average Brix value of 8.6°, with a Brix value range from 7.0° to 9.3° and a standard deviation of 0.5° based on 72 measurements, for the period of January 1, 1990, through December 12, 1990; and (2) an average Brix value of 8.1° with a Brix value range from 6.9° to 9.8° and a standard deviation of 0.5°, based on 39 measurements during the period of January 1, 1991, through July 31, 1993. No specific value was suggested for a minimum Brix for carrot juice in this comment.

A comment from a manufacturer of concentrated carrot juice recommended a Brix value of 8.0° for the reconstituted carrot juice. The comment provided information on daily average Brix value levels of freshly expressed carrot juice (each day's volume was between 30 to 50 tons) showing that: (1) The daily Brix average values (n=31) ranged from 5.4° to 8.0° with an overall average of 7.0° during the period of January 31, 1991, through June 12, 1991, and (2) the average daily values (n=20) ranged from 6.9° to 8.3° with an average of 7.6° during the period of October 1, 1991, through January 21, 1992. The comment stated that the firm has processed in excess of 3,000 tons of carrots for juice and concluded that the values submitted are indicative of the true Brix value of single-strength carrot juice.

Only two comments provided data on the Brix of carrot juice. The average Brix Values from both sources and the industry recommended Brix are considerably lower than the proposed Brix of 11.0°. The Brix averages of the four data sets received are 7.0°, 8.6°, 8.1°, and 7.6°, with an overall average Brix value of 7.8°. The proposed Brix value of 11.0° was based on data from USDA Handbook 8-11, which lists 11.12 percent of total solids in canned carrot juice, of which 9.9 percent is total carbohydrate (Ref. 6). Because the Brix measures soluble solids content, and not all of the total solids or total carbohydrate content of carrot juice is expected to be soluble (e.g., insoluble cellulose or fiber), the use of these values as the Brix value would result in

a figure that is higher than would result from measurement of the Brix by refractometer. Therefore, based on tills information, FDA is adopting the value of 8.0° in new § 101.30(h)(1). The Brix value of 8.0°, set out in the regulation below, was recommended by the manufacturer of carrot juice and is very close to the calculated overall average Brix in the data supplied to the agency in the comments.

iv. Celery juice.

FDA proposed to establish a minimum Brix value of 4.5° for celery juice based on the NJPA Brix value submitted in December 1989. Subsequently, in 1990, NJPA submitted a lower Brix value of 3.6° for celery juice, based on data from NFPA. NJPA did not provide justification as to why this value was more appropriate than the earlier submission. As in the case with carrots, FDA published the higher Brix value of 4.5° because it was based on Government data rather than solely on industry practice.

Two comments received in response to the July 2, 1991, proposal claimed that the proposed Brix value level of 4.5° for celery juice, based on NJPA's December 1989 submission to the agency, was too high, but these comments did not provide any data in support of the claim. One of these comments, from a trade association, stated that members had expressed concern over the proposed minimum level of 4.5°, and that it is soliciting data on levels for celery juice. However, no data were received on the Brix of celery juice from the trade association during the comment period.

A comment from a food processor recommended a Brix value of 3.0° for reconstituted celery juice. The comment stated that daily average Brix levels of freshly expressed celery juice, during the period of April 9, 1991, through May 10, 1991, ranged from 2.95 to 3.4° (n=10), with an overall Brix value average of 3.1° and for December 23, 1991, the 1-day average Brix value was 2.64°. The mean of the 11 average Brix values is 3.09°.

NJPA suggested Brix value of 4.5° for celery juice was based on information from USDA Handbook 8-11, which reflects the total solids content of celery, and thus may be too high. The data on the Brix of celery juice from the food processor and NJPA's May 1990 submission also suggest that proposed minimum Brix value of 4.5° is too high. USDA Handbook 8-11 lists the total carbohydrate content of celery as 3.63 g/100 g (per edible portion), of which 0.80 g is crude fiber (Ref 6). Thus, the soluble carbohydrates (sugars) content would comprise approximately 2.83

percent by weight. FDA recognizes that the other constituents may affect the Brix determination by refractometer, and that the use of the soluble solids, determined by difference, from Handbook 8-11 can only serve as a rough approximation. However, in view of this calculation and the data supplied by the food processor, both values supplied by NJPA appear to be too high for celery juice. Because neither NFPA or NJPA provided a basis for the Brix value of 3.6° for celery juice, FDA concludes that for the purpose of labeling the content of celery juice from concentrate that a more appropriate Brix value is 3.1°, based on the mean of the data submitted by the food processor. Therefore, FDA is revising new § 101.30(h)(1), accordingly.

v. Cherry juices.

FDA proposed a single Brix value of 14.0° for juice from both sour cherry and sweet cherry varieties, based on the data submitted by NJPA.

A comment from a firm that processes juice beverages stated that it has encountered large variations in Brix between the varieties of sweet cherries and sour cherries, and that the single-strength Brix values should reflect these differences. The comment maintained that the proposed Brix value of 14.0° is a compromise that does not reflect the actual situation for either cherry classification. In support of this contention, the comment included summary data from its U.S. supplier for dark sweet cherries and for red sour cherries obtained from the Pacific northwest.

Data from the supplier for the dark sweet cherries, collected during the years 1982 to 1999, showed a mean Brix value of 20.0°, a median of 19.9°, with a standard deviation of 3.0° (n=120) and a Brix value range from 14.0° to 30.0°. Using these data, the comment suggested that the minimum Brix value for dark sweet cherries be set at one standard deviation below the mean Brix value or 17.0°.

With respect to the red sour cherries, the comment supplied data for the years 1983 to 1990 that showed a mean Brix value of 15.8, a median of 14.0°, with a standard deviation of 3.4° (n=23) and a range from 11.2° to 22.9°. Using these data, the comment suggested that the minimum Brix value for sour cherries be set at one standard deviation below the mean Brix value or 12.4°. The comment also supplied data for five other mean Brix values or ranges for red sour cherries. These Brix values were for products obtained from Germany, Austria, and the United States, and ranged from a low Brix value of 10.0° to a high Brix value of 13.0°. This

comment also pointed out that the German RSK Brix values (Ref. 7) for sour cherry juice are as follows: 14.71° mean Brix value, 12.36° minimum Brix value, and a Brix value range of 12.36° to 19.30°.

The comment also noted that food processors generally do not find that sweet cherry and sour cherry varieties are interchangeable in their beverage products.

FDA concurs with the comment that it should establish specific Brix values for sweet cherry and for sour cherry varieties because of the differences between the two types of cherries. Sweet cherries are higher in sugar and lower in acid than sour cherries. Accordingly, FDA has amended new § 101.30(h)(1) to reflect the differences, based in part of the data supplied by the comment.

In making this determination, FDA compared the suggested Brix value of 12.4° for sour cherries to data collected by FDA in 1962 (Ref. 11) for red sour pitted cherries that show a mean Brix value of 14.3° (n=15, std. dev. = 0.96° and range = 12.7° to 16.0°). FDA believes that the suggested Brix value of 12.4° may be too low in view of the FDA data, the median value of 14.0° cited by the comments and the RSK mean value, 14.71°. In keeping with establishing Brix values close to the mean Brix value, but in the lower portion of the Brix range, FDA believes that a more appropriate Brix value for sour cherries is 14.0°, as proposed. This value is slightly lower than the RSK mean value, the mean from the FDA data, and the mean value submitted by the comment. It is also consistent with the median value for sour cherries submitted in the comment. Therefore, FDA is retaining the proposed Brix value of 14.0° for sour cherries in new § 101.30(h)(1).

In the case of sweet cherries, FDA compared the suggested Brix value for dark sweet cherries of 17.0° (mean=20°, median=19.9°, std. dev.=3°) to data collected by FDA in 1962 on authentic sweet cherries (Ref. 11) that show a Brix range of 18.0° to 21.9° for sweet cherries (n=3). Because the mean values from the comment and the FDA data, as well as the median value supplied by the comment, cluster around 20.0°, the agency believes that the Brix value of 20° is more representative of the Brix value of sweet cherries than is the value of 17.0° suggested by the comment or the value of 14.0° for all types of cherries proposed by FDA. Therefore, FDA is modifying § 101.30(h)(1) to include a Brix value of 20.0° for sweet cherries.

FDA notes that the new Brix values are consistent with the single

requirement established for cherries in the standard of identity for fruit jelly, i.e., 14.3°, the reciprocal of the factor, 7, in §150.140(b)(1)(21CFR 150.140(b)(1)). The information that FDA has received suggests that there may be a need to revise the standard of identity for fruit jelly to reflect the separate values for the two classes of cherries, sour cherries and sweet cherries. In consideration of amending the standard of identity for fruit jelly, FDA requests information as whether substantial amounts of sweet cherries are being used in the manufacture of fruit jelly, and whether it should incorporate a specific value for sweet cherries in the standard.

vi. Coconut juice.

In the July 2, 1991, proposal, FDA stated that it has no data to support a specific Brix level for juice from coconut and requested comments on, and data for, an appropriate Brix level. The agency also noted that there are two portions of the coconut that can conceivably be used to produce a juice, i.e., the coconut water (liquid from coconut) and the coconut meat. FDA asked for information on the feasibility of using both portions of the coconut to produce juice and comments on whether there should be one or two Brix value levels for coconut.

According to one comment, there are no data to support a specific Brix value level for juice from coconut. The comment also noted that the method used for determining the Brix value of oilier juices may be inappropriate for use with coconut juice because of coconut juice's fat and oil content and their effects on refractometer readings. The comment stated that when data become available that might be useful to FDA in establishing a Brix or other value for determining what constitutes 100 percent coconut juice, it will submit such data.

In the absence of data on the soluble solids content of single-strength coconut juice, FDA is not establishing a minimum value for the food. Diluted or blended beverages made with coconut juice should be labeled with the percentage of coconut juice based on the content of the full-strength juice used. If made from coconut juice concentrate, the dilution should be based on the composition of the juice used in making the concentrate.

vii. Grape juice.

NJPA submitted a Brix value of 16° for grape juice in December 1989, based on information obtained from the Concord Grape Association. Subsequently, in May of 1990, NJPA suggested a lower Brix value of 13° based on the USDA File code 147-A-2 (March 1988). FDA

proposed the higher Brix value of 16° for grape juice and solicited comments on the appropriate Brix level.

A comment from NJPA supported the proposed Brix value of 16.0° for grape juice. The comment stated that the higher Brix level for single-strength grape juice, recommended in its May 1990 comments, was based on comments it received from NFPA and the Concord Grape Association. NJPA stated that this level is the appropriate level.

A comment from a distributor and processor of juice products stated that in this country, no one in the industry is using a Brix level of 16.0° for grape juice, as set out in proposed § 101.30(j)(1), and urged that the final rule establish a minimum Brix level of 13.0° for single-strength grape juice. Citing two Federal regulations, the comment argued that FDA already recognizes 14.3° as the appropriate Brix value for grape juice in the standard of identity for fruit jelly in § 150.140, and that USDA uses a Brix value of 13° in the USDA standards for grades for frozen concentrated sweetened grape juice in 7 CFR 52.2460(b)(1) which, the comment maintained, is closer to reality.

FDA disagrees with this comment. The comment from the juice distributor cited the value for grape juice in USDA grade standard for frozen concentrated "sweetened" grape juice (7 CFR 52.2451 through 52.2464). FDA does not consider this Brix value to be applicable in defining the appropriate Brix for 100 percent grape juice. The USDA standard in 7 CFR 52.2452(a) states that not less than 50 percent of the total soluble solids of the finished concentrate shall be derived from Concord type grapes of the Labrusca species. In 7 CFR 52.2453, USDA requires a minimum Brix value of the finished concentrate including added sweetening ingredients to be 24.8° when the concentrate is made to be diluted 1 to 1 before consumption. The standard further states that in grading the prepared "grape juice beverage" from frozen concentrated sweetened grape juice, the Brix value of the beverage is not less than 13.0°. This "beverage" is the sweetened diluted grape juice product and thus is not relevant in determining the Brix of unsweetened, undiluted grape juice.

FDA notes, however, that the current USDA standards for grades for canned grape juice, in 7 CFR 52.1341-52.1351, list Brix values for two types of "unsweetened grape juice." Type I juice is from the Concord type grapes of the Labrusca species (slip skin varieties), and type II juice is from any type of grape other than the Concord type. The

standard requires a minimum Brix value of 15.0° for both types of Grade A unsweetened grape juice and a minimum Brix value of 14.0° for both types of U.S. Grade B unsweetened grape juice. When the canned grape juice is sweetened, the minimum Brix value for each grade is increased by 2° to 17.0 and 16.0°, respectively (7 CFR 52:1350(a) and (b)).

The agency recognizes that much of the grape juice in the marketplace may have been sweetened or diluted because the strong and somewhat astringent flavor of freshly expressed grape juice may not appeal to some individuals. However, consumers have a right to know v/hen the juice has been sweetened or diluted. Thus, FDA must establish a minimum Brix for the unsweetened full-strength grape juice to serve as the basis for the percent juice declaration on diluted juice beverages and reconstituted grape juice products.

FDA notes that the proposed Brix value of 16.0°, in accordance with the NJPA submission, was based on information from the Concord Grape Association. This value is also supported by information in the literature. Data reported by C.S. Pederson on grape juice support that the Brix value of the juice is around 16° for *Vitis labrusca* (Concord grapes) (Ref. 10). Average soluble solids levels for Concord grapes were 15.1, 16.4, and 16.7 for three regions in New York State in a 1949 publication by Robinson, et al., cited by Pederson (Ref. 10). The ranges for these three average Brix values were 12.9° to 17.8°, 13.1° to 19.5°, and 22.7° to 20.0°, respectively. Pederson also stated that nearly all grape juice prepared in the United States is from Concord grapes. The German RSK minimum Brix value for grape juice is 15.88°, based on a range of 15.88° to 19.330 and a mean of 17.03° (Ref. 7).

Based on these observations, FDA concludes that the minimum Brix value for grape juice should be at least 16.0°. Therefore, FDA is retaining the proposed Brix value of 16.0° for grape juice in new § 101.30(h)(1).

According to one comment, approximately 20 million gallons of 68 degree Brix grape juice concentrate (worth \$130 million) is used annually in juice blends. The comment stated that because much of the juice is used at the 13° to 14° Brix level, an increase in the Brix level to 16.0° for purposes of juice percentage declaration, would have devastating economic effects. At an average cost of \$6.50 per gallon, the comment claimed, this would represent a loss of \$32.5 million which when passed on to consumers would become

much larger. The comment further stated that calorie conscious consumers will shy away from higher Brix juices in favor of others with lower Brix levels. Thus, a Brix value of 16.0° could also result in substantial losses in market volume that would be impossible to calculate.

FDA does not agree with the cost analysis in the comment. If the minimum Brix value is set at a higher level than food processors are currently using, food processors can still maintain the same diluted juice blend formulations. They simply will have to label the percentage of juice in the beverage appropriately.

viii. Grapefruit juice.

FDA proposed to adopt a minimum Brix value of 10.0° for grapefruit juice. This value was submitted by NJPA in December 1989 and is the same as that established in the standard of identity in § 146.132 (21 CFR 146.132) for grapefruit juice made from concentrated grapefruit juice exclusive of any added sweeteners.

A comment from a foreign government expressed support for a minimum Brix value of 9.0° for fresh or reconstituted grapefruit juice. The comment stated that this value would be consistent with the USDA standards for grades for unsweetened U.S. Grade A and U.S. Grade B grapefruit juice (7 CFR 52.1228, Table I).

FDA notes that the Brix value of 9.0° for fresh single-strength grapefruit juice is not applicable to "grapefruit juice from concentrate" (i.e., reconstituted grapefruit juice) in the United States or for use in calculating the percentage of juice contained in a juice blend in accordance with new § 101.30(h)(1). The standard of identity for grapefruit juice in § 146.132, as noted above, and the USDA standards for grades for grapefruit juice in 7 CFR 52.1228 (Table II, U.S. Grade A and U.S. Grade B), list a Brix value of 10.0° for unsweetened grapefruit juice from concentrate. The Brix value of freshly expressed grapefruit juice is not specifically designated in the standard of identity nor in the regulation (new § 101.30(h)(1)) set forth below. The Brix value for freshly expressed grapefruit juice is the Brix of the particular lot of grapefruit juice, before the addition of any water, sweetener, or any other additives, as determined by refractometer and corrected for acidity in accordance with § 146.132(a).

FDA is not revising the proposed Brix value of 10.0° for grapefruit juice because it was established by formal rulemaking (47 FR 43364, October 1, 1982). At the time that FDA adopted the standard, citrus processors and growers

indicated that the preponderance of grapefruit juice produced in the United States contains, on average, 10.0 percent soluble solids or greater. Comments on the proposed standard of identity at that time also maintained that to establish a minimum soluble solids content of 9.0 percent would be to allow dilution of the finished product to a level substantially below that of the juice from the grapefruit fruit from which the concentrate is made. Therefore, FDA is adopting the 10.0° Brix value as proposed.

ix. Guava juice.

FDA proposed a minimum Brix value of 7.7° for guava juice, as suggested by NJPA. This value is consistent with the Brix value in the standards of identity for canned nectars (§ 146.113 and fruit jelly (21 CFR 146.140)), the U.S. Customs Service requirements (19 CFR 151.91), and USDA File code 147-A-2 (March 1988).

One comment stated that using a statistical approach, it had calculated a standard Brix value of 6.6° for guava juice. The comment explained that its Brix data (mean of 7.1°, standard deviation of 0.5, a minimum of 6.0 and a maximum of 8.0°, median 7.1°, 20 data points, and mean minus 1 standard deviation to yield 6.6°) came from a single supplier of Hawaiian guava juice, who forwarded the weighted mean Brix values for each month's production. Using these data, the comment recommended a Brix value of 6.6° as the minimum level for a single-strength guava juice.

FDA has been unable to corroborate the suggested lower Brix value for guava juice in the published studies. FDA notes that one reference states that the Brix of guava averages around 9° (Ref. 12). Another reference lists soluble solids for the fruit from selected Hawaiian guava seedlings, which range from 8.0 to 11.5° Brix, and total soluble solids contents that range from 7.80 to 10.53 percent (n=10) (Ref. 10). In view of the published data on the Brix value of guava juice, FDA is adopting the proposed Brix value of 7.7°, which reflects FDA and U.S. Customs Service regulations, as well as USDA specifications. FDA recognizes that this value is higher than the mean and median in the comment's data, but the Brix published in the literature support a higher value than that suggested by the comment.

FDA is open to submission of information on the appropriateness of this value for 100 percent guava juice as a basis of a proposal to amend the standards of identity for fruit butter and fruit jelly. Any petition submitted to amend the fruit butter or fruit jelly

standards (§ 150.110 (21 CFR 150.110)) and § 150.140) should be accompanied by data representative of the varieties of guava used in the manufacture of these products, as well as data on possible effects of factors such as maturity, growing conditions, and processing on the Brix of the fruit.

x. Orange juice.

FDA proposed a Brix value of 11.8° based on the requirement in the standard of identity for orange juice from concentrate in § 146.145. This value is also consistent with the Brix value submitted by NJPA.

A comment from a foreign government opposed the proposed Brix value of 11.8° for reconstituted orange juice and suggested a minimum Brix value of 9.7°. The comment stated that its suggested value would be consistent with the regulation in that country which establishes a minimum Brix value of 9.7° for orange juice (B.11.128 Food and Drugs Regulations, Canada).

FDA is not making the requested change. FDA notes that the Brix value of 11.8° set forth in new § 101.30(h)(1) for orange juice is the same as that established in the standard of identity for orange juice from concentrate in § 146.145. This value was established after a public hearing (28 FR 10900, October 11, 1963), by formal rulemaking, and represents a consensus of what interested parties believed to be appropriate at the time. A Brix value of 11.8° seemed reasonable and practical because it was equivalent to the approximate soluble solids content of reconstituted orange juice made in the home by consumers by diluting frozen concentrated orange juice. Frozen concentrated orange juice (§146.146 (21 CFR 146.146)) is generally made to 42° Brix and is diluted before consumption by adding 3 parts water, such that the resulting Brix value ranges from not less than 11.8° to 12.4°. FDA sees no reason for different values in the standard of identity for orange juice from concentrate and the regulation for defining "100 percent juice" for percent juice labeling purposes in new § 101.30(h)(1). Therefore, FDA is not revising the minimum Brix value of 11.8° for orange juice in new § 101.30(h)(1), as requested by the comment.

xi. Passion fruit juice.

NJPA suggested a Brix value of 12.0° for passion fruit juice based on the USDA File code 147-A-2 (March 1988). However, FDA proposed a minimum Brix value of 14.5° based on the Brix of passion fruit juice in the stayed canned nectar standard of identity (§146.113). FDA noted the variation in the two Federal specifications and expressed the

opinion that if there was justification for the lower suggested value, that it would be forthcoming in comments on the July 2, 1991, proposal.

A comment from NJPA stated that its Original May 1990 suggestion of 12.0° as the minimum Brix value for passion fruit juice was based on a USDA data base, and that it has been unable to locate any other differing data except for the German RSK "guide" value for passion fruit juice of 13.5°. Noting that the FDA proposed Brix value of 14.5° was based on the canned nectar standard in § 146.113, which has been stayed for many years, the comment maintained that industry believes that the Brix levels contained in that standard are too high.

Another comment provided data obtained from its suppliers in 1990 on the soluble solids content of single-strength (unconcentrated) passion fruit juice from Ecuador (average Brix value of 14°) and Peru (Brix value range of 14° to 16°). The comment recommended that FDA adopt a minimum Brix level of 14.0° for the single-strength (100 percent) passion fruit juice.

FDA notes that the German RSK Brix value is based on a data range of 12.0° to 18.0° with a mean Brix of 14.0° and a standard value (minimum value) of 13.5°. Wallrauch, et al., (Ref. 7) stated that the data on passion fruit juice were based on extensive analyses of all industrially important varieties and provenances (South America, Africa, Australia, New Zealand, Fiji Islands, Sri Lanka, Taiwan, and Hawaii). It further stated with respect to the Brix of passion fruit juice, that only rarely and only for Brazilian juice has a Brix value for passion fruit juice been found to be as low as 11.5°. Wallrauch et al., also noted that a mean Brix value of 14° can be used in the dilution of concentrate to single-strength so as to maintain all of the organoleptic and analytical features of passion fruit juice.

FDA is adopting a Brix value of 14.06 for passion fruit juice based on the analytical data provided in the comments and supported by Wallrauch, et al. This value also is the same as the mean RSK Brix value reported by the German fruit industry (Ref. 7).

xii. Peach juice.

NJPA suggested a Brix value of 11.8° for peach juice which was published in the proposed § 101.30(j)(1), This Brix value is incorporated in the standards of identity for fruit butters (§ 150.110 (21 CFR 150.110)) and fruit jelly (§ 150.140) on September 5, 1940 (5 FR 3558) and in the standard of identity for canned nectars (§ 146.113) on May 7, 1968 (33 FR 6862) which was stayed because of objections on July 27, 1968 (33 FR

10713). It was based on the analysis of 33 authentic samples during the period 1924 to 1935 (Ref. 2). This Brix value is also used by the U.S. Customs (19 CFR 151.91) and by USDA in its specifications for its diluted juice products (USDA File code 147-A-2, March 1988).

One comment stated that its analyses of peaches over a 5-year period (1986—1990) showed an average Brix value of 10.5°, with a standard deviation of 0.9°. The average value was based on a total of 1,190 measurements. The comment recommended adoption of a Brix value of 10.5° in the final rule.

Based on its review of the data in the comment, FDA is adopting a Brix value of 10.5 as the minimum level for a single-strength peach juice because it is based on the data from over 1,000 samples obtained during a recent 5-year period. Thus, FDA has revised new § 101.30(h)(1) to reflect this minimum Brix value for peach juice.

FDA is open to additional information on the appropriateness of this value for 100 percent peach juice as a basis for a proposal to amend the standards of identity for fruit butter and fruit jelly. Any petition submitted to amend the fruit butter or fruit jelly standards (§§ 150.110 and 150.140) should be accompanied by data representative of the varieties of peaches used in the manufacture of these products, as well as data on possible effects of factors such as maturity, growing conditions, and processing on the Brix value of the fruit.

xiii. Pear juice.

NJPA suggested a Brix value of 11.0° for pear juice based on the USDA File code 147-A-2 (March 1988). FDA believed that this value may be too low and proposed a minimum Brix value of 15.4° based on the Brix value of pear juice in the stayed canned nectar standard of identity (§ 146.113). FDA noted the variation in the two Federal specifications and anticipated receipt of data in support of an appropriate Brix value for pear juice.

Seven comments stated that the proposed Brix value level of 15.4° for pear juice is unrealistically high. A comment from a university professor stated that it is common commercial practice to use a Brix value of 12.0° to represent single-strength pear juice. The comment stated that the RSK Brix values, which are widely applied as typical compositional indices for single-strength juice, list a Brix value range of 11.18° to 13.54° and mean of 12.13° for pear juice. According to the comment, pears are high in sugar content, even when harvested at the green and hard, but full-sized, stage of maturity. It noted

that in one university study of changes in sugars and acids during the ripening of Bartlett pears, the data showed that green, hard pears contain 12.0 g of sugars per 100 g (12 percent) which increases to a maximum of 13.5 percent and then decreases to 12.4 percent at the fully ripe stage. The comment also stated that juice is easier to express from the green, hard fruit, and that processors often prefer to press at: that stage of maturity. The comment reported a Brix range of 11.7° to 14.2° for pilot-plant processed pear juice (three varieties, unripe and ripened fruit, n=8). This comment did not recommend a specific Brix value.

One comment from a trade association stated that data from its members show that the proposed Brix value of 15.4° for pear juice is clearly excessive and recommended that the agency adopt a Brix value of 11.5° for pear juice from concentrate. According to the comment, the majority of pear concentrate is prepared from Bartlett pears. Other varieties may have a higher Brix, but they are normally marketed as fresh pears and have only limited use in the juice market. Therefore, the comment contended, other varieties should not be considered when establishing a minimum Brix level for pear juice from concentrate.

A comment from a juice products distributor provided data on unconcentrated pear juice that it collected from worldwide suppliers. The data included yearly average Brix values from Australia (1960), central and northern Argentina (1988 to 1991), and the northwestern United States (1988 to 1991). The overall weighted average Brix was 12.1° and the average Brix values ranged from a low of 10.5° to a high of 13.4°, with a standard deviation of 0.8°. Based on these data, the comment recommended that FDA adopt the Brix value of 12.2° as the minimum level of single-strength pear juice.

A comment from a fruit and vegetable processing and marketing cooperative stated that for the past 5 years, they have tested Brix levels in pear juice, and their results are much lower than FDA's proposed Brix value. The comment presented a summary of the data of Brix analyses for the years 1986 through 1990 (n = 2,446 measurements, mean Brix = 12.0°, and standard deviation = 0.8°). Based on these data, the comment recommended a Brix value of 12.0° as the minimum Brix level of single-strength pear juice.

One comment provided a summary of Brix data for more than 1,800 measurements on pear juice samples. The Brix averages for the last 3 years

were 11.7°, 11.6°, and 11.7°. The comment stated that many canners have been packing pears in pear juice for many years, and that the juice consistently runs between 11° and 12° Brix. No specific Brix level was suggested for the final rule.

A comment from a firm that imports apple and pear juice stated that data obtained from its research on pear juice suppliers in both the Northern and Southern Hemisphere showed that concentrate is produced from pears having a maximum Brix value not exceeding 12.3°, with a seasonal Brix value range of 11.3° to 12.3°. The comment recommended adoption of a Brix value of 11.0° for reconstituted single-strength pear juice.

One comment from a trade association expressed the opinion that a Brix value of 15.4° is too high and should be lowered. The comment cited a report showing that Brix values for unripe, fined Bartlett, Cornice, and d'Anjou pear juice ranged from 11.7° to 14.1°, and that the majority of pear juice is produced from hard winter pears which generally average 11.0° Brix (Ref. 7). According to the comment, although some ripened Bartlett pears are juiced, they would have to be extremely ripe to approach even 15.0° Brix, and in that condition, they would be virtually impossible to press.

FDA agrees with the comments that a Brix of 15.4° for pear juice is too high. In proposing this value, which was based on the stayed canned nectar standard (§ 146.113), FDA acknowledged that the values had been challenged and specifically requested information on what values would be appropriate. NJPA's recommended Brix value of 11.0° was based on the USDA procedure for inspection of 50 percent juice drinks and juice drink products under the Child Nutrition Labeling Program (USDA file code 147§ A§ 2). According to USDA, this Brix value was recognized by industry as being appropriate in 1980. As far as this agency can determine, there is no identifiable data base that supports the USDA value.

Having reviewed the data in the comments, FDA concludes that the proposed Brix of 15.4° is not consistent with current commercial practice. The reported Brix values in the comments ranged from a low of 10.5° to a high of 14.1°. Industry recommendations for the minimum Brix value range from a low of 11.0° from a trade association to a high of 12.2° from a juice processor, with a mean recommended Brix value of 11.7°.

FDA acknowledges that the information provided consistently

points to a lower Brix value for pear juice than the FDA proposed value of 15.4°. As stated above, however, one standard deviation below the mean is too low and is not in the best interest of the consumer. In this case, most of the data point to a mean Brix value around 12°. In fact, one comment recommended a minimum value of 12.2°, another 12°, and the university professor observed a Brix of 12.0° in his research. In addition, the German RSK "mean" Brix value is 12.13°. Use of a mean value of 12.0° would facilitate processing of pear juice which, according to the comments, is done most efficiently at the hard, green stage when the Brix of the juice is lower. Therefore, FDA is revising the minimum Brix for pear juice by lowering the level from 15.4° to 12.0°.

xiv. Pomegranate.

In the July 2, 1991, proposal, the agency solicited comments, as well as data, on any additional fruits and vegetables whose Brix values should be added to the final rule (56 FR 30452 at 30460). In response to this request, NJPA submitted data on the Brix value of pomegranate juice based on data from one of its members and suggested that a minimum Brix value of 16.0° be established as the Brix for 100 percent pomegranate juice. The suggestion was based on the firm's production records for the 1988, 1990, and 1991 processing seasons. Of the 257 samples taken during these seasons, the Brix values of samples ranged from 13.3° to 18.8°, with a weighted average of 15.9°. NJPA stated that the wide range in values is related to early season low Brix fruit versus late season high Brix fruit, varietal differences, and seasonal (climatic) variations.

FDA notes that the comment requested a minimum Brix value of 16.0° based on the firm's analyses over a 3-year period. FDA has an established Brix for pomegranate in the standard of identity for fruit jelly of 18.2°, expressed as the reciprocal by the designated factor of 5.5 for pomegranate (§ 150.140(b)(1)). This value was taken from data obtained before 1940 from authentic samples of pomegranates. According to USDA Handbook 8-9, pomegranates contain 17.17 percent total carbohydrate and 0.20 percent of fiber, or approximately 17.0 percent of sugars and other carbohydrate substances (Ref. 5). The agency recognizes that total carbohydrate content is only a rough approximation of the soluble solids content, and that other constituents of the juice may affect the refractometer readings.

Thus, FDA concludes that it is reasonable to adopt the comment's

suggested lower value of 16.0° for pomegranate juice, which was based on actual analyses, instead of the higher value of 18.2° in the standard of identity for fruit jelly. In addition, the information from Handbook 8-9 suggests that a value lower than 18.2 would be more representative of the average Brix of pomegranate juice. Therefore, FDA is including the suggested minimum Brix of 16.0 for pomegranate juice in new § 101.30(h)(1) as set out below.

xv. Red raspberry juice.

In its 1989 submission of Brix data, NJPA suggested a Brix value of 9.0° for 100 percent red raspberry juice based on current industry practice. However, in evaluating the NJPA suggested value for red raspberry juice, FDA found that single-strength red raspberry juice can range between 5.6° and 10.7° (Ref. 3 at page 390). Other reports show Brix levels of 8.9°, 11.3°, and 10.8° (Ref. 3). Because these data (median value 10.7°) were not inconsistent with the Brix value set out in the standard of identity for fruit jelly (the reciprocal of the designated factor, 9.5, that equates to a Brix value of 10.5°) in § 150.140, FDA proposed a minimum Brix value for red raspberry juice from concentrate of 10.5°.

Four comments maintained that the proposed Brix value of 10.5° is too high for red raspberry juice. Two comments, one from a food processor and one from a trade association provided data on the Brix level for red raspberry juice obtained from three sources: (1) Lots of Pacific northwest red raspberries processed by the firm from 1985 to 1990 (mean Brix of 10.1°; standard deviation = 1.0°; n = 124); (2) 1988 European suppliers (mean Brix of 9.7°, standard deviation = 1.8, n = 16); and (3) 1990 European suppliers (mean Brix = 9.4°, standard deviation = 1.1°, n = 242). The comment from the food processor also included another compilation of seven average Brix values or Brix ranges provided by other juice suppliers from four countries (Austria—2 suppliers: mean Brix value of 8.5° and 6.3°; Belgium—mean Brix of 8.8°, with a range of 6.8 to 12.0°; Germany—Brix range of 7° to 8°; and United States—3 suppliers; Brix of 9° to 9.5°, 8.5°, and 8.5°). The comment also noted that the average RSK mean Brix value for raspberry juice is 8.7° with a range of 5.3° to 13.6°. Based on these data, both comments recommended a minimum Brix value of 8.4° for red raspberry juice.

Another comment, from a university professor, requested that the mean Brix values for red raspberry juice obtained from his research be considered in adopting a new standard. A statistical

summary of the Brix values resulting from the study are as follows: Mean of 9.95° (n = 41); std. dev. of 1.93°; and a range from 7.0° to 15.0°. The comment stated that if data for the underripe and overripe samples are excluded from the data base, the following summary values are obtained: mean of 9.50° Brix (n=26); standard deviation of 1.65°; and a range from 7.0° to 13.2°. Although the sampling protocol was not designed for the purpose of determining the "true" mean Brix value for single-strength red raspberry juice, the comment stated that these new data are relevant to the proposed regulations because the major commercial varieties from the Pacific Northwest and from Poland predominate in the sample set. Fall-bearing raspberries and several unusual varieties such as Golden are also included. The comment concluded that the proposed Brix level of 10.5° is too high and suggested that the 9.5° to 9.95° Brix values from the current research be considered in adopting the new standard.

One comment from a distributor of 100 percent fruit juice blends stated that the Brix value proposed by FDA for red raspberry fruit is incorrect and is not consistent with establishing a minimum acceptable value for a juice to be considered full-strength. The comment provided a brief summary of the Brix values collected from suppliers in northwestern United States (1990) and Europe (1991). It provided two average Brix values, 10.1° (range 9.0° to 12°) and 8.5° (no range provided) for the United States and an average Brix of 8.0° and a range of Brix values, 7.0° to 9.0° Brix for Europe, resulting in an overall average Brix value of 9.1° with standard deviation of 0.7°. The comment recommended 9.1° as the minimum Brix level of single-strength (100 percent juice) red raspberry.

FDA has reconsidered its proposed value of 10.5° Brix for red raspberries and agrees, based on the data submitted in the comments, that this value should be revised.

FDA also notes that soluble solids analyses conducted by the agency in 1964 and 1965 on five types of authentic red raspberries resulted in an average Brix of 8.91° (range 8.13° to 10.9° Brix; standard deviation 0.68°) (Ref. 14). In deciding to lower the proposed Brix value, FDA noted that most values cited in the comments tend to cluster between 8.5° and 9.7° Brix. Thus, FDA concludes that the suggested value of 8.4° is too low. The agency believes that a more appropriate minimum Brix value would be 9.2°, a Brix value in the lower portion of the range of suggested values provided in the comments. Accordingly,

FDA has incorporated the value of 9.2° in new § 1.30(h)(1).

xvi. Other comments on specific values.

29. Several comments from the juice canning industry noted that FDA did not list any Brix values for beets, parsley, bell peppers, garlic, and onion. However, the comments did not propose any values or provide any information as to appropriate Brix values for these foods.

The July 2, 1991, proposal requested comments on, and data for, any additional fruits and vegetables whose Brix values should be added to the regulation. Because the comments provided no information or data, the agency is not placing these foods in the Brix value table. If a percentage juice determination is made for any fruit or vegetable juice not found in the Brix table in the regulation, the calculation for percentage juice declaration is to be made on the basis of the soluble solids content of the single-strength (unconcentrated) juice used to produce such a concentrated juice.

30. One comment proposed calculating the percentage juice at a Brix level equal to the average of the single-strength (unconcentrated) juice produced from that fruit in the United States.

Because the comment provided no data for the agency to review or evaluate, the agency cannot evaluate the comment's suggestion. Therefore, the percentage juice declaration will continue to be determined by using the Brix values in the table as revised in this final rule.

31. Several comments stated that acid correction of the Brix value in the calculation of percentage juice should be provided for certain juices, e.g., cranberry, lemon, lime, and raspberry as is currently provided in the standards of identity for grapefruit and pineapple juice (§§ 146.132 and 146.185 (21 CFR 146.185)). However, the comments stated that the methodology to do this correction at present is complex and not widely distributed. The comments suggested that Government and industry work together under the auspices of the Association of Official Analytical Chemists (AOAC) to determine the proper reliable methodology.

NJPA commented that the Brix values submitted by them in December 1989 and May 1990 were based on the assumption that the refractometric readings of Brix values were corrected for acidity to obtain the total soluble solids. They also stated that a footnote should be added to the table of values in new § 101.30(h)(1), stating that the Brix value, if determined by

refractometer, is corrected for acidity by the method set forth in the grapefruit juice standard. Another comment that supported the NJPA suggested Brix values recommended that a correction for acid content be applied in the Brix value determination for ail juices, and that this correction be based on the predominant acid type inherent to the individual juice (e.g., corrected on a citric acid, malic acid, or tartaric acid basis). NJPA suggested that the predominant acid type be identified as part of new § 101.30(h)(1) to provide a clear and consistent means for the determination of the Brix values. A comment from another trade association also stated that any method used to calculate the Brix value level of the juice should provide for an acidity correction factor in determining the actual Brix value level.

FDA notes that the correction factors in the grapefruit standard are specific to citric acid. Yeatman, et al., developed two correction factors based on percent of citric acid to be added to the sucrose values obtained by the refractometer to yield true soluble solids and true Brix for grapefruit juice (Ref. 8). The data used to develop the correction factors were based on data collected by Stevens and Baier (Ref. 9) for citric acid content in citrus juice products. There are other predominant acids in fruit juices, but data, similar to that for citric acid, would have to be collected for these other fruit acids before a correction factor could be established.

Consequently, the above suggestions are not workable because these correction factors are applicable only to citric acid.

FDA notes that NJPA's list of Brix values cited references that predate the 1976 date of the Yeatman publication on the citric acid correction factors. In addition, Brix values for the fruit butter and fruit jelly standards were proposed in September 1940, and the fruit nectars standard was stayed in 1968. Thus, FDA does not believe that all of the proposed Brix values would have been corrected for acidity. The suggestion of a joint Government and industry effort to determine reliable methodology will be considered. Until acid correction factors are established for other juices, FDA will use the Brix values as specified in new § 101.30(h)(1).

32. One comment mentioned that FDA had not addressed the need for temperature correction when determining the percent soluble solids by refractometer.

FDA disagrees with this comment. The cited method of analysis (56 FR 36452 at 30458), published by AOAC, for determining the percent soluble

solids by refractometer includes a temperature correction (AOAC Official Methods of Analysis, 15th ed., 1990, section 8976.20 and 983.17).

33. Some comments stated that a "100 percent juice" claim should mean that only juice is present, and that no preservatives or other ingredients have been added. On the other hand, one comment stated that the percentage juice calculation should be a function of total juice solids in the final product, and that any added ascorbic acid, natural flavors, and acidulents should be treated as ingredients that do not affect the 100 percent juice claim as long as there are sufficient juice solids present to substantiate the juice content declaration. Another comment asked whether the Brix measurement included salt added to vegetable juices. It requested clarification as to whether adding salt to a 100 percent juice would prohibit declaration of the juice as 100 percent.

The juice content declaration is based on the percent by volume of single-strength (100 percent) juice in the product. It is intended to provide information on whether a juice is diluted and if so, by how much. For example, a declaration of 10 percent juice means one part juice plus nine parts water, 50 percent juice means 1 part juice plus 1 part water, and 100 percent juice means 1 part juice and no water.

Further, the agency recognizes that certain ingredients, such as salt, are used to affect flavor, and that others may be added, for example, as nutrients or as preservatives. In most instances, these additives, excluding bulky ingredients such as carbohydrate sweeteners, are not added in volumes significant enough to result in a diminution of the juice's soluble solids content and therefore do not affect the percent juice calculation. The juice products in the beverage must contain sufficient juice soluble solids to meet the minimum Brix level for 100 percent juice where established by regulation, before the addition of any non-juice ingredients, where such requirements have been established. For example, under the standard of identity for grapefruit juice, when the juice product is made from concentrate, and liquid sweeteners are added, the Brix value of the juice must comply with the required Brix of 10° (and corrected for acidity) exclusive of any added sweetener.

The agency believes that limiting the 100 percent juice declaration to juice beverages that contain no additives, such as vitamin C would discourage some manufacturers from producing

beverages that contain such useful added ingredients.

However, FDA agrees that it is necessary to clarify the issue of a 100 percent juice declaration on a product that includes non-juice ingredients because it may be interpreted by some to mean the beverage contains juice and no other ingredients. The agency has advised repeatedly for a number of years that an unqualified 100 percent juice declaration on the principal display panel is misleading when the juice also contains non-juice ingredients (Ref. 16). The agency believes that the industry is already in substantial compliance with this policy. Particularly for a beverage made from only one fruit or vegetable juice, the "100 juice" declaration introduces a precision to the description of the product that can result in the consumer concluding that the juice is the only ingredient. Because an ingredient statement is required only if a product contains two or more ingredients the consumer would not likely look for an ingredient statement under these circumstances. A 100 percent juice declaration appearing on the information panel is not likely to similarly mislead the consumer because it is in reasonable proximity to the ingredient statement, so that it will be read by the ordinary consumer in conjunction with that statement under normal conditions of purchase. Similarly, if there is no information panel, and the principal display panel bears an ingredient statement, a 100 percent juice declaration would not likely be misleading. In addition, the agency recognizes that some of these products declare the presence of the non-juice ingredients as part of the statement of identity (e.g., "prune juice with added vitamin C").

Accordingly, FDA is requiring in § 101.30(b)(3) that for those products that do not declare the presence of the non-juice ingredient in the statement of identity, when a "100 juice" declaration appears on a panel of a juice beverage that does not also bear the ingredient statement, and the product contains a non-juice ingredient, the 100 percent juice declaration shall be accompanied by the qualifying phrase "with added ———", the blank filled in with the generic term "ingredient" or a term such as "preservative" or "sweetener." For example, a beverage blend containing 100 percent juice with an added sweetener in any or all the juices would bear the phrase "100 juice with added sweetener" when the declaration appears on a panel that does not also bear the ingredient statement.

Therefore, the agency is not granting the comments' request but is permitting a qualified 100 percent juice declaration on the principal display panel of 100 percent juice beverages that contain non-juice ingredients that do not significantly affect product volume, such as preservatives, provided that these ingredients do not result in a diminution of the juice soluble solids content or otherwise adulterate the beverage.

The agency advises that in this discussion, it is not evaluating the appropriateness of any of these low volume ingredients for addition to specific juices. Determinations of whether a substance is suitable as an ingredient in a food are beyond the scope of this rulemaking. This discussion addresses only the effect on the declaration of 100 percent juice of the presence of suitable ingredients that do not have a significant effect on product volume, further, FDA advises that the presence of such ingredients in these beverages may require specific label declaration.

2. Juice Not From Concentrate

FDA proposed in § 101.30(k), (redesignated as new § 101.30(i)) that juices expressed directly from a fruit or vegetable, i.e., not concentrated and reconstituted, be considered to be 100 percent juice and be declared as "100 percent juice." Likewise, the percentage of expressed juice, and not Brix level, is to be used in calculating the percentage of juice in diluted juice beverages made directly from expressed juice. Therefore, FDA proposed in § 101.30(l) (redesignated as new § 101.30(j)) to require that calculations of the percentage of juice in a juice beverage made directly from expressed juice (not from concentrate) be based on the percentage of the expressed juice in the product computed on a volume/volume basis.

34. One comment stated that expressed juice products should not be excluded from the Brix method of calculating percentage juice. The comment expressed concern that if manufacturers were not required to meet a specified Brix level, some might dilute high solids content expressed juice with water to a lower Brix level and sell the product as full-strength (100 percent) juice.

As FDA stated in the July 2, 1991, proposal, diluting expressed juice to a lower Brix level but still calling it 100 percent juice would constitute adulteration and misbranding. Such a product would be misbranded under section 403(a) of the act because its labeling would be false and misleading

in that it failed to reveal the material fact that the juice was diluted. It would also be adulterated under section 402(b) of the act (21 U.S.C. 342(b)) because it had been diluted with water.

The agency discussed in the July 2, 1991, proposal that it was necessary to exclude expressed juices from the requirement for a single Brix level because such a provision would result in high solid content juice being diluted to the standard Brix level (56 FR 30452 at 30460). FDA stated that such dilution was not acceptable, and that expressed juice had to be declared as 100 percent with the solids content of the juice as expressed. The agency believes that the adulteration and misbranding provisions cited above will deter manufacturers from diluting expressed juice with water. Thus, FDA concludes that the concerns expressed in the comment are unfounded. Accordingly, as proposed, § 101.30(i) and (j) exclude expressed juice from the provision that percent of juice is to be calculated using specified Brix levels.

35. Another comment expressed concern that allowing expressed juice to have a different Brix value than juice of the same fruit made from concentrate could lead to organoleptic as well as nutritional inconsistencies in the product.

The agency recognizes that organoleptic as well as nutritional inconsistencies may be created by requiring that manufacturers of juice products that consist solely of expressed juice base their calculation of the juice content of the product on the juice as expressed rather than on a Brix level. The agency has concluded that Brix values are the best standardized criteria for calculating percentage of juice from concentrate primarily because of the industry practice of commingling large quantities of concentrated fruit juice, often from foreign sources, with differing and possibly unknown soluble solids values.

However, because the actual percentage of the source expressed juice is known, the percentage of expressed juice, and not Brix level, must be used in calculating the percentage of juice in full-strength and in diluted juice products made directly from expressed juice. Additionally, because the Brix levels of expressed juice from the same fruit or vegetable grown in different regions may vary within a large range, e.g., the Brix value for expressed apple juice ranges from 9° to 14°» it would be economically unfair to penalize producers of expressed juice from fruit or vegetables grown in regions that have a lower Brix value by not allowing them to declare 100 percent fruit or vegetable

juice, when in fact the juice was directly expressed from the fruit or vegetable as it occurred in nature.

Also, FDA finds that consumers will not be misled by the differences between juices made from concentrate and expressed juices. While consumers expect juice from concentrate to be processed into a uniform product, they understand that expressed juice may vary because of variation in the fruit. For example, a particular brand of frozen concentrated orange juice will taste the same from purchase to purchase, but fresh squeezed, home prepared orange juice will vary in sweetness and taste, depending on the maturity and quality of the oranges used to prepare the juice.

Therefore, the agency is finalizing the provision that juices expressed directly from fruits or vegetables be considered 100 percent juice.

36. One comment stated that the proposed method of calculating the juice content based on the Brix value was not applicable to blends of full-strength juice and concentrated juice because the total amount of juice in the product may be greater than 100 percent. The comment suggested that the final rule be amended to state that the Brix values are to be used for labeling purposes only when the product is a single juice beverage that is derived from concentrate.

FDA acknowledges that the total soluble solids content exceeds the minimum level necessary to declare that the juice is full-strength (100 percent) when concentrates are blended with single-strength juices. FDA does not intend that these products be exempt from declaration of the percent of juice. The agency recognizes that strongly flavored juice concentrates may be blended with single-strength juices to provide flavor and color in blended juice products. As a result, the total level of juice soluble solids in the blend will be greater than the total of such juices if the concentrate were diluted to single-strength before its use in the blend. In such cases, unless the blended juice is to be further diluted by the consumer, FDA considers a declaration of more than 100 percent juice to be misleading. Thus, the juice should be labeled as 100 percent juice. The agency has no objection to manufacturers making a truthful statement on the label concerning the actual level of juice soluble solids contained in the blend provided that it is made in a manner that is not misleading to consumers.

37. Several comments requested that the fruit component of nectars not be required to be declared as percent of fruit juice. They stated that pulp and

puree are the fruit ingredients in nectars, not fruit juice. Comments suggested alternate fruit content declarations, such as "apricot nectar-contains 45 percent apricot pulp" or "—————percent fruit + juice." The comments expressed concern that consumers might be confused by a declaration, for example, of 100 percent juice on a beverage in which only two of the ingredients are declared as juice while the other two ingredients are declared as fruit puree.

The agency acknowledges that there is generally more fruit or vegetable fiber or pulp present in nectars than in juice, which is otherwise processed, clarified, or filtered. However, the Brix values listed in the July 2, 1991, proposal were calculated to take into consideration that some of the starting materials may be puree or pulp, e.g., banana, papaya, or guava. Further, many comments expressed support for the agency's position that standardized criteria are needed to facilitate consistency in calculating percentage of juice. The Brix concept for percent juice calculation, while not without limitations, is a standardized criterion and provides a consistent and equitable frame of reference for manufacturers in determining percent juice in beverages derived from concentrates. The agency is unaware of a comparable standardized criterion for fruit content as opposed to fruit juice content. Therefore, FDA rejects the suggested alternative percent fruit content declaration or declarations such as "contains 45 percent apricot pulp" or "————— percent fruit + juice" in lieu of the prescribed percentage juice content declaration based on Brix for nectars. However, the agency does not object to voluntary disclosure of such fruit component information provided that it is factual. These comments did not provide alternative standardized criteria for consistently determining fruit content in nectars or purees by themselves and in combination with other fruit juice in beverages as opposed to fruit juice content based on Brix values.

F. Modified Juice

The agency proposed in § 101.30(m) (redesignated as new § 101.30(k)) that if major modifications (i.e., changes in the color, taste, or other organoleptic properties) are made to a juice to the extent that the original juice is not recognizable, or if its nutrient profile has been diminished, then the juice may not be included in the total juice percentage declaration. However, in the July 2, 1991, proposal, FDA pointed out that it is appropriate to include in the

total percentage juice declaration juices with minor modifications, such as acid-reduced orange juice, that are easily recognizable to consumers (56 FR 30452 at 30461).

38. One comment suggested that the industry work with FDA to develop information and data that will provide normal ranges for the constituents in juice, such as minerals, acids, and sugars. Such data would be used to determine at what point in the process modification of the juice is beyond the normal range of these constituents. According to the comment, a project has been initiated to develop these parameters for apple juice obtained from sources throughout the world. Additional juices are to be added to the project in the future.

FDA is aware of this information development project and is providing guidance as to the kind of information that would be useful in making agency decisions. The agency encourages industry to develop data bases that would be helpful in establishing reasonable guidelines for juices, in particular, the levels and types of nutrients, ranges for these levels, and effects of processing on nutrient content. Such data bases would facilitate decisions that promote fairness to both consumers and the industry.

39. Several comments expressed concern that the description of major modifications in § 101.30(k) would not be interpreted appropriately. One comment stated that if the phrasing "if its nutrient profile has been diminished" is strictly interpreted, juice made from concentrate would be excluded from the juice content declaration. The comment explained that there is some difference in nutrient content in any juice that is filtered and concentrated. Some comments stated that the language of §101.30(k) should be clarified by adding: "at the time processing is complete" after "recognizable;" and "to a level below the naturally occurring nutritional range for the juice" after "diminished," so that minor modifications of juices do not preclude the juice from being included in the percentage juice calculation and declaration. They cited as examples of such minor changes acid adjustments and removal of naringin from navel oranges to facilitate production of a more uniform product.

The agency agrees with the comments and is clarifying the provision because it was intended to address significant modifications of organoleptic properties and significant modifications of nutritional values. Significant modifications in organoleptic properties would include removal of the typical

color, taste or flavor, or aroma such that the juice is no longer recognizable as the typical juice of the fruit or vegetable. In the case of nutrient content of modified juices, significant nutritional modifications would include decreases in the content of any essential nutrient that is present in a measurable amount (excluding fat or calories), i.e., present at a level of 2 percent or more of the Reference Daily Intake (RDI) for any vitamin or mineral listed under § 101.9(c)(7)(iv). However, FDA recognizes that some nutrient losses can be expected as a result of heat treatment, filtration, and clarification used to make the modified juice product. FDA expects that such losses would be minor, and that the resulting modified juices will provide levels of essential nutrients comparable to the naturally occurring nutritional range published in recognized data bases, such as the USDA Handbooks on Food Composition (Refs. 5 and 6), for the unmodified juice product.

The agency is adopting the suggested changes to the regulation with one exception. It believes that the term "normal nutrient range" is more appropriate than "naturally occurring nutritional range." As stated in the comment, the naturally occurring nutrient range, i.e., nutrient levels in expressed juice, may be slightly different from the range of nutrients normally present in juice that has been processed, for example, filtered and concentrated. FDA believes these differences should be taken into account in determining which changes in a juice constitute major modifications.

Accordingly, FDA has revised new § 101.30(k) by adding the phrase "at the time processing is complete" after "recognizable" and the phrase "to a level below the normal nutrient range for the juice" after "diminished," to specify that comparisons of the organoleptic properties of the original juice and the modified juice will be made "at the time processing is complete" and to specify that the nutritional profile must not be diminished "to a level below the normal nutrient range."

40. Some comments requested clarification of how the percentage juice content of dehydrated juices should be determined. One requested that dehydrated fruit and vegetable powders be treated similarly to fruit and vegetable juice concentrates, i.e., based on the Brix value, and therefore, the percent of juice should be based on the soluble solids content of the rehydrated product.

Another comment questioned the status of dry drink mixes which are

prepared from spray dried juices that have not been modified in any way other than that the water has been largely removed. The comment expressed the opinion that when these products are properly reconstituted, they should be considered to be a juice.

FDA is not providing for the declaration of the percent of juice from dehydrated fruit or vegetable juices. At this time, the agency does not have information on the manufacture of such products or on the properties of the finished products with which to determine whether dehydration is a minor modification that does not significantly change the juice. The agency believes that many dehydrated juices may contain ingredients other than simply juice solids. Maltodextrins are often added to prevent stickiness during juice drying operations. Fruit essence or flavors may be added to compensate for volatile flavor components lost during processing. However, according to the literature, processes are being developed in which juices may be dehydrated without the addition of additives such as maltodextrins or glucose syrups (Ref. 15).

The agency requests information on how the specific dehydrated juices are made, so that it can determine appropriate means of labeling dehydrated juice products in juice beverages. Until such time as FDA can establish rules governing the declaration of dehydrated juices in juice beverages, it will evaluate the labeling of such dehydrated products on a case-by-case basis to determine if it is misleading. However, FDA advises that in the meantime, any declaration of percent of juice made on a rehydrated juice should be based on the fruit or vegetable solids before any other soluble substances are added to the product.

41. One comment stated that it is possible to remove some or most of the sugar from a juice and not otherwise change the nutrient profile of the juice. The comment stated that, with an alternative sweetener, the product will have the color, taste, and other organoleptic properties consumers associate with the original juice. The reduced-sugars juice will have levels of ascorbic acid, citric acid, and minerals that are equivalent to those of the standard juice. The comment maintained that an alternate method to the Brix calculation will have to be used in calculating juice content for such products. Thus, the comment suggested that the regulation recognize this possibility and permit manufacturers to use an alternative method to calculate

the juice content, provided they have data to substantiate the method.

FDA recognizes that current technology is such that sugars or other components may be removed from juice. The agency recognizes that the reduction of sugars from a juice or a standardized juice, and the subsequent sweetening of the juice with a sweetener that provides an insignificant amount of calories, results in a modified juice. If the juice is a standardized juice, e.g., orange juice, that has been reduced in sugars so that it qualifies for use of a nutrient content claim and complies in all other aspects to new § 130.10, then the product is a food defined by new § 130.10 and must be labeled accordingly. The actual name of the food will depend on its nutrient content. Similarly, if the original juice is not a standardized juice, it may qualify to bear a nutrient content claim defined in part 101.

However, as stated above, when sugars are removed, the resulting product is a modified juice and not juice. Therefore, like other modified juices, it cannot be included in calculating the percent juice in the product.

III. Common or Usual Name Regulation

The 1990 amendments require that the percentage juice declaration for fruit or vegetable juice beverages be on the information panel of the label. Accordingly, FDA proposed to delete from the common or usual name regulation for diluted fruit or vegetable juice beverages (§ 102.33) the provisions that deal with percentage juice declaration as a part of the name of the product and to amend the regulation to pertain only to how these beverages should be named. The agency also proposed changes in the provisions for naming diluted juice beverages. The proposed regulation included a requirement that the name of a beverage that contains juice but that is less than 100 percent juice include a qualifying term like "beverage," "cocktail," or "drink," to indicate that the product is not 100 percent juice. In addition, the agency requested comment on whether the term "diluted" should be required for these products. Further, the proposed regulation addressed such issues as how individual juices in a multiple-juice beverage should be declared, and how modified juices should be declared.

42. One comment requested clarification of the applicability of § 102.33. It noted that there were differences in phrasing in proposed § 102.33(a), (b), and (c) with respect to the products covered. It said that in

§ 102.33(a), FDA addressed diluted juice beverages by saying, " * * * beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice." On the other hand, in § 102.33(b) the product is described as a "diluted, multiple-juice beverage or blend of single-strength juices," and in § 102.33(c), as a "multiple-juice beverage or blend of single-strength juices * * *." The comment stated that it was clear that § 102.33(a) applies to dilute beverages and does not apply to nondilute beverages, but that it was not clear whether both § 102.33(b) and (c) apply to dilute and nondilute beverages, or whether § 102.33(c) applies only to nondilute beverages.

The agency advises that the difference in phrasing in § 102.33(b) and (c) was inadvertent. Both provisions are intended to apply to both dilute and nondilute beverages. Accordingly, § 102.33(c) has been revised to refer to a "diluted multiple-juice beverage or blend of single-strength juices."

A. Identity of Diluted Juice Beverages

The agency proposed in § 102.33(a) that if a product contains less than 100 percent juice and uses the word "juice" in the common or usual name, then the word "juice" must be qualified by a term that indicates dilution, such as "beverage," "cocktail," or "drink," appropriate to advise the consumer that the product is less than 100 percent juice. In addition, FDA requested comments on whether the term "diluted," or a similar term, should be required as part of the common or usual name for juices that are less than full-strength (100 percent) juice.

43. Several comments supported the July 2, 1991, proposal to qualify the term "juice" on products containing less than 100 percent juice, and none objected. However, the majority of comments addressing the issue objected to a requirement for the term "diluted" in the name of beverages containing less than 100 percent juice. The comments stated that the term would give consumers the Impression that the product was "watered down." On the other hand, several comments expressed the belief that the term "diluted" should be used. Alternatively, these comments suggested that if the term "diluted" is not used, a declaration of the total percent of juice should appear on the principal display panel if the beverage is not 100 percent juice.

The comments requesting that the term "diluted" be required did not provide information to demonstrate that such a declaration was needed or would be useful to the consumer. Consequently, the agency has no

grounds on which to base such a requirement at this time. Therefore, in accord with most of the relevant comments, while requiring use of a term that indicates dilution, FDA is not requiring that the term "diluted" be included in the name of juice products that contain less than 100 percent juice and is adopting § 102.33(a) as proposed.

Further, the agency disagrees with the alternative suggestion to require total percent juice declaration on the principal display panel of the juice beverage if it is not 100 percent juice and does not bear the term "diluted." Percentage juice is required to be declared on the information panel, and, as discussed in comment 12 of this document, the agency does not have an appropriate legal basis for requiring an additional percentage juice declaration on the principal display panel.

44. One comment stated that soft drinks (sodas) that purport to contain real fruit juice should have a common or usual name such as "imitation grape drink." This comment said that such a name is applicable when a product named "grape soda" bears vignettes or words indicating the presence of grape juice.

The agency disagrees. Under § 101.3(e), a food is an imitation if it is a substitute for, and resembles another food, and is nutritionally inferior to that food. However, if the food is not nutritionally inferior to the food for which it substitutes, it is permitted to be labeled descriptively and need not bear the term "imitation."

The requirements for labeling a beverage as an imitation are not evoked by use of vignettes or words suggesting that grape juice is present. These vignettes or words would, however, make the beverage subject to the requirements in § 101.30 for declaration of juice content. The agency finds that such a product with a percent of juice declaration would be informatively labeled and would not be misleading. Accordingly, FDA is not requiring beverages which purport to contain fruit juice to be labeled "imitation" unless the criteria in § 101.3(e) are met.

B. Identity of Multiple-Juice Beverages

FDA proposed to require in § 102.33(b) that if a product is a diluted, multiple-juice beverage or a blend of single-strength juices and declares, names, implies, or represents on the label, other than in the ingredient statement, one or more of the individual juices (represented juices), then the names of the represented juices must be included in the common or usual name in descending order of predominance by volume, unless the common or usual

name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink).

In the July 2, 1991, proposal, the agency noted that blends or mixtures of several juices, with one or two juices present in only minor amounts giving them flavor, are difficult to label (56 FR 30452 at 30462). Therefore, FDA did not propose an exact labeling format for such products. The agency proposed in § 102.33(c) that if a diluted multiple-juice beverage or blend contains a represented juice and one or more that are not represented, i.e., not named or implied through words or vignettes other than in the ingredient statement, then the common or usual name for the product must state that the nonrepresented juices are present (e.g., "Raspcranberry: raspberry and cranberry juice in a blend of two other fruit juices").

45. Comments addressing the issue of which juices should be declared in the common or usual name when more than one juice is present in the product were markedly different. Some comments asserted that all juices (represented and nonrepresented) should be included in the common or usual name because consumers may be confused when the common or usual name reflects certain juices and the ingredient statement declares additional juices. One of these comments disagreed with FDA's proposed position that it was appropriate to exclude from the category of represented juices (and consequently from the requirement for declaration in the name) those juices whose presence in the product is disclosed only in the ingredient statement. The comment stated that the agency had offered no legal justification for this position. The comment provided no justification for its position that the presumption should be that juices declared only in the ingredient list are "represented."

Other comments stated that it would be unreasonably cumbersome for products that include many juices to list them all in the statement of identity. They said that the combination of a truthful, descriptive statement of identity, the ingredient list, the percentage total juice declaration and, optionally, a vignette would provide enough information about the juices present.

The first comments are not persuasive. The agency stated in the July 2, 1991, proposal that because all ingredients of a product must be declared in the ingredient statement, if the criteria for what is a "represented juice" included being listed anywhere on the label, all juices would be

considered to be represented (56 FR 30452 at 30456). FDA stated that it was more appropriate to exclude juices listed only in the ingredient statement from the category of represented juices, so that a distinction can be made between those juices represented as being present in the product, through word or vignette, and those not so represented. The comment did not provide any information that would justify different position.

The basis for the agency's position is provided by the basic principles for common or usual names in § 102.5. It is not necessary to list all juices in the name of a beverage to adequately describe the product. The basic nature of the product can be described in various ways, e.g., as a blend of five juices, with a declaration of the name of the juice or juices that provide the characterizing flavor, as long as it is clear from the name that other juices are present. Under sections 201(n) and 403(a) of the act, the name of the food must not omit any material facts. The names of all the juices in the five-juice beverage example, however, are not necessarily material facts in this context. Consequently, FDA concludes that its position that a juice whose presence in the product is disclosed only in the ingredient list of a beverage product is not a "represented" juice is appropriate and consistent with the act.

The agency also concludes that it is not necessary to require that each juice in a beverage be named to ensure that the label is not be misleading. As discussed in the response to comment 10 of this document and in response to subsequent comments, there are several ways in which a multiple-juice beverage can be appropriately labeled. For example, for a product containing apple, grape, raspberry, and cranberry juice, the names "Raspberry and cranberry flavored juice beverage in a blend of two other juices" or "Raspcranberry; Raspberry and cranberry juice beverage, 10 to 15 percent cranberry juice and 3 to 8 percent raspberry juice" would be acceptable under the act.

However, while FDA is not requiring that each juice in a beverage be declared in the name of the product, it encourages such declarations. They may provide useful information for the consumer provided that the declaration does not misrepresent the contribution of any individual juice to the product.

46. One comment suggested that for a multiple-juice beverage, the principal display panel should display by words, vignette, or other means each juice ingredient or the number of juices in the beverage. It stated that such a requirement would remove the need to

distinguish between represented and nonrepresented juices and would assure clarity and uniformity in labeling.

The agency agrees that such labeling would be informative and encourages manufacturers to identify on the principal display panel each juice ingredient or the number of juices in the beverage. FDA is not convinced that it is necessary or appropriate to limit label declarations for all multiple-juice beverages to those described in this comment because there are other ways to adequately name these beverages. The agency has provided in response to other comments in this document examples of other nonmisleading ways to name a multiple-juice beverage. Consequently, FDA is not adopting the requested requirement.

47. A number of comments objected to the requirement in proposed § 102.33(b) that each juice represented on the label be named in the statement of identity in descending order of predominance by volume. Some suggested that where all juices in a multiple-juice beverage are depicted in a vignette, naming all those juices in the common or usual name would not provide significant benefit to the consumers. They said that instead, naming all such represented juices would require excessive label space. A number of comments stated that in those instances where a blended juice product includes a juice that imparts the predominant flavor but that does not predominate by volume, the declaration of the name of the prominent or characterizing juice flavor should be made first, rather than being declared in order of predominance by volume, because the consumer needs to know the flavor to be expected in the product.

The agency has evaluated these comments and others discussed below and is revising the provisions of new § 102.33(b) so that it does not require declaration of all represented juices in the common or usual name of the beverage. Consistent with the approach discussed in response to comment 10 of this document, FDA concludes that while beverage labels are clearly misleading if they misrepresent the contribution of one or more individual juices to the nature of the product, not all multiple-juice beverage labels that bear representations of individual juices misrepresent their contribution to the total product. For example, a vignette that depicts all the fruits or vegetables in the product may not misrepresent the contribution of an individual juice to the nature of the product. Accordingly, the agency has revised new § 102.33(b) to clarify that all represented juices need not be named. In addition, FDA is

retaining the provision that juices that are declared in the name must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). The name of the characterizing juice may therefore be declared first although it is not the most predominant juice. However, as discussed below, this provision does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner. The agency believes that this revision of new § 102.33 along with the others discussed below are adequate to prevent misleading labels on multiple-juice beverages.

48. Several comments supported proposed § 102.33(c), which states that when the represented juice is not the only juice present, the common or usual name of a multiple-juice beverage should reflect that fact. No comments objected. The agency is therefore retaining this provision. However, given other changes in the final regulation, FDA has used a different example to illustrate the requirement, so that there will not be confusion as to the completeness of the name provided in the example.

49. One comment noted the requirement in § 101.22(15) that the term "flavor" or "flavored" accompany the name of certain foods containing added flavors. The comment requested that juice products labeled as "_____ flavor" be exempt from common or usual name requirements in proposed § 102.33. It requested clarification with respect to naming a diluted juice product containing three juices (cranberry, grape, and lemon) and a juice flavor (cranberry flavor). This comment stated that § 101.22(i)(1)(iii) requires such a product to be labeled as "cranberry flavor," however, the proposed regulations in § 102.33 require the statement: "in a blend of _____ other juices." The comment stated that requiring this statement is not reasonable, because the term "cranberry flavor" adequately informs the consumer in accordance with § 101.22, and the percent total juice and percent cranberry juice would be on the information panel.

The agency advises that an acceptable description of the product described in the comment would be "cranberry flavored juice in a blend of two other juices." Another adequately descriptive term would be "cranberry juice in a blend of two other juices, with added cranberry flavor." The agency has not specified the precise wording that must

be used as the name of such a beverage. However, both §§ 101.22 and 102.33 are intended to ensure that the label communicates essential information to consumers. These provisions are intended to provide manufacturers with flexibility for labeling products while providing consumers with information that they need to determine the nature of the product. The agency concludes, that both kinds of label information discussed here are essential to adequately describe the nature of the product. One type of information informs the consumer when flavoring substances have been added to the product. The other type describes other aspects of the basic nature of the product. Thus, FDA is not making the requested revision.

In addition, the suggestion in the comment included mandatory declaration of the percent of cranberry juice. In addition to percent of total juice. As discussed in comment 10 of this document, declaration of percentage of individual juices represented on the label is not required as a part of the juice content declaration under this final rule. Therefore, not all the label information discussed in the comments alternative approach will be required on the product.

50. Some comments that objected to mandatory declaration of the percentage of each individual juice represented on the label of a multiple-juice beverage suggested alternatives in the form of labeling schemes centered around the common or usual name of the product that they said would adequately describe multiple-juice beverages. These label schemes included statements of identity that: name the characterizing juice where needed to provide information on taste or flavor of the product; where appropriate, declare that the product was prepared from concentrate; and include terminology like "blended" or "blend of juices" to convey the multiplicity of juice ingredients. In addition, declaration of the presence of added flavors in accordance with § 101.22(i) would be required. The comments said that this information, together with the percentage of total juice and declaration in the ingredient list of all juices (or juice concentrates) in descending order of predominance by weight, would provide the consumer with sufficient information to make a product selection.

The agency agrees that the labeling schemes suggested by the comment would provide adequately descriptive labeling for some products and, as discussed in other comments, is requiring in the final regulation the declarations suggested. However, it does

not agree that this scheme would ensure that all multiple-juice beverages would bear labels that are not misleading.

As discussed above, FDA finds that it is not necessary that all multiple-juice beverages identify each represented juice in the name of the product and declare the percentage of each represented juice. The agency has given examples of label statements that would not be misleading. However, FDA is not persuaded that the recommended schemes would ensure the labeling of multiple-juice beverages in which the named juice is not the predominant juice would provide enough information to describe the product for the consumer. FDA agrees with those comments that expressed concern that consumers are being misled into believing that named juices are present in greater amounts than is actually the case. The agency is aware of a number of products currently on the market for which the suggested labeling would not inform the consumer that the named juice is present in only a minor amount.

The agency notes that the regulation on the general principles for common and usual names provides in § 102.5(1)(21 CFR 102.5(b)) that when the proportion of a characterizing ingredient in a food has a material bearing on price or consumer acceptance, or when the label or labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient is present in an amount greater than is actually the case, the percentage such characterizing ingredient shall be declared as part of the common or usual name of the food. This provision formed the basis for the requirement in the previous version of § 102.33 for declaration of percent of juice, both for total juice and for each individual juice represented on the label.

FDA agrees with comments that stated that declaration of the percentage of individual juices will provide informative labeling. While the agency has decided not to require percentage declaration of represented individual juices in all multiple-juice beverages, it concludes that for multiple-juice beverages that name one or more but not all of the juices present other than in the ingredient list, there is great potential for the label to misrepresent the contribution of the named juice to the product. When the named juice is the predominant juice in the product, FDA considers that the consumer will not be misled with regard to its contribution because naming it will not over emphasize its contribution. However, when the named juice is not the predominant juice, the consumer can be

misled. Therefore the final regulation, in § 102.33(d), requires that the common or usual name of the product specifically describe the contribution of the named juice if it is not the predominant juice. The agency has provided two ways for the common or usual name to include this information.

In § 102.33(d)(1), the agency has provided that manufacturers can use a product name that identifies the juice that provides the characterizing flavor and specifically shows that that juice is used to flavor the product (e.g., "raspberry flavored apple and pear juice drink" or "apple and pear juice drink flavored with raspberry juice"). The agency believes that using the term "flavor" with the name of the characterizing juice will inform the consumer that the juice is present in an amount sufficient to flavor the beverage but will not imply that the content of that juice is greater than is actually the case. This alternative is consistent with the agency's approach of not requiring percentage total juice declaration for bottled waters that contain juice for flavoring in small amounts (usually less than 2 percent) (see comment 4 of this document). Accordingly, FDA is providing in § 102.33(d)(1) that a multiple-juice beverage may use a product name that specifically shows that the named juice is used as a flavor.

Alternatively, consistent with § 102.5(b), the agency is providing in § 102.33(d)(2) for the declaration of the amount of the named juice in multiple-juice beverages that name one or more but not all of the juices in the product. As explained in the **Federal Register** of March 14, 1973 (38 FR 6964), the disclosure of the amount of a characterizing ingredient is a material fact.

Among the reasons given in comments that disagreed with the proposed requirement for declaration of percentage of individual juices was the need to have flexibility in the formulation of the beverage to accommodate variations in raw material juices and price changes. The comments included a report that documented that changes in formulation occur frequently and in a significant number of products. The agency is persuaded by the comments that an accommodation is warranted. It agrees that declaration of individual juice content in 1-percent increments is not practicable. Accordingly, FDA is providing in § 102.33(d)(2) that the juice content declaration of individual juices may be made using a 5 percent range, e.g., 2 to 7 percent raspberry juice or 5 to 10 percent cranberry juice. The agency considers that a 5 percent range is large

enough to provide for changes in formulation for juices that are present in small amounts.

Comments did not provide specific information on individual juice content, but it is reasonable to assume that a minor juice in a multiple-juice beverage would not be present at greater than about 25 percent of the total product. The 5 percent range is one-fifth of this amount. The agency concludes that a 5 percent range would provide this kind of flexibility to accommodate minor fluctuations in amounts of juice needed to compensate for differences in raw material. In addition, some comments contended that declaration of percent of individual juices in 1-percent increments constitutes an inappropriate disclosure of proprietary formulation information. The agency believes that declaration of individual juice content in 5 percent ranges would in any case not reveal the product formula. Finally, the 5 percent range declaration will provide enough information for consumers to be able to understand the contribution to the product made by the named juice and not be misled into believing that the juice is present in an amount greater than is actually the case.

Accordingly, FDA has provided these two labeling alternatives for multiple-juice beverages that name one or more but not all of the juices in the product in new § 102.33(d). In addition, the final regulation requires in new § 102.33(d) that the percent individual juice declaration be a part of the name of the product and meet the type size requirements in § 102.5(b)(2).

51. Several comments stated that juice beverages may be made from dehydrated as well as fresh fruits and vegetables in products such as vegetable cocktail, vegetable juice cocktail, juice cocktail, and bloody mary mix. One comment requested clarification that the names "vegetable juice cocktail," "vegetable cocktail juice," and "vegetable cocktail" can be used interchangeably on such products, when they are made from any combination of expressed juice, juice concentrate, and dehydrated fruits and vegetables.

The agency does not have information with which to determine whether beverages made from dehydrated fruits or vegetables differ from beverages made from concentrated or expressed juice. The agency welcomes any data or other information on the nature of beverages made from dehydrated fruits and vegetables, particularly on how they differ from beverages made from expressed or concentrated juice. The agency advises that it will evaluate the labels of such products on a case-by-case basis to determine whether the

labeling is misleading. However, FDA advises that irrespective of the form of the vegetable ingredients, the term "vegetable cocktail juice" may not be interchangeable with the other two terms. It uses the word "juice" without a term indicating dilution. Accordingly, it can be used only on beverages that are not diluted juice products. The terms "vegetable juice cocktail" and "vegetable cocktail" would apply to diluted vegetable juice beverages.

C. Vignettes

The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a label vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate.

52. Some comments, from both consumers groups and manufacturers, stated that vignettes should depict all juices in a product. Other comments stated that such a provision is not necessary because a descriptive name together with declaration of each juice by order of predominance in the ingredient list and the percent of total juice would provide enough information to ensure that the consumer is adequately informed.

The agency agrees that it is not always necessary that the label of a multiple-juice beverage depict each juice in a vignette. The agency believes that a vignette that pictures only some of the fruit or vegetables in the beverage would not be misleading where the name of the food adequately and appropriately describes the contribution of the pictured juice. For example, for a 100 percent juice product consisting of apple, grape, and raspberry juices, in which the raspberry juice provides the characterizing flavor, a vignette depicting raspberries would not necessarily be misleading if the statement of identity were "raspberry juice in a blend of apple and grape juice." Similarly, the vignette would not be misleading if the beverage were named "raspberry flavored fruit juice blend" or "raspberry juice in a blend of two other juices, 3 to 8 percent raspberry juice." Moreover, if these three juices were in a beverage containing 50 percent total juice, a vignette picturing raspberries would not be misleading in the presence of a name like "raspberry flavored juice beverage."

Accordingly, FDA is not requiring that vignettes depict the fruits or vegetables for all juices present. However, FDA believes that a vignette that pictures the fruit or vegetable

sources of all juices present in a product would provide useful information and thus encourages manufacturers to use such vignettes.

Conversely, vegetables or fruits not present in the beverage cannot be depicted in vignettes or other pictorial representations on the label. The agency considers that depicting a fruit or vegetable in a vignette on a juice beverage implies that the fruit or vegetable is in the product, either in the form of a juice or of a natural or artificial flavor of the depicted fruit or vegetable. A vignette that pictures a fruit or vegetable that is not present in the product results in a label that is false and misleading and therefore in violation of section 403(a) of the act.

53. Some comments that wanted all fruits and vegetables pictured in the vignette also requested that the fruits and vegetables be depicted in proportion to the amount of each juice present. However, most comments requested that the agency not impose a specific requirement regarding the relative amounts of the various fruits or vegetables because the relative size and shape of various fruits and vegetables make it difficult to portray by vignette. They stated that both the relative size and the quantity of those fruits and vegetables are difficult to represent in a manner that would allow the consumer to readily recognize the quantity relationship.

The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate. While information in comments emphasized the difficulties in displaying fruits and vegetables quantitatively, there was no information on how useful quantitative displays could be devised. The agency, therefore, is not requiring that fruits and vegetables pictured in vignettes be depicted in proportion to the amount of each juice present.

54. Several comments requested that the agency not make specific requirements regarding flavor characterizations in vignettes. They stated that the taste of a product is best communicated to the consumer through means other than the label vignette alone, and that any requirement should rely on wording to describe product flavor, e.g., "raspberry (flavor) in a blend of _____ other juices."

The agency agrees with the comments that vignettes alone should not be required to communicate the flavor

characteristics of the beverage and is not establishing such requirements. It also agrees that more explicit information is provided by the wording on the label, especially in the statement of identity of the product. However, FDA advises that in order for a beverage label to not be misleading, it is necessary that the vignette and other label statements on the beverage not conflict in any way. The agency has discussed above the circumstances under which the name of the beverage may be misleading. It will determine on a case-by-case basis whether a vignette is misleading because it is not consistent with other label information or for other reasons.

D. Modified Juices

In the July 2, 1991, proposal, the agency stated that the consumer must not be misled as to the nature of the juices used to make a juice or diluted juice beverage (56 FR 30452 at 30461). FDA stated that the appropriate common or usual name for a modified juice or a beverage containing a modified juice should be determined by the nature and extent of modification. For example, the appropriate common or usual name for frozen orange juice concentrate in which the acid content is reduced is "reduced acid frozen concentrated orange juice" (21 CFR 146.148).

However, FDA also acknowledged that beverages may contain modified juices that are markedly altered and added to beverages to increase the declared juice content but are actually "stripped" juices, i.e., juice derived, rather than sugar derived, sweetening ingredients, e.g., deflavored, decolorized white grape juice.

The agency proposed in § 102.33(d) (redesignated as new § 102.33(e)) to permit a juice that has been modified to be referred to by a common or usual name that includes the word "juice" so long as the exact nature of the modification is specified in the common or usual name. The description of the modification would therefore appear as part of the name wherever it is used.

Further, the agency proposed that a product would be misbranded if a label vignette depicts the source fruit or vegetable of a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable, or if its nutrient profile has been diminished.

55. One comment suggested three classifications for juice as the basis for developing labeling policy for modified juices:

First, minor modifications that do not alter the basic characteristics of the juice outside the normal range for that juice.

Secondly, more significant modifications that alter one or more basic characteristic of the juice but not to the extent that the juice would not still be acceptable if offered as a single juice product. The comment stated that such products would require a descriptive term as part of the product name to indicate the nature of the change but could still be identified as "juice."

Thirdly, products that have undergone major modifications that remove virtually all significant nutrients, resulting essentially in a sugar water product. The comment stated that while such products are acceptable as sweeteners, they should not be identified as juice or counted toward the juice content declaration.

The agency agrees that modified juices could be considered in three categories. It used a similar approach in the July 2, 1991, proposal (56 FR 30452 at 30460). The comment's first category is essentially the group of products that have undergone modifications so minor as to be within the normal range of properties of the original juice. These products do not require a modification of the name "_____ juice," where the blank is filled with the name of the source fruit or vegetable.

The second category is illustrated in the July 2, 1991, proposal using "reduced acid frozen concentrated orange juice" and "acid-reduced pineapple juice" (56 FR 30452 at 30461). These products would require a name that describes the modification (§ 102.33(e)) but would not be prohibited under new § 101.30(k) from being included in the calculation of total juice percentage.

The third category described in the comment is clearly within the description in proposed § 102.33(e) (redesignated as new § 102.33(f)) and requires a name that fully describes the major modification. In suggesting that these products not be identified as "juice," the comment would prohibit the use of the word "juice" in the name of these modified juices. As discussed in the July 2, 1991, proposal and in response to comment 56 of this document, which follows. FDA disagrees and concludes that a name that fully describes the modifications made in the juice may include the word "juice" and its source.

56. A number of comments disagreed with the proposed provisions for naming juices that had undergone major modifications. They referred to these products as "stripped juices" and

"sugar water." They stated that the term "juice" should not be included in the name of such modified products. Some comments suggested alternative names such as "grape syrup," "apple syrup," or a similar term.

The agency proposed in § 102.33(d) (redesignated as new § 102.33(e)) that the common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "deflavored, decolorized grape juice"). The agency believes that there is enough information in the description of the modification that consumers will be able to recognize the ingredient as different from the original juice.

Further, since juices with major modifications may not be included in the total percentage juice declaration, and the source fruit or vegetable from which the modified juice was derived may not be depicted on the label or other pictorial representation, consumers should not be misled by inclusion of the word "juice" in the name of juices in the ingredient list. Therefore, the agency is not granting the comments' request.

In addition, the suggestions for alternative names covered only some of the products in the category of juices that have undergone significant modifications. For example, other comments (comments 20 and 41 of this document) addressed juices from which the sugars had been removed. As discussed in response to those comments "reduced sugar—juice" may be an appropriately descriptive term for such a product with the name of the alternative sweetening ingredient appropriately declared.

Comments that addressed the issue supported the provision in proposed § 102.33(e) (redesignated as new § 102.33(f)) that the fruit or vegetable source of a modified juice may not be depicted on the label by vignette or other pictorial representation.

Accordingly, FDA concludes that except for conforming the wording of § 102.33(f) to reflect the decision made with respect to modified juices in comment 39 of this document, the provision should be retained. The agency wishes to clarify that the provision addresses juice products that have undergone major modification and as a result are no longer recognizable at the time processing is complete, or whose nutrient profile has been diminished to a level below the normal nutrient range for the juice. The prohibition against depicting the fruit or vegetable on the label does not apply to juices that have been slightly modified but that still retain the basic properties

of the original juice, e.g., acid-reduced grape juice.

IV. Other Issues

57. One comment stated that where a beverage is prepared from one or more juice concentrates this fact should be declared as part of the common or usual name.

The agency agrees. FDA's longstanding policy with regard to juice beverages made from concentrate is that a term such as "from concentrate" or "reconstituted" must be a part of the name of the juice, in letters not less than one-half the height of the letters in the name of the juice, e.g., lemon juice (§ 146.114) and orange juice from concentrate (§ 146.145). Accordingly, FDA has added as § 102.33(g) a requirement that when one or more of the juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such term may either be included in the name of each individual juice where appropriate, or it may be stated once adjacent to the product name so that it applies to all the juices (e.g., "cherry juice (from concentrate) in a blend of 2 other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in type size no less than one-half the height of the letters in the name of the fruit or vegetable juice. This type size requirement is consistent with similar provisions in existing regulations (e.g., §§146.114 and 146.145).

58. One comment pointed out that under § 101.22(i)(1)(iii) in the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors. It requested that § 102.33(b) be amended to clarify this.

The agency agrees that the requested clarification may be helpful to readers of the regulation and is revising § 102.33(b) accordingly. Because the provision is already a part of FDA's food labeling regulations, this amendment is not substantive. It simply conforms §102.33(b) to §101.22(i)(1)(iii).

59. Comments supported the proposal to revoke the common or usual name regulations for noncarbonated beverage products that contain no fruit or vegetable juice (§ 102.30) and for diluted orange juice beverages (§ 102.32). They agreed with FDA's position that because these products would be covered under new §101.30 and the revised § 102.33, the separate regulations are no longer

needed. Accordingly, as proposed, FDA is revoking these two regulations.

V. Effective Date

FDA proposed to make the percent juice labeling regulations effective on the same date as the mandatory nutrition labeling final rule (i.e., May 8, 1993). However, the agency pointed out that the 1990 amendments state in section 10(c) of the 1990 amendments that percent juice labeling was to take effect 1 year after enactment. Thus, on November 8, 1991, the statutory provision for percent juice declaration was to go into effect.

In response to the July 2, 1991, proposal many comments from the food industry strongly urged FDA to reconsider the effective date for percent juice labeling regulations. The comments argued that a November 8, 1991, effective date would not allow the food industry enough time to develop the required labeling and would significantly increase costs because present inventory would have to be discarded. The comments strongly urged FDA to establish a uniform effective date for the requirement for percent juice declaration with section 403(q) of the act (mandatory nutrition labeling) and section 403(r) of the act (health and nutrient content claims), which were added to the act by the 1990 amendments. Although FDA agreed with these comments, it had no authority to provide the requested exemptions or extend the effective date.

A technical amendment (Pub. L. 102-108) was enacted on August 17, 1991, in which Congress amended the 1990 amendments to delay the effective date of the percent juice labeling requirements. Notice of this change in the effective date was given in the **Federal Register** of November 27, 1991 (56 PR 60877). Under this amendment the new percent juice labeling requirements for fruit and vegetable juice beverages apply to labels attached to these products after May 8, 1993.

60. Many comments responding to this proposal objected to the proposed effective date of November 8, 1991, for compliance with the requirements of the percentage juice declaration provisions because of the cost and time involved in making the necessary labeling changes. The agency also received a comment requesting a temporary exemption from the May 8, 1993, statutory effective date established by the technical amendment. The comment requested that the requirement for percentage juice declaration on the labels of beverages purporting to contain juice be implemented concurrently with any later applicability date that the agency

may prescribe for the nutrition labeling regulations pursuant to section 10(a)(3)(B) of the 1990 amendments. The comment suggested that the effective date for the percent juice declaration be delayed until May 8, 1994, on the basis of the provision section 403(i) of the act which states that: " * * * to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary." The comment cited case law and previous FDA policy as precedent for the requested temporary exemption.

The agency is not persuaded by the arguments and assertions presented in the request for a temporary exemption from the statutory compliance date of May 8, 1993, for the requirement of percentage juice declaration. The agency acknowledges that section 403(i) of the act provides authority for exemption, and some such exemptions have been temporary. However, in light of the specific date (May 8, 1993) established by the technical amendment, and the failure of Congress to include provisions for a delay of the application of this provision, in contrast to the provision that it made for such a delay for the nutrition labeling and nutrient content claims provisions in the 1990 amendments, and without any indication in the legislative history that Congress wished to delay any longer the implementation of percentage juice declaration on beverages purporting to contain juice, the agency finds that a temporary exemption based on section 403(i) of the act is not sustainable. Therefore, the agency is not granting a temporary exemption from compliance with the percent juice declaration requirements or extending the effective date until May 8, 1994. However, because the amendments to part 102 are not directly responsive to section 7 of the 1990 amendments, and in order to minimize costs, FDA is making the amendments to part 102 effective on May 8, 1994.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the \$100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs

and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857 and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in July 2, 1991, proposal, the agency determined that under 21 CFR 25.24(a)(11), that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required. No new information or comments have been received that would effect the agency's previous determination.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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4. Snyder, Carl S., and Lester D. Hammond, "Weights per U.S. Gallons and Weights per Cubic Foot of Sugar Solution," National Bureau of Standards, Circular 457, Table 1, pp. 3-26, 1946

5. USDA Handbook 8-9: Composition of Foods: Fruits and Fruit Products, Raw, Processed Prepared, Rev. August, 1982.

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14. Frederick E. Boland, Victor H. Blomquist, and Ben Estrin, "Chemical Composition of Fruits," *Journal of the Association of Official Analytical Chemists*, vol. 51, No. 6, pp. 1203-1205, 1968.

15. Monzini, A. and E. Maltini, "Production of Juice Powders without Additives by Vacuum Belt Drying," *Flussiges Obst*, vol. 57, No. 2, pp. 89-90, 1990.

16. Food and Drug Administration, State Cooperation Information Letter No. 48, June 26, 1950. Stutsman, Martin J., letter to City of Los Angeles Department of Aging, April 18, 1989. Scheineson, Marc J., letter to Bob Graham, United States Senator, May 14, 1992.

List of Subjects

21 CFR Part 101

Food Labeling, Reporting and recordkeeping requirements.