No. 12-761

# In the Supreme Court of the United States

POM WONDERFUL LLC, PETITIONER

*v.*

THE COCA-COLA COMPANY

*ON WRIT OF CERTIORARI*
*TO THE UNITED STATES COURT OF APPEALS*
*FOR THE NINTH CIRCUIT*

**BRIEF FOR THE UNITED STATES**
**AS AMICUS CURIAE SUPPORTING NEITHER PARTY**


DONALD B. VERRILLI, JR.
*Solicitor General*
*Counsel of Record*
STUART F. DELERY
*Assistant Attorney General*
EDWIN S. KNEEDLER
*Deputy Solicitor General*
MELISSA ARBUS SHERRY
*Assistant to the Solicitor General*
MARK B. STERN
SUSHMA SONI
*Attorneys*

*Department of Justice*
*Washington, D.C. 20530-0001*
*SupremeCtBriefs@usdoj.gov*
*(202) 514-2217*

WILLIAM B. SCHULTZ
*General Counsel*
ELIZABETH H. DICKINSON
*Chief Counsel, Food and Drug Division*
ANNAMARIE KEMPIC
*Deputy Chief Counsel for Litigation*
JULIE DOHM
*Associate Chief Counsel*
*Department of Health and Human Services*
*Washington, D.C. 20201*

## QUESTION PRESENTED

Whether and to what extent the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and regulations promulgated under that Act, preclude a food manufacturer from challenging the label of its competitor's product under Section 43(a) of the Trademark (Lanham) Act of 1946, 15 U.S.C. 1125(a), which provides a cause of action against anyone who, *inter alia*, "uses in commerce any word, term, name, symbol, or device, or any combination thereof * * * which * * * misrepresents the nature, characteristics, [or] qualities * * * of his * * * goods." 15 U.S.C. 1125(a)(1) and (B).

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## INTEREST OF THE UNITED STATES

This case concerns whether and to what extent the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and regulations promulgated thereunder, preclude a food manufacturer from challenging the label of its competitor's product under Section 43(a) of the Trademark Act of 1946 (Lanham Act), 15 U.S.C. 1125(a). By virtue of the regulatory and enforcement responsibilities of the Food and Drug Administration (FDA), and shared enforcement authority of the Federal Trade Commission (FTC), the United States has a substantial interest in that issue. At the Court's invitation, the Solicitor General filed an amicus brief on behalf of the United States at the petition stage of this case.

## STATEMENT

1. a. "Congress has regulated food and beverage labeling for more than 100 years." *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331 (3d Cir. 2009). It did so first in the Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, then in the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040 (21 U.S.C. 301 *et seq.*), and later through amendments to the FDCA. In 1990, Congress amended the FDCA to address nutrition labeling for nearly all food products for human consumption, including juices. Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353. Throughout those efforts, "[m]isbranding was one of the chief evils Congress sought to stop." *62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951).

The FDCA bans the introduction into or receipt in interstate commerce of "misbranded" foods. 21 U.S.C. 331(a) and (c). "Food" includes any "article[] used for food or drink for man." 21 U.S.C. 321(f). Of relevance here, a food is misbranded if "its labeling is false or misleading in any particular," 21 U.S.C. 343(a)(1); if required information is not sufficiently prominent and conspicuous on the label or labeling, 21 U.S.C. 343(f); or if its label fails to bear "the common or usual name of the food, if any there be, and * * * in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient," 21 U.S.C. 343(i)(1) and (2).[1]

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[1] The FTC shares with FDA enforcement authority over deceptive food labeling, advertising, and promotion. See 15 U.S.C. 45(a)(2), 52(a); 36 Fed. Reg. 18,539 (Sept. 16, 1971) (memorandum of understanding). Although the parties do not contend that the FTC's enforcement authority bears on the viability of petitioner's claim,

To implement those provisions, and to "promote honesty and fair dealing in the interest of consumers," 21 U.S.C. 341, FDA has regulated many aspects of the naming and labeling of juices and juice beverages. See, *e.g.*, 58 Fed. Reg. 2897-2926 (Jan. 6, 1993) (removing and promulgating scattered Sections of 21 C.F.R. Pts. 101, 102).[2] Particularly relevant here are provisions of 21 C.F.R. 102.33 that govern the "common or usual name" for multiple-juice beverages:[3]

- Under Section 102.33(b), juices identified by name on the label (other than in the ingredient statement)—"named juices" for short—"must be [named] in descending order of predominance by volume unless the name specifically shows that [a nonpredominant] juice [supplying a] represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink)."
- Under Section 102.33(c), if a named juice is not the only juice present, "then the common or usual

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the breadth of the court of appeals' reasoning could intrude on that authority.

[2] Although FDA's juice-labeling regulations also implemented certain provisions of the NLEA, including one specific to juice labeling, those provisions are not directly at issue here. See NLEA § 7(2), 104 Stat. 2364 (21 U.S.C. 343(i)(2)) (declaring beverage containing fruit juice misbranded if it does not contain "a statement with appropriate prominence on the information panel of the total percentage of such fruit * * * juice contained in the food"); 58 Fed. Reg. at 2899-2901 (interpreting that provision as requiring disclosure of the total percentage of juice in the product); 21 C.F.R. 101.30.

[3] The "common or usual name of a food may be established by," *inter alia*, "common usage or by establishment of a regulation in subpart B of [Part 102]." 21 C.F.R. 102.5(d); see 21 C.F.R. 101.3(b) and (e)(3).

> name for the product shall indicate that the [named] juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')."

- Under Section 102.33(d), if a named juice is not the only juice present and is not the predominant juice, then the "common or usual name for the product shall" either (1) "[i]ndicate that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)" or (2) "[i]nclude the amount of the named juice, declared in a 5- percent range * * * in the manner set forth in [Section] 102.5(b)(2)."

The foregoing requirements are not privately enforceable. See 21 U.S.C. 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States."); *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). In addition, in a provision added by the NLEA, the FDCA expressly preempts any State from "directly or indirectly" establishing any requirement "that is not identical" to, *inter alia*, certain food-misbranding provisions that include 21 U.S.C. 343(f), (i)(1) and (2), but not 21 U.S.C. 343(a). See 21 U.S.C. 343-1(a). The FDCA does not expressly address its relationship to other federal laws.

b. The Lanham Act amended existing trademark law to make "actionable the deceptive and misleading use of marks" in interstate commerce, to "protect persons engaged in such commerce against unfair competition," and to "provide rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the

United States and foreign nations." 15 U.S.C. 1127. As amended, Section 43(a) of the Lanham Act creates a private civil action against

> [a]ny person who, on or in connection with * * * any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof * * * which * * * misrepresents the nature, characteristics, [or] qualities * * * of his * * * goods.

15 U.S.C. 1125(a)(1) and (B). Such an action may be brought "by any person who believes that he or she is or is likely to be damaged by such act." 15 U.S.C. 1125(a)(1).

2. Petitioner "produces, markets and sells bottled pomegranate juice and pomegranate juice blends, including a pomegranate blueberry juice blend." Pet. App. 1a. Respondent, doing business "under the brand Minute Maid, is one of [petitioner's] primary competitors in the bottled pomegranate juice market." *Id.* at 84a. In 2007, respondent announced a new product consisting of "99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice." *Id.* at 1a-2a. The product's front label displays a graphic vignette depicting grapes, blueberries, and raspberries in front of a halved pomegranate and halved apple. Below the vignette appear the words "Pomegranate Blueberry" in the same type but on separate lines; below "Blueberry," in smaller type, are the words "Flavored Blend Of 5 Juices"; below that, in still smaller type and separated by a blank line, are the words "From Concentrate With Added Ingredients"; and, finally, below those words in the same type are the further words "And Other Natural Flavors." See *id.* at 2a (reproducing label); Pet. Br. 9 (same).

3. In 2008, petitioner sued respondent under Section 43(a) of the Lanham Act.[4] Pet. App. 3a. Petitioner challenged the name, label, marketing, and advertising of respondent's juice, alleging that they mislead consumers to believe that respondent's juice consists predominantly of pomegranate and blueberry juices when it in fact consists predominantly of less expensive apple and grape juices, thereby injuring petitioner as a competitor. *Id.* at 84a-85a. Petitioner described respondent's juice label as containing "many misleading elements not required by federal or state regulation." J.A. 61a. And petitioner sought damages, recovery of respondent's profits, and an injunction barring further false advertising of respondent's juice. J.A. 64a-65a, 68a-69a.

The district court granted partial summary judgment to respondent on the Lanham Act challenges relating to the juice's name and label, finding those claims precluded. Pet. App. 21a-73a.[5] The court believed that "FDA has directly spoken on the issues that form the basis of" petitioner's claim in 21 C.F.R. 102.33(c) and (d), and that the juice's name is "expressly permitted (required here) by the FDA." Pet. App. 65a. The court further noted that 21 U.S.C. 343(f) requires only that respondent "prominently place the label on the Juice's bottle," which respondent "does sufficiently," Pet. App. 63a-64a; that petitioner failed to identify any regulation providing that

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[4] Petitioner also brought claims under various California laws. The district court found those claims expressly preempted. No. 08-cv-6237, 2013 WL 543361 (C.D. Cal. Feb. 13, 2013). Petitioner appealed, No. 13-55770 (9th Cir.), and those proceedings have been stayed pending resolution of this case.

[5] Petitioner later stipulated to dismissal of the advertising and marketing claims, Pet. App. 17a-19a, and subsequent proceedings have been limited to material on the juice's label.

the name "must appear on one single line, must be in one font, or must be centrally located" on the bottle, *id.* at 63a; and that the fruit vignette on respondent's label is "within the FDA's purview" and "clearly complies with FDA requirements," *id.* at 65a-67a.

4. The court of appeals affirmed in relevant part. Pet. App. 1a-14a. It began by describing the FDCA as "comprehensively regulat[ing] food and beverage labeling." *Id.* at 6a. Next, acknowledging that "the Lanham Act and the FDCA can conflict with each other" but should each be given "as much effect * * * as possible," the court identified several scenarios in which, in its view, "the FDCA limits claims under the Lanham Act." *Id.* at 6a-7a (internal quotation marks and citation omitted). "A plaintiff may not, for example, sue under the Lanham Act to enforce the FDCA or its regulations," or "maintain a Lanham Act claim that would require a court originally to interpret ambiguous FDA regulations," or pursue a Lanham Act "claim [that] would require litigating whether [certain] conduct violates the FDCA." *Id.* at 7a (citing cases illustrating those principles). On the whole, the court concluded that "the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority," but that a court must still "focus on the circumstances before it to strike a balance that disrupts the two statutory schemes as little as it can." *Id.* at 8a.

Applying those principles, the court of appeals concluded that "the FDCA and its regulations bar pursuit of both the name and labeling aspects of [petitioner's] Lanham Act claim." Pet. App. 9a. The court explained that, because 21 C.F.R. 102.33(d) permits a manufacturer to name a beverage using the name of a flavoring juice that is not predominant, "as best we can tell, FDA regulations authorize the name [respondent] has chosen." Pet.

App. 9a. Thus, the court reasoned, petitioner's challenge to the name "'Pomegranate Blueberry Flavored Blend of 5 Juices' would create a conflict with FDA regulations and would require [the court] to undermine the FDA's apparent determination that so naming the product is not misleading." *Ibid.*

The court of appeals likewise concluded that petitioner's Lanham Act claim was precluded with respect to the label's presentation of the words "Pomegranate Blueberry" in "larger, more conspicuous type" than the words "Flavored Blend of 5 Juices" appearing below them. Pet. App. 10a. The court believed that the FDCA and FDA regulations "have specified how prominently and conspicuously those words and statements must appear." *Ibid.* (citing 21 U.S.C. 343(f) and (i); 21 C.F.R. 102.33(c) and (d)). "Congress and the FDA have thus considered and spoken to what content a label must bear, and the relative sizes in which the label must bear it, so as not to deceive," but "ha[ve] not (so far as we can tell) required that all words in a juice blend's name appear on the label in the same size." *Ibid.* The court observed that "[i]f the FDA believes more should be done to prevent deception, or that [respondent's] label misleads consumers, it can act." *Id.* at 11a.

The court of appeals emphasized that it was not "hold[ing] that [respondent's] label is non-deceptive," or that "mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability." Pet. App. 11a-12a. Rather, the court stated that it was guided by what it understood to be "Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* at 12a. "In the circumstances here," the court concluded,

"the appropriate forum for [petitioner's] complaints is the [FDA]." *Ibid.* (citation omitted) (second set of brackets in original).

## SUMMARY OF ARGUMENT

Petitioner's Lanham Act claim is barred only to the extent the FDCA or FDA regulations specifically require or authorize the challenged aspects of respondent's juice label. Because the court of appeals dismissed petitioner's claim in its entirety based on an overly broad view of preclusion, the decision below should be vacated and the case remanded for further proceedings.

A. FDA regulations specifically permit respondent to name its juice "Pomegranate Blueberry Flavored Blend Of 5 Juices," if pomegranate and blueberry juices are present as flavors or flavoring. Those regulations were adopted to address possible consumer confusion regarding the content of multiple-juice beverages, and the naming conventions FDA adopted were based on its considered determination that compliant names would not be misleading. To allow a Lanham Act challenge to a name that complies with those regulations would directly contravene FDA's judgment by declaring misleading what FDA determined to be nonmisleading.

It is true that the FDCA and its implementing regulations did not *require* respondent to name its juice "Pomegranate Blueberry," but impossibility is not the proper standard for finding preclusion here. FDA promulgated specific juice-naming regulations, pursuant to food-labeling provisions of the FDCA which predate the general private-right-of-action afforded under the Lanham Act. The naming regulations reflect the agency's balance of competing considerations, which could be easily upset by intrusion of a general private remedy.

Petitioner's suggestion that the name of respondent's juice may not, in fact, comply with FDA regulations rests in part on a misunderstanding of the governing regulations, and lacks support in the existing record. The lower courts should consider any unresolved factual questions in the first instance.

B. Petitioner's Lanham Act claim is not limited to the name of respondent's juice, and it should be allowed to proceed insofar as it challenges features of the juice's label not specifically required or authorized by the FDCA or FDA regulations.

The court of appeals erroneously found petitioner's entire Lanham Act claim barred based on a kind of "field" preclusion. An agency's mere authority to regulate in an area and its exercise of that authority to some extent are insufficient to impliedly preempt state law, let alone to bar an otherwise available federal remedy. Neither the FDCA nor FDA regulations purport to occupy the field of juice labeling. To the contrary, the carefully calibrated express preemption provision added to the FDCA by the NLEA in 1990, and FDA's regulatory approach, support a more nuanced inquiry.

Nor is categorical preclusion warranted to prevent courts from interpreting the FDCA or FDA regulations, to protect against "backdoor" private FDCA enforcement actions, or to preserve FDA's regulatory authority. Courts are called upon to interpret FDA regulations in various contexts. And the absence of a specific FDA regulation or enforcement action is neither indicative of a preference for no regulation nor a sign of tacit approval.

The courts below did not identify any statutory or regulatory provision specifically authorizing the other challenged features of respondent's juice label. Re-

spondent now points to 21 C.F.R. 101.22(i)(1)(i) as allowing the type-size on its label, but that reliance is misplaced. In any event, that provision would (at best) authorize a particular type-size for the word "flavored"; it would have no impact on the remainder of petitioner's labeling claim.

## ARGUMENT

### PETITIONER'S LANHAM ACT CLAIM IS PRECLUDED ONLY TO THE EXTENT THE FDCA OR FDA REGULATIONS SPECIFICALLY REQUIRE OR AUTHORIZE THE CHALLENGED ASPECTS OF RESPONDENT'S JUICE LABEL

This case concerns the interplay of two federal statutes that prohibit false or misleading statements in food labeling. "[W]hen two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-144 (2001) (*J.E.M.*) (citation omitted). Although Section 43(a) of the Lanham Act and the FDCA overlap, in that each applies to the label of respondent's juice, they are generally capable of coexistence, *except* when a Lanham Act claim would prohibit what the FDCA or FDA regulations specifically require or permit. That approach gives maximum effect and respect to each statute.

The alternative approach to preclusion adopted by the court of appeals is too broad, and the approach advocated by petitioner is too narrow. On the one hand, FDA's authority to regulate juice labeling and its exercise of that rulemaking authority does not purport to occupy the field, and Lanham Act claims may often reinforce (not subvert) congressional and agency objectives. On the other, a Lanham Act claim that effectively challenges FDA regulations premised on a determination that cer-

tain information on a juice label would not be misleading would trench upon FDA's regulatory authority in a way that Congress did not intend.

Applying those principles, petitioner's challenge to the name of respondent's juice ("Pomegranate Blueberry Flavored Blend Of 5 Juices") is precluded if the named juices are present as flavors or flavoring. In those circumstances, FDA regulations specifically authorize respondent to choose that name, based on the determination that it would *not* be misleading to do so, and petitioner cannot now collaterally attack that determination in a Lanham Act suit contending that it *is* misleading. But petitioner's challenge to the presentation of the juice's name on the label (as opposed to what the name *is*) and to other aspects of the label that neither the FDCA nor FDA regulations specifically address should not be precluded.

### A. Petitioner's Lanham Act Challenge To The Name Of Respondent's Juice Is Precluded If The Named Juices Are Present As Flavors Or Flavoring

An FDA regulation (21 C.F.R. 102.33) specifically permits respondent to name its juice "Pomegranate Blueberry Flavored Blend Of 5 Juices," if pomegranate and blueberry juices flavor the beverage. That regulation was adopted to address the potential for consumer confusion regarding the individual-juice content of multiple-juice beverages. The naming conventions FDA adopted were based on its considered judgment that compliant names would not themselves be misleading. A Lanham Act challenge to a name that complies with FDA's juice-naming regulation is precluded because it would directly contravene FDA's judgment by declaring misleading what that expert agency expressly found nonmisleading.

***1. FDA regulations specifically permit a juice's name to include only juices present as flavors without declaring the percentage of named juices***

Petitioner's name-based challenge rests on the undisputed fact that the predominant (and cheaper) juices in respondent's product are apple and grape and that (the more expensive) pomegranate and blueberry juices represent a collective 0.5% of that product. Pet. App. 1a-2a. Petitioner thus suggests that calling the juice "Pomegranate Blueberry" is misleading and that, perhaps, a more accurate name would be "Apple Grape." J.A. 61a; see J.A. 62a ("By name alone, one would expect that the primary ingredients * * * are pomegranate and blueberry juice."). In promulgating regulations, FDA considered that question and reached a different conclusion.

In 1993, FDA promulgated a regulation establishing a "common or usual name" for multiple-juice beverages. See 58 Fed. Reg. 2918-2923 (Jan. 6, 1993). That regulation (21 C.F.R. 102.33) makes three things clear. First, the name does not have to include all juices contained in the product, so long as it "indicate[s] that the represented juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')." 21 C.F.R. 102.33(c). Second, the name does not have to include the predominant juices, so long as *either* (1) the name indicates that the nonpredominant juice "is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)," *or* (2) the amount of the nonpredominant juice is declared "in a 5- percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice) * * * in the manner set forth in [Section] 102.5(b)(2)." 21 C.F.R.

102.33(d)(1)-(2). Third, and relatedly, the name does not have to include the percentage of the named juice contained in the product, so long as the named juice is "present as a flavor" and is designated as such. 21 C.F.R. 102.33(d)(1).

The name "Pomegranate Blueberry Flavored Blend Of 5 Juices" appears to be consistent with that regulation. Cf. pp. 22-23, *infra* (noting potential factual dispute). The name indicates that pomegranate and blueberry are not the only juices present (*i.e.*, "Blend Of 5 Juices") and that the named juices are present only as flavors or flavoring (*i.e.*, "Pomegranate Blueberry Flavored"). Indeed, the name of respondent's juice closely parallels examples that FDA offered as permissible common or usual names for juice mixtures. See 21 C.F.R. 102.33(c) ("apple juice in a blend of two other fruit juices"); 21 C.F.R. 102.33(d)(1) ("raspberry and cranberry flavored juice drink"); see also FDA, *A Food Labeling Guide* 9 (Jan. 2013) (*FDA Guide*), http:// www.fda.gov/downloads/Food/Guidance Regulation/UCM265446.pdf (same example for "beverage that is primarily white grape juice with raspberry and cranberry juices added"); *id.* at 11 ("cranberry-raspberry flavored juice drink in a blend of three other juices"); *id.* at 12 ("raspberry flavored fruit juice blend").

The juice-naming regulation was adopted after a lengthy rulemaking process. 56 Fed. Reg. 30,452 (July 2, 1991) (detailing 25-year history of juice-labeling regulations); see 58 Fed. Reg. at 2897 (agency received over 200 comments from, *inter alia*, consumers and consumer groups). The rulemaking focused on how to name multiple-juice beverages that contain minor amounts of "characterizing juice"—specifically, how to do so in a manner that would "accurately represent the contents of

the product while not providing misleading information to the consumer." 55 Fed. Reg. 3268 (Jan. 31, 1990); see 56 Fed. Reg. at 30,452, 30,455. And the agency homed in on the precise concern that petitioner raises here. See *id.* at 30,455 (acknowledging that "[m]any multiple-juice beverages * * * contain only a small amount of a highly flavored, expensive juice," and that the name of the product "[o]ften" suggests "that the expensive juice * * * is present in a substantial quantity, and that, therefore, the beverage is of good value, when in fact there is only a small amount of the juice present"); 58 Fed. Reg. at 2920 (noting agency's "aware[ness] 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"); *id.* at 2920-2921 (recognizing that consumers can "be misled" when "the named juice is not the predominant juice"); see also 56 Fed. Reg. at 30,461, 30,462.

Alternatives were considered. See 45 Fed. Reg. 39,249-39,250 (June 10, 1980) (adopting final rule, never put into effect, requiring percentage declaration of each named juice in certain multiple-juice beverages)[6]; 49 Fed. Reg. 22,831-22,833 (June 1, 1984) (proposal to make individual-juice percentage declarations voluntary); 52 Fed. Reg. 26,691 (July 16, 1987) (proposal to make all percentage declarations voluntary); 55 Fed. Reg. at 3268 (listing several different approaches); 56 Fed. Reg. at 30,462 (commenter suggesting that consumers were mostly concerned with taste and that juices should be listed in order of flavor, not volume). And the proposed rule that preceded the 1993 regulation would have required a percentage declaration of every juice repre-

[6] The effective date of that final rule was repeatedly delayed, and it never went into effect. See 56 Fed. Reg. at 30,452.

sented on the label (other than in the ingredient statement). 56 Fed. Reg. at 30,456, 30,465. But FDA ultimately rejected those approaches.

Instead, FDA provided "two alternative[]" ways to describe "the contribution of the named juice" when "one or more but not all the juices are named and the named juice is not the predominant juice." 58 Fed. Reg. at 2900; see *id.* at 2921 ("two labeling alternatives"). The agency explained why "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." *Ibid.* And it concluded that the final rule (*i.e.*, 21 C.F.R. 102.33) is "adequate to prevent misleading labels on multiple-juice beverages." 58 Fed. Reg. at 2920; see *id.* at 2919 ("[I]t is not necessary to require that each juice in a beverage be named to ensure that the label is not misleading."); *ibid.* (describing examples as "nonmisleading ways" to name a multiple-juice beverage).

***2. FDA's juice-naming regulation is not merely a "floor" that can be supplemented by the Lanham Act***

To preserve the naming aspect of its Lanham Act claim, petitioner contends that its claim must survive unless there is an "irreconcilable conflict" between the two statutes (Br. 20-28), and that there is no such conflict here because FDA's juice-naming regulation merely sets a "floor" that standards imposed in a Lanham Act suit may supplement (Br. 32-40). That argument lacks merit.

a. Petitioner appears at times to argue that there is no "irreconcilable conflict" (Br. 22-23, 24-25) because it is not physically impossible to comply with both statutes. That argument fails for three reasons.

First, to the extent petitioner relies for this argument on the proposition that the FDCA did not impliedly repeal the Lanham Act (Br. 20-21), petitioner has the chronology wrong. The FDCA food-labeling provisions and FDA's authority to promulgate regulations implementing those provisions were enacted eight years before Section 43(a) of the Lanham Act. See FDCA §§ 401, 403(a), (f) and (i), 701(a), 52 Stat. 1046-1048, 1055; Lanham Act § 43(a), 60 Stat. 441. The question, then, would seemingly be whether the later-enacted statute (here, the Lanham Act) impliedly repealed the earlier-enacted statute (here, the FDCA). See *National Ass'n of Home Builders* v. *Defenders of Wildlife*, 551 U.S. 644, 662 (2007) ("repeals by implication are not favored") (citation and internal quotation marks omitted).

Second, the FDCA food-labeling provisions are "specific provision[s] applying to a very specific situation. [Section 43(a) of the Lanham Act], on the other hand, is of general application." *Morton* v. *Mancari*, 417 U.S. 535, 550 (1974). This Court has repeatedly made clear that, "[w]here there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment." *Id.* at 550-551; see *Radzanower* v. *Touche Ross & Co.*, 426 U.S. 148, 153 (1976) ("[A] statute dealing with a narrow, precise, and specific subject is not submerged by a later enacted statute covering a more generalized spectrum."). Here, it is not "absolutely necessary" to give the Lanham Act the construction petitioner urges in order to ensure that it has some meaning. *Ibid.* (citation omitted). To the contrary, under the government's interpretation, the FDCA's food-labeling provisions "will have no impact whatever upon the vast majority of lawsuits brought under that Act." *Id.* at 156. And even with respect to

juice labeling, a Lanham Act suit will lie where FDA has not promulgated regulations governing the particular issue or the defendant has not complied with such regulations.

Third, and relatedly, FDA's juice-naming regulation (which was adopted after the Lanham Act) speaks with even more specificity, and essentially serves to supply the standards to be applied in a Lanham Act suit in determining whether a juice name is misleading. None of the cases on which petitioner relies involved a conflict between specific agency regulations and a generally applicable statute. In this context, the task is to reconcile the statutory *and* regulatory schemes without intruding on one more than necessary to preserve the other.

b. Petitioner is also wrong to describe (Br. 32, 37) FDA's juice-naming regulation as merely a "floor" that can be supplemented by a Lanham Act suit without contravening its purpose. To be sure, respondent could have named its juice "apple grape juice blend," or "apple grape pomegranate blueberry raspberry juice," without running afoul of those regulations. And it could have identified the percentage of pomegranate and blueberry juices in the product name under Section 102.33(d)(2). But, contrary to petitioner's contention (Br. 22-25), "[t]he conflict" between the changes petitioner seeks to impose under the Lanham Act and FDA's juice-naming regulation "does not evaporate" because the "regulation simply permits, but does not compel," the name respondent chose. *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 155 (1982) (applying this principle in preemption context).

FDA, moreover, has never endorsed petitioner's all-or-nothing view of the agency's regulations. See Pet. Br.

34-37, 46-47. It is true that "compliance with one aspect of [FDA's] juice-naming regulations does not, by itself, render a juice label non-misleading." Pet. Br. 34-35; see p. 26, *infra*. But compliance with FDA's juice-naming regulations does make the juice's *name* nonmisleading. "FDA's enforcement position[]" (Pet. Br. 37) is entirely consistent with that understanding. FDA, for example, could not (and would not) bring an enforcement action against a manufacturer under 21 U.S.C. 343(a)(1) or (i) for naming its product "Raspcranberry; raspberry and cranberry flavored juice drink," if raspberry and cranberry juices were present as flavors, even if the drink was primarily white grape juice. See p. 14, *supra*.[7] Allowing the naming aspect of petitioner's claim to proceed in precisely those circumstances would not supplement FDA's enforcement resources (Pet. Br. 52-54); it would supplant FDA's regulatory judgment.

FDA's juice-naming regulation reflects the agency's "weigh[ing of] the competing interests relevant to the particular requirement in question." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 501 (1996). And the agency "reached an unambiguous conclusion about how those competing considerations should be resolved." *Ibid.*; see 58 Fed. Reg. at 2920 ("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."). That balance

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[7] The warning letter petitioner cites (Br. 37 & n.6) did not find the juice labels misleading based on the juices' *name*; it found the labels misleading based on relative placement, lettering, type-size, spacing, and other similar features. See Letter from Roberta F. Wagner, FDA, to Brad Alford, Nestle U.S.A. (Dec. 4, 2009), http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm.

could be easily upset by different legal rules imposed in a private suit such as that provided under Section 43(a) of the Lanham Act. Cf. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 874-886 (2000) (explaining how imposition of a general tort duty there would frustrate a delicately crafted motor vehicle safety regulation intended to afford manufacturers flexibility). A successful challenge to a name that complies with FDA's juice-naming regulation would effectively negate that regulation. In those circumstances, the two statutes are no longer "capable of coexistence," *J.E.M.*, 534 U.S. at 143 (citation omitted), and the Lanham Act must give way.

*Wyeth* v. *Levine*, 555 U.S. 555 (2009), does not counsel otherwise. See Pet. Br. 32-40. In that case, the Court found that a state-law duty to provide a stronger drug warning would not obstruct the purposes of the federal regulation, even though FDA had pre-approved the drug's labeling. 555 U.S. at 573-581. That holding rested primarily on three factors that are absent here. First, Congress had *not* enacted an express preemption provision for prescription drugs, evidencing an intent that "FDA oversight" not be exclusive. *Id.* at 574-575. Second, FDA had at times described its labeling standards as a "floor" or as "minimum standards" and had suggested that common-law suits would be "complementary." *Id.* at 577-579. And third, the factual record suggested that FDA did not give "more than passing attention," *id.* at 572-573 (citation omitted), to the risk at issue and did not affirmatively "consider and reject a stronger warning," *id.* at 581 n.14. Here, in contrast, Congress enacted a provision that expressly preempts state law with respect to a food's name, 21 U.S.C. 343-1(a)(2) and (3) (albeit, not a provision that expressly precludes application of other federal laws); there is nothing "com-

plementary" about federal or state courts second-guessing FDA's juice-naming regulation and the agency has never suggested otherwise; and FDA extensively considered the precise issue in notice-and-comment rulemaking, see pp. 13-16, *supra*.

***3. Petitioner's argument that respondent's juice name may not comply with FDA regulations is unsupported by the existing record***

Petitioner now briefly contends (Br. 49-52) that the name of respondent's juice may not, in fact, comply with FDA regulations. Petitioner's arguments misconstrue the regulations and lack support in the existing record.

a. Petitioner first suggests that the name of respondent's juice must include the percentage of pomegranate and blueberry juices because the "proportion" of those juices "has a material bearing on price or consumer acceptance" and because "the labeling or the appearance of the food may otherwise create an erroneous impression that" those juices are "present in an amount greater than is actually the case." Br. 51-52 (quoting 21 C.F.R. 102.5(b)). Petitioner's reliance on Section 102.5(b) is misplaced.

That provision sets forth "[g]eneral principles" to "govern[] the [FDA's] establishment of a common or usual name for a food under Subpart B." 37 Fed. Reg. 12,327 (June 22, 1972); see 39 Fed. Reg. 20,908 (June 14, 1974); 21 C.F.R. 102.5(d) ("common or usual name of a food may be established by * * * regulation in subpart B"). Once FDA establishes a common or usual name in Subpart B, however, that specific naming regulation controls. See 21 C.F.R. 102.5(b) ("The following requirements shall apply unless modified by a specific regulation in subpart B of this part.").

FDA did precisely that with respect to multiple-juice beverages. See 58 Fed. Reg. at 2919 (Section 102.33 was adopted pursuant to "the basic principles for common or usual names in [Section] 102.5."). The agency provided two different ways to indicate that the named juices are not predominant. One expressly cross-references the requirements of Section 102.5(b), 21 C.F.R. 102.33(d)(2); the other (quite consciously) does not, 21 C.F.R. 102.33(d)(1). See 58 Fed. Reg. at 2920 (explaining, after discussing Section 102.5(b), that FDA "decided not to require percentage declaration[s]" if the name complies with 21 C.F.R. 102.33(d)(1)). That should be the end of the matter. See *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2575 & n.3 (2011) ("The FDA's views are 'controlling unless plainly erroneous or inconsistent with the regulation[s]' or there is any other reason to doubt that they reflect the FDA's fair and considered judgment.") (brackets in original) (quoting *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997)).

b. Petitioner also suggests (Br. 49-51) that respondent may not be able to rely on Section 102.33(d)(1) because respondent's product may not contain enough pomegranate or blueberry juice to independently characterize it. Petitioner does not point to anything in the record to support that suggestion; rather, petitioner rests on what it asserts is respondent's "telling admission that its product contains so little pomegranate and blueberry juice that those juices do *not* independently characterize the product." Br. 50. Petitioner's argument conflates two different regulations. A juice manufacturer can rely on Subsection (d)(1) so long as the "named juice is present as a flavor or flavoring." 21 C.F.R. 102.33(d)(1); see 58 Fed. Reg. at 2921. But a juice can be "present as a flavor or flavoring" under 21 C.F.R.

102.33(d)(1) and still be insufficient to "*independently* characterize the food" under 21 C.F.R. 101.22(i)(1)(i) (emphasis added). Because the record does not appear to answer the relevant question (*i.e.*, whether pomegranate and blueberry juices in respondent's product are present as flavors or flavoring), there may be an unresolved factual dispute for the lower courts to address on remand. Cf. U.S. Cert. Amicus Br. 21-22 (noting other ambiguities in the record).[8]

**B. Petitioner's Lanham Act Challenge To Aspects Of Respondent's Juice Label That Are Not Specifically Required or Authorized By The FDCA Or FDA Regulations Is Not Precluded**

Petitioner's Lanham Act claim is not limited to the name of respondent's juice. Petitioner also argues, for example, that respondent's juice label is misleading because of "how [respondent] presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label." Pet. App. 10a; see Pet. Br. 2, 10, 17, 47. Nothing in the FDCA or its implementing regulations affirmatively authorizes that labeling decision or embodies a determination by FDA that it is not misleading. Petitioner therefore should be permitted to pursue that aspect of its claim and others that the FDCA and FDA regulations do not specifically address.

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[8] In its amicus brief at the certiorari stage of this case (at 17), the government stated that the court of appeals "was correct to recognize that FDA's regulations preclude a Lanham Act challenge to the common name of respondent's juice." That statement was based on the understanding at that time that the parties did not "seriously contest" (*ibid.*) either the name's compliance with 21 C.F.R. 102.33 or the relevant facts.

### *1. The FDCA and its implementing regulations do not occupy the field of juice labeling*

The court of appeals' decision that petitioner's Lanham Act claim was barred in its entirety rested on faulty reasoning. In the court's view, Congress had "entrust-[ed] matters of juice beverage labeling to the FDA"; the FDA had "comprehensive[ly] regulat[ed]" that "labeling"; and petitioner's claim could not proceed "[o]ut of respect for th[at] statutory and regulatory scheme." Pet. App. 12a. The court's analysis parallels that used in "so-called field pre-emption" cases, where "the scope of a [federal] statute indicates that Congress intended federal law to occupy a field exclusively." *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1266 (2012) (brackets in original) (quoting *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995)).[9] That approach is inappropriate here.

To be sure, FDA has authority to regulate in the area, it has exercised that authority to some extent, and it could adopt further regulations if it saw fit. But neither the authority to regulate nor the exercise of that authority in some respects is sufficient to exclude another federal statute from that field. Cf. *English* v. *General Elec. Co.*, 496 U.S. 72, 87 (1990) ("the mere existence of a federal regulatory or enforcement scheme," even a particularly detailed one, "does not by itself imply pre-emption of state remedies"); *Geier*, 529 U.S. at 884 ("[T]he Court has looked for a specific statement of pre-emptive intent where it is claimed that the mere 'volume and complexi-

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[9] Although federal-state implied preemption principles do not control the inquiry into whether "two [federal] statutes are capable of co-existence," *J.E.M.*, 534 U.S. at 143 (citation omitted), they may assist the inquiry because they are calculated to identify laws that cannot co-exist.

ty' of agency regulations demonstrate an implicit intent to displace *all* state law in a particular area.") (citation omitted). To hold otherwise would be "tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." *Hillsborough Cnty.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985).

Congress did not intend the FDCA or its implementing regulations to occupy the field of juice labeling to the exclusion of other federal laws. Under 21 U.S.C. 343-1(a), a State is forbidden from "directly or indirectly" establishing any requirement "that is not identical" to certain requirements under the FDCA. 21 U.S.C. 343-1(a); see 21 C.F.R. 100.1(c)(4). Not all misbranding requirements are included; 21 U.S.C. 343(a)(1), for example, is not one of the enumerated provisions. States can petition FDA to exempt a non-identical state requirement from preemption. 21 U.S.C. 343-1(b); see 21 C.F.R. 100.1. And States can at times directly enforce certain requirements of the FDCA and its implementing regulations. 21 U.S.C. 337(b); see 21 C.F.R. 100.2. That arrangement thus permits some state unfair-competition claims and bars others. It is counterintuitive to conclude that Congress intended a total displacement of a federal remedy but only a partial displacement of state remedies of a similar nature, given that the express preemption provision was designed to promote "[n]ational[ly] uniform" labeling, 21 U.S.C. 343-1.[10]

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[10] There is also little reason to think Congress intended to preclude federal Lanham Act claims to the same extent state-law claims are expressly preempted. Congress limited the express preemption provision to non-identical requirements under *state* law, which suggests that Congress did not deem co-extensive preclusion of other *federal* law necessary to achieve national

Moreover, nothing in FDA's regulations or the preambles to those regulations suggests that FDA has marked the metes and bounds of all possible misleading material on juice labels, or that its authority must be deemed exclusive even as to matters the agency has not yet addressed. To the contrary, the preamble to the final juice-labeling regulations makes clear that even when a manufacturer complies with 21 C.F.R. 102.33, there remains considerable potential for particular labels to prove misleading. For example, although 21 C.F.R. 102.33(b) permits the characterizing juice to be declared first even if "it is not the most predominant juice," FDA cautioned that "this provision does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner." 58 Fed. Reg. at 2920; see also, *e.g.*, *id.* at 2922 ("[FDA] 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."); *FDA Guide* 12.

***2. None of the other grounds identified by the courts below supports categorical preclusion***

The other reasons articulated by the lower courts for finding the labeling aspects of petitioner's Lanham Act claim precluded are also without merit.

First, the courts below relied on a "line of cases" holding that a Lanham Act claim cannot proceed if the court "would be required to interpret and then apply [the

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uniformity. See Pet. Br. 29; *id.* at 29-31 (arguing Congress was "well aware that the Lanham Act applied to misleading food labels when it decided to displace only state-law labeling requirements"). Accordingly, even if some of petitioner's state-law claims were expressly preempted (a question that is currently pending before the court of appeals, see note 4, *supra*), that would not resolve the question presented here.

FDCA's] statutory or regulatory provisions." Pet. App. 50a-51a (citation omitted); see *id.* at 11a; *Schering-Plough Healthcare Prods., Inc.* v. *Schwarz Pharma, Inc.*, 586 F.3d 500, 505-509 (7th Cir. 2009). Such considerations—which mirror those underlying the doctrine of primary jurisdiction, see *Reiter* v. *Cooper*, 507 U.S. 258, 268-269 (1993)—lack force here. The application of primary-jurisdiction-like principles presupposes that the parties may "apply to the [agency] for a ruling." *Id.* at 268 n.3 (citation omitted). But FDA does not accept formal petitions to take discretionary enforcement action (see 21 C.F.R. 10.30(k)), and its decision whether to initiate an enforcement action would not be subject to judicial review (see *Heckler* v. *Chaney*, 470 U.S. 821, 837-838 (1985)). Petitioner could petition FDA to revise its labeling regulations for juice mixtures (21 U.S.C. 371(e)(1)(B); 21 C.F.R. 102.19(a)), but that would not itself redress petitioner's competitive injury.

The courts, moreover, are capable of interpreting the FDCA and FDA's food-labeling regulations, with appropriate deference to FDA's interpretation. Indeed, that is a task courts must perform to determine whether a state-law claim is expressly preempted or to adjudicate an "identical" state-law claim. See 21 U.S.C. 343-1(a); 21 C.F.R. 100.1(c)(4); cf. *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 453 (2005) (remanding to determine whether state-law labeling requirements were "equivalent" to federal statutory and regulatory misbranding standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*).[11]

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[11] To the extent FDA disagrees with a court's interpretation of an ambiguous FDCA provision or regulation, the agency can exercise its interpretive discretion through subsequent rulemaking

Second, and relatedly, the district court noted the need to "tread carefully," lest private parties use the Lanham Act to do indirectly what they cannot do directly—*i.e.*, enforce the FDCA and its implementing regulations. Pet. App. 50a; cf. *Cottrell, Ltd.* v. *Biotrol Int'l, Inc.*, 191 F.3d 1248, 1255 (10th Cir. 1999) (plaintiff "must not be permitted to bring a FIFRA claim dressed up as a Lanham Act claim"). That reasoning has no application here. Petitioner does not seek to prove its Lanham Act claim by showing that respondent's juice label violates the FDCA or FDA regulations; rather, it seeks to show that the label bears a misrepresentation independently made actionable by the Lanham Act. Respondent's preclusion *defense* injects FDCA compliance questions into the case, but that does not make this a backdoor private enforcement action.

Third, both courts below allowed the *absence* of a specific regulation to bar petitioner's claim in its entirety. The court of appeals, for example, noted that "the FDA has not (so far as we can tell) required that all words in a juice blend's name appear on the label in the same size or that words hew to some other standard that [petitioner] might have us impose." Pet. App. 10a. The district court, for its part, faulted petitioner for failing to show that the juice's common or usual name "*must* appear on one single line, *must* be in one font, or *must* be centrally located on the Juice's bottle." *Id.* at 63a (emphases added). That turns preclusion analysis on its head. There is no indication that FDA affirmatively "*deci[ded]* not to impose the requirements urged by [petitioner]." *Id.* at 12a. And the fact that FDA could have (but did not)

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or guidance. See *National Cable & Telecomms. Ass'n* v. *Brand X Internet Servs.*, 545 U.S. 967, 982-983 (2005).

adopt such regulations is an insufficient basis on which to conclude that the two federal statutes cannot coexist.[12]

Certainly, the FDCA touches on label presentation issues by providing that a food is misbranded if required label material (such as a juice mixture's common name) "is not prominently placed [on the label] with such conspicuousness * * * as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase." 21 U.S.C. 343(f). The regulations, in turn, set forth certain ways in which label material "may lack that prominence and conspicuousness." 21 C.F.R. 101.15(a); see 21 C.F.R. 101.2(c), 101.3(d). The FDA, however, has not adopted absolute or relative type-size requirements for every word in a juice's name. Compare 21 C.F.R. 102.33(d)(2) and (g)(1), 102.5(b)(2) (specifying type-size and other presentation standards for percentage declarations and the words "from concentrate"), with 21 C.F.R. 102.33(c) and (d) (not specifying any type-size or other presentation standards for words like "blend" or "flavored").[13]

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[12] The absence of an FDA enforcement action against respondent is similarly inconsequential. FDA does not have a process for approving particular juice labels, and its failure to initiate an enforcement action cannot be construed as implicit approval. See *Chaney*, 470 U.S. at 831; *Altria Grp., Inc.* v. *Good*, 555 U.S. 70, 89 (2008) ("agency nonenforcement of a federal statute is not the same as a policy of approval") (citing *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002)).

[13] Indeed, FDA's response to the frequently asked question, "[w]hat type sizes must be used in naming juices," referred only to 21 C.F.R. 102.5(b)(2), 102.33(d) and (g) (governing juice-percentage declarations and the words "from concentrate"). *FDA Guide* 10. And when asked whether "the entire common or usual name of a juice beverage [must] be in one place and in a single type-size," FDA responded that "[t]he entire common or usual

In addition, the FDA has made clear that information on a food label may be insufficiently prominent or conspicuous, or misleading, for "reasons" "other" than those specifically enumerated. See 21 C.F.R. 101.15(a); p. 26, *supra* (expressly cautioning manufacturers naming their products in accordance with 21 C.F.R. 102.33 about the potential for their labels to still mislead); note 7, *supra* (discussing warning letter). A suit under Section 43(a) of the Lanham Act successfully challenging material on a label as inconspicuous would tend to *reinforce*, not undo, the statutory and regulatory requirements. Cf. *Bates*, 544 U.S. at 450 ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA.").

***3. No statutory or regulatory provision specifically requires or authorizes the other features of the label challenged by petitioner***

The court of appeals did not identify any statutory or regulatory provision requiring or affirmatively authorizing respondent to present the juice's common or usual name (or other matter) on the label in the manner that it appears.[14] Respondent, however, now contends (Supp. Cert. Br. 3) that 21 C.F.R. 101.22(i)(1)(i) specifically addresses "the font-size issue," that its juice label com-

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name must be in one place" and, again, noted the type-size requirements for "from concentrate" juices. *Id.* at 11.

[14] To the extent petitioner challenges the fruit vignette as misleading (Br. 52; but see Pet. App. 10a (suggesting that argument was not "meaningfully" pursued on appeal)), nothing in the FDCA or its implementing regulations precludes that claim. The district court relied on the preamble to the final rule (*id.* at 65a-69a), but FDA specifically considered whether to formally regulate the content of such vignettes and ultimately opted for a case-by-case assessment. See p. 26, *supra*.

plies with that regulation, and that any Lanham Act challenge to its juice label is thereby precluded. Respondent is incorrect for three reasons.

First, the provisions of 21 C.F.R. 101.22(i) apply to juice labeling only to the extent they are "pertinent." 56 Fed. Reg. at 30,462. Subparagraph (1)(i), on which respondent relies, explains how to declare the existence of a characterizing flavor when the food contains natural flavors, but not the ingredient itself or not enough of the ingredient to "independently characterize the food." 21 C.F.R. 101.22(i)(1)(i); see 21 C.F.R. 101.22(a)(3) (defining "natural flavor"); 21 C.F.R. 101.22(i) (defining "characterizing flavor"). In those circumstances, the "name of the food" must be "accompanied by the common or usual name of the characterizing flavor," which must be "immediately followed by the word flavored in letters not less than one-half the height of the letters in the name of the characterizing flavor." 21 C.F.R. 101.22(i)(1)(i). For example, the designation "lemon flavored cake" would be appropriate for "cake" (the name of the food) that is represented as "lemon" (the characterizing flavor) and that contains lemon oils and an insufficient quantity of lemon juice to independently flavor the food ("flavored").

That provision has no logical application here. Even if respondent's juice contains natural pomegranate and blueberry *flavors* and not enough pomegranate or blueberry *juice* to independently characterize the product (a factual question not resolved by the courts below and on which the government is not in a position to opine), its common or usual name *already* declares that the juice is pomegranate blueberry "flavored." That is required by 21 C.F.R. 102.33(d), because pomegranate and blueberry are not the predominant juices but are (presumably) "present as a flavor of flavoring" (cf. pp. 22-23, *supra*),

and because respondent opted not to declare the percentage of each of those juices. In those circumstances, having the phrase "pomegranate and blueberry flavored" stated again to "accompan[y]" the "name of the food" would be at best duplicative and at worst confusing. See *PLIVA*, 131 S. Ct. at 2575 (deferring to FDA's interpretation of its own regulations even though plaintiffs offered other ways to interpret them); 58 Fed. Reg. at 2920 (noting that Sections 101.22(i) and 102.33 are both "intended to ensure that the label communicates essential information to consumers").[15]

Second, the two federal statutory schemes can comfortably coexist unless FDA's food-labeling regulations specifically permit (or require) the allegedly misleading material. In promulgating 21 C.F.R. 102.33, FDA did not decide whether any absolute or relative type-size of the word "flavored" would (or would not) be misleading in the context of a fruit-juice label where the named juices were present only as a flavor and where the predominant juices were not named. See p. 29, *supra* (not-

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[15] That does not mean that 21 C.F.R. 101.22(i) is inapplicable to respondent's juice label in its entirety. Section 101.22(i)(1)(iii), for example, applies to foods that contain both a characterizing flavor from the product whose flavor is simulated (*e.g.*, natural flavors from lemon for lemon cake) and other natural flavor which simulates, resembles, or reinforces the characterizing flavor (*e.g.*, natural oils from other citrus fruits). If respondent's juice contains other natural flavors that simulate, resemble, or reinforce the pomegranate or blueberry flavor, the label would have to include the words "with other natural flavor." 21 C.F.R. 101.22(i)(1)(iii). Those words would have to "immediately follow[]" "the name of the food * * * in letters not less than one-half the height of the letters used in the name of the characterizing flavor." *Ibid.*

ing that FDA *did* make that sort of determination with respect to other aspects of fruit-juice labels).

Third, Section 101.22(i)(1)(i) sets forth a type-size requirement only for the word "flavored." It does not specify a type-size for the words "Blend Of 5 Juices." See 21 C.F.R. 102.33(c) (no discussion of type-size). It does not address placement of "Flavored Blend Of 5 Juices" on a line below "Blueberry" and two lines below "Pomegranate." And it does not address any other aspect of respondent's juice label. Accordingly, even if Section 101.22(i)(1)(i) applies, and even if respondent's juice label complies with the type-size requirements contained therein, petitioner's Lanham Act claim would not be barred in its entirety.

## CONCLUSION

The judgment of the court of appeals should be vacated and the case remanded for further proceedings.

Respectfully submitted.

WILLIAM B. SCHULTZ
*General Counsel*
ELIZABETH H. DICKINSON
*Chief Counsel, Food and Drug Division*
ANNAMARIE KEMPIC
*Deputy Chief Counsel for Litigation*
JULIE DOHM
*Associate Chief Counsel*
*Department of Health and Human Services*

DONALD B. VERRILLI, JR.
*Solicitor General*
STUART F. DELERY
*Assistant Attorney General*
EDWIN S. KNEEDLER
*Deputy Solicitor General*
MELISSA ARBUS SHERRY
*Assistant to the Solicitor General*
MARK B. STERN
SUSHMA SONI
*Attorneys*

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## APPENDIX

1. 15 U.S.C. 1125(a) provides in pertinent part:

**False designations of origin, false descriptions, and dilution forbidden**

**(a) Civil action**

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

* * * * *

2. 21 U.S.C. 337 provides:

**Proceedings in name of United States; provision as to subpoenas**

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has set-

tled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

3. 21 U.S.C. 341 provides:

**Definitions and standards for food**

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty

and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

4. 21 U.S.C. 343 provides in pertinent part:

**Misbranded food**

A food shall be deemed to be misbranded—

**(a) False or misleading label**

If (1) its labeling is false or misleading in any particular, * * *

* * * * *

**(f) Prominence of information on label**

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

* * * * *

**(i) Label where no representation as to definition and standard of identity**

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title[1] unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. 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.

5. 21 U.S.C. 343-1 provides:

**National uniform nutrition labeling**

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 341

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[1] So in original. Probably should be followed by a comma.

of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale sub-

stantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 343(q)(5)(H)(ix) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a) of this section, under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

6. 21 U.S.C. 371 provides in pertinent part:

**Regulations and hearings**

**(a) Authority to promulgate regulations**

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

* * * * *

**(e) Procedure for establishment**

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

7. 21 C.F.R. 101.2(c) provides in pertinent part:

**Information panel of package form food.**

* * * * *

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than one-sixteenth inch in height unless an exemption pursuant to paragraph (f) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§101.105(h) (1) and (2) and 101.15.

* * * * *

8. 21 C.F.R. 101.3 provides in pertinent part:

**Identity labeling of food in packaged form.**

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

* * * * *

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

9. 21 C.F.R. 101.15(a) provides:

**Food; prominence of required statements.**

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 403(f) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

10. 21 C.F.R. 101.22 provides in pertinent part:

**Foods; labeling of spices, flavorings, colorings and chemical preservatives.**

* * * * *

(a)(3) The term *natural flavor* or *natural flavoring* means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natu-

ral essence or extractives obtained from plants listed in §§182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in §172.510 of this chapter.

* * * * *

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in "strawberry shortcake", and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than one-half the height of the letters in

the name of the characterizing flavor, e.g., "natural strawberry flavored shortcake," or "strawberry flavored shortcake".

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

11. 21 C.F.R. 102.5 provides:

**General principles.**

(a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states,

in clear terms, what it is in a way that distinguishes it from different foods.

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in subpart B of this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) ___ percent (or %) ___ " or "___ percent (or %) ___" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words "___ percent or %) ___" shall appear following or directly below the word "containing" (or contains), or directly below the part of the common or usual name of the food

required by paragraph (a) of this section when the word "containing" (or contains) is not used, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

(c) The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. The following requirements shall apply unless modified by a specific regulation in subpart B of this part.

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words "containing (or contains) ___" or "containing (or contains) no ___" or "no ___" or "does not contain ___", with the

blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under paragraph (c)(1) and/or (2) of this section shall appear following or directly below the part of the common or usual name of the food required by paragraphs (a) and (b) of this section, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the alternatives established under paragraphs (b)(2) (i) and (ii) of this section.

(d) A common or usual name of a food may be established by common usage or by establishment of a regulation in subpart B of this part, in part 104 of this chapter, in a standard of identity, or in other regulations in this chapter.

12. 21 C.F.R. 102.33 provides:

**Beverages that contain fruit or vegetable juice.**

(a) For a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual name shall be a descriptive name that meets the requirements of §102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice

(e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, 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). In accordance with §101.22(i)(1)(iii) of this chapter, 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.

(c) If a diluted multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit juices.")

(d) In a diluted multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall:

(1) Indicate that the named juice is present as a flavor or flavoring (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or

(2) Include the amount of the named juice, declared in a 5- percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice). The 5-percent range, when used, shall be declared in the manner set forth in §102.5(b)(2).

(e) 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., "acid-reduced cranberry juice," "deflavored, decolored grape juice").

(f) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then the source fruits or vegetables from which the modified juice was derived may not be depicted on the label by vignette or other pictorial representation.

(g)(1) If one or more 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 terms must be included in the name of each individual juice 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 two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a

type size no less than one-half the height of the letters in the name of the juice.

(2) If the juice is 100 percent single species juice consisting of juice directly expressed from a fruit or vegetable whose Brix level has been raised by the addition of juice concentrate from the same fruit or vegetable, the name of the juice need not include a statement that the juice is from concentrate. However, if water is added to this 100 percent juice mixture to adjust the Brix level, the product shall be labeled with the term "from concentrate" or "reconstituted."