No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF FOR RESPONDENT

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QUESTION PRESENTED

Whether a juice manufacturer that employs a juice name and label authorized by a nationally-uniform standard under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Nutrition Labeling and Education Act of 1990 ("NLEA"), is subject to suits by private plaintiffs under section 43(a) of the Lanham Act that seek to impose standards different from the FDCA/NLEA standard.

RULE 29.6 STATEMENT

Respondent's Rule 29.6 Statement appears in the Brief in Opposition at ii.

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STATUTES AND REGULATIONS INVOLVED

Relevant provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*; the Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990); FDA's regulations, 21 C.F.R. pts. 101 & 102; and the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, are set forth in the Appendix, *infra*.

INTRODUCTION

In this case, a private litigant invoking the Lanham Act seeks to disrupt the national uniformity Congress has required in the naming and labeling of food and juice products. In enacting the Federal Food, Drug and Cosmetic Act ("FDCA"), Congress foreclosed any private right of action to enforce the statute's provisions, and in enacting the Nutrition Labeling and Education Act of 1990 ("NLEA"), Congress included an express preemption provision foreclosing state-law suits that might seek to impose naming or labeling standards that are not identical to enumerated standards authorized by the FDCA. That provision, tellingly entitled "National Uniform Nutrition Labeling," was intended to enable food and juice manufacturers to choose a single nationwide name and label for certain products, without facing the burdens and inefficiencies that would result if private plaintiffs across the country could impose their own idiosyncratic naming and labeling standards, as petitioner seeks to do here.

To be sure, Congress expressly preempted only suits under *state law*, and was silent as to suits under *federal* laws like the Lanham Act. But this Court has long held that a specific federal law (here, the FDCA/NLEA) may narrow the scope of a general federal law (here, the Lanham Act) even if Congress

has not expressly stated as much. The Court has instead discerned Congress's intent to narrow the scope of the general law from the specific law's text, structure, and purpose, see, *e.g.*, *Elgin* v. *Dep't of the Treasury*, 132 S. Ct. 2126, 2133 (2012)—just as in any statutory-interpretation case where Congress has failed to address the precise issue that later arises.

Congress's intent to preclude private Lanham Act suits under the circumstances here is evident, and it would be anomalous to allow a Lanham Act suit that poses the same threat to national uniformity as the state-law suits that Congress expressly preempted. The FDCA/NLEA and its implementing regulations allow a juice manufacturer like respondent to name its product "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES …" so as to indicate the presence of minority juices (here, pomegranate and blueberry) through the words "Flavored Blend Of 5 Juices." And the FDCA requires the phrase "Flavored Blend Of 5 Juices" to appear only with "such conspicuousness … as to render it likely to be read and understood by the ordinary individual." If private plaintiffs could invoke the Lanham Act to deem respondent's name or label misleading, a patchwork of requirements would result, varying by state and jury. One plaintiff might insist that the predominant components (apple and grape) be included in the name; another might demand identification of the percentage contribution of each component; and a third might argue that the juice should be named *only* by the predominant components. Likewise, one plaintiff might seek to require that "Flavored Blend Of 5 Juices" be three-quarters rather than half the height of the words in the earlier part of the juice's name; a second might insist on equal height; a third might demand equal height and bold lettering. And so on.

This is not the regime of "National Uniform Nutrition Labeling" that Congress envisioned and enacted.

The United States correctly rejects (Br. 11-12) petitioner's argument that a specific federal law may never impliedly narrow a general one, and agrees (Br. 12-23) with respondent that petitioner's Lanham Act challenge to the name of respondent's juice is precluded. But the United States errs (Br. 23-33) in ignoring the force of the NLEA's express "national uniform[ity]" provision insofar as petitioner's challenge to the *non*-naming aspects of respondent's juice is concerned. While recognizing (Br. 20) that the express preemption provision distinguishes this case from *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the United States incorrectly declines (Br. 25) to draw any inference from that provision regarding Congress's intent to preclude private Lanham Act suits that pose the same threat as state-law suits to national uniformity. Congress viewed *all* state-law requirements "not identical" to those under the FDCA as within the scope of the NLEA's preemption clause. It is thus inconsistent with Congress's intent to ask case-by-case, as the United States would (Br. 30), whether a Lanham Act plaintiff's particular proposed non-identical requirements would "tend to *reinforce*, not undo, the [FDCA's] statutory and regulatory requirements." And in assuming that Congress would welcome private efforts to heighten the federal standard, the United States conspicuously omits to note FDA's express recognition in the wake of the NLEA that stringency is not to be achieved at the cost of national uniformity:

> [O]ne of the goals of the 1990 amendments is national uniformity in certain aspects of food labeling, so that the food industry can market

> its products efficiently in all 50 States in a cost-effective manner. Thus, in enacting the 1990 amendments, Congress decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result.

58 Fed. Reg. 2462, 2462 (Jan. 6, 1993) (internal citation omitted).

The FDCA provisions and FDA regulations, especially when interpreted against the backdrop of Congress's national-uniformity goal, authorize the name and label of respondent's product. Respondent acted reasonably in complying with those provisions and regulations. Petitioner's proposed regime allowing private Lanham Act challenges to that name and label interferes with Congress's intent. The judgment of the court of appeals should be affirmed.

STATEMENT

A. Statutory And Regulatory Background

1. The FDCA And NLEA

Congress enacted the FDCA in 1938 and amended it, as relevant here, in 1990 through the NLEA. Contrary to petitioner's description (Br. 6-7), the FDCA's food provisions do not rest solely on a purpose to protect public health and safety; they additionally "promote honesty and fair dealing in the interest of consumers." 21 U.S.C. § 341. The FDCA expressly reserves enforcement to the United States and bars private causes of action. See 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain

violations, of this chapter shall be by and in the name of the United States."). See also *id*. § 337(b) (granting limited enforcement rights to the States).[1]

FDCA § 403 prescribes circumstances under which "[a] food shall be deemed to be misbranded." 21 U.S.C. § 343. See also *id.* §§ 321(n) (a food can be "alleged to be misbranded because the labeling … is misleading"); 321(f) ("food" includes "drink"). For example, a food is misbranded "[u]nless its label bears … the common or usual name of the food, if any there be," *id.* § 343(i)(1), or "[i]f any word, statement, or other information required by or under authority of this chapter to appear on the label … is not prominently placed thereon with such conspicuousness (as compared with other words …) … as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use," *id.* § 343(f).

FDA has adopted implementing regulations, including 21 C.F.R. § 102.33, which prescribes requirements for the name of a fruit-juice beverage that contains a "blend of single-strength juices." That regulation provides, *inter alia*, that the name need not include the names of those juices "in descending order of predominance by volume [if] the name specifically shows that the juice with the represented flavor is used as a flavor." *Id.* § 102.33(b). Thus, a juice blend that contains more apple and pear than raspberry need not be named "apple, pear, and raspberry juice drink," and may instead be named "raspberry-flavored

[1] FDA may enforce the FDCA's provisions through a variety of administrative, civil, and criminal tools. See, *e.g.*, 21 U.S.C. §§ 336 (warning letters); 332 (civil judicial proceedings seeking injunction); 334(a) (civil judicial proceedings seeking seizure); 333(a) (imprisonment or fines).

apple and pear juice drink." *Ibid.* Indeed, the regulation provides that not all of the juice components need even be included in the name, so long as the name "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.')." *Id.* § 102.33(c). And a juice that is included in the name may be a minority component, so long as the name "(1) [i]ndicate[s] that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink); or (2) [i]nclude[s] the amount of the named juice, declared in a 5-percent range …." *Id.* § 102.33(d).[2] The concept of allowing the name to include a minority component followed by "flavored" is not unique to fruit-juice beverages but applies also to other foods. For example, a version of strawberry shortcake that contains very few actual strawberries may be named "'strawberry flavored shortcake.'" 21 C.F.R. § 101.22(i)(1)(i).

Other FDA regulations amplify FDCA § 403(f) regarding the "conspicuousness" of information on the label. For example, where a "food" (which, as noted, includes "drink") contains a "natural flavor which simulates, resembles or reinforces the characterizing flavor," FDA has provided that the label need not identify the flavor that "simulates, resembles or reinforces," but instead may set forth the name of "the characterizing flavor" if "immediately followed by the words 'with other natural flavor' in letters not less than one-half the height of the letters used in the

[2] FDA has regulated the names and labels of fruit-juice beverages since at least 1967. See 56 Fed. Reg. 30452, 30452-53 (July 2, 1991) (recounting history).

name of the characterizing flavor." 21 C.F.R. § 101.22(i)(1)(iii).

The NLEA amended the FDCA by, *inter alia*, adding a provision entitled "National Uniform Nutrition Labeling." NLEA § 6 (codified in part at 21 U.S.C. § 343-1). As codified, this clause provides that "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 … any requirement for the labeling of food of the type required by section … 343(f), … [or] 343(i)(1) … of this title that is not identical to the requirement of such section …." 21 U.S.C. § 343-1(a)(3).

Congress provided that § 343-1(a)(3) would become effective only after, *first*, completion of a study "whether [the enumerated FDCA] sections and regulations adequately implement the purposes of such sections," NLEA § 6(b)(1)(B), and *second*, FDA's publication of a "list of [FDCA] sections which are adequately being implemented," *id.* § 6(b)(3)(B). The Institute of Medicine performed the study and reported, *inter alia*, that 21 U.S.C. §§ 343(f) and 343(i)(1) were adequately implemented. See Inst. of Medicine, *Food Labeling: Toward National Uniformity* 102, 113 (1992). FDA concurred, 58 Fed. Reg. 2470, 2473-74 (Jan. 6, 1993), thus making the preemption clause effective as to State requirements that are "not identical" to these FDCA subsections.

2. The Lanham Act

Congress enacted the Lanham Act in 1946 and amended its § 43(a) most recently in 1988, Pub. L. No. 100-667, § 132, 102 Stat. 3935, 3946 (1988). Section 43(a) is not specific to foods, but rather speaks broadly of "any goods or services, or any container for goods."

15 U.S.C. § 1125(a)(1). It provides a civil cause of action to an entity that is injured by another's "false or misleading description" or "representation" in connection with "goods or services." *Ibid.* Only business entities, not consumers, may sue under this provision. *Lexmark Int'l, Inc.* v. *Static Control Components, Inc.*, 572 U.S.___ (2014) (slip op. at 13, 22).

B. Factual Background

Coca-Cola's Minute Maid® division markets a 100% juice product that contains about 99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice. Pet. App. 2a. The largest feature on the front label is a "vignette" depicting half an apple, half a pomegranate, three blueberries, three grapes, and two raspberries. JA 38a. Below the vignette appears the word "POMEGRANATE"; below that in identical font size the word "BLUEBERRY"; below that in slightly smaller font size (but more than half the height of "POMEGRANATE") the words "FLAVORED BLEND OF 5 JUICES"; below that in slightly smaller font size (but again, more than half the height of "POMEGRANATE") the words "FROM CONCENTRATE WITH ADDED INGREDIENTS"; and below that in the same font size the words "AND OTHER NATURAL FLAVORS." *Ibid.*

The back label lists the beverage's ingredients in descending order by volume, beginning: "APPLE, GRAPE AND POMEGRANATE JUICES FROM CONCENTRATE, FRUIT AND VEGETABLE JUICES (FOR COLOR), BLUEBERRY JUICE FROM CONCENTRATE, NATURAL FLAVORS,

RASPBERRY JUICE FROM CONCENTRATE ….” JA 39a.[3]

C. Proceedings Below

1. Pom, which markets pomegranate juice and pomegranate juice blends, JA 58a; Pet. App. 1a, sued Coca-Cola in the U.S. District Court for the Central District of California, asserting, *inter alia*, a claim under Lanham Act § 43(a). Pom centrally alleged:

> [T]he main ingredients in Coca Cola's Pomegranate Blueberry Product are neither pomegranate nor blueberry juice, but rather, apple and grape juice. … Notwithstanding that Coca Cola's product actually contains little pomegranate or blueberry juice, Coca Cola labels its product as “Pomegranate Blueberry” juice.

JA 26a. In opposing Coca-Cola's motion to dismiss, Pom explained that “Defendant's purported compliance with FDA juice labeling regulations does not preclude Pom's Lanham Act claim. These regulations establish minimum, rather than maximum, standards.” Opp. To Mot. To Dismiss at 1, No. 08-06237 (C.D. Cal. Dec. 15, 2008).

2. The district court (Otero, J.) granted Coca-Cola's motion to dismiss in relevant part. At the outset, the court observed that, because “the []FDCA, unlike the Lanham Act, does not provide for a private right of action,” it is appropriate to “tread[] carefully when applying the Lanham Act to … goods … that are also subject to regulation by the []FDCA.” Pet. App. 87a

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[3] In the ingredient statement, *every* ingredient (apart from minor exceptions not relevant here) must be listed “in descending order of predominance by weight.” 21 C.F.R. § 101.4(a)(1).

(internal quotation marks omitted; second ellipsis in original). The court dismissed Pom's claim because, *inter alia*, Pom's "claim may be construed to challenge FDA regulations ...." Pet. App. 89a. See also *id.* at 89a-90a ("The []FDCA and the FDA implementing regulations … involve a number of requirements for labeling a multiple-juice beverage.") (citing 21 U.S.C. §§ 343(f), 343(i)(1); 21 C.F.R. § 102.33).

Portions of Pom's Lanham Act claim that the district court did not dismiss went forward and, on cross-motions for summary judgment, the court adhered to but elaborated on its prior ruling dismissing Pom's challenge to the name and label of Coca-Cola's product. The court addressed for the first time the relative font sizes of the words in the name (an issue that had arisen for the first time on summary judgment), finding that Coca-Cola's label complies with the FDCA in this respect as well. Pet. App. 62a-64a.[4]

3. The court of appeals (D.W. Nelson, O'Scannlain, and N.R. Smith, JJ.) affirmed in a unanimous opinion authored by Judge O'Scannlain. Pet. App. 1a. The

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[4] Pom also asserted state-law claims challenging the name and label. The district court granted summary judgment to Coca-Cola on the ground that Pom lacked "standing" under the relevant California statutes to pursue the claims. Pet. App. 58a-60a. The court of appeals later vacated that part of the judgment based on intervening California Supreme Court precedent. Pet. App. 13a. On remand, the district court again granted summary judgment to Coca-Cola on the state-law claims, this time on the ground that they are preempted by the NLEA. *Pom Wonderful LLC* v. *The Coca-Cola Co.*, No. CV 08-06237, 2013 WL 543361, at *3-*5 (C.D. Cal. Feb. 13, 2013). Pom appealed, and the court of appeals accepted the parties' suggestion to postpone briefing until this Court's decision. No. 13-55770, Dkt. No. 19 (9th Cir. Jan. 31, 2014).

court found that the FDCA precludes Pom's challenge to the name of Coca-Cola's product because "FDA has concluded that a manufacturer may name a beverage using the name of a flavoring juice that is not predominant by volume," so long as the manufacturer "states that those juices are not predominant," as in FDA's example ""Raspcranberry'; raspberry and cranberry flavored juice drink.'" *Id.* at 9a (citing 21 C.F.R. § 102.33(c), (d), and quoting § 102.33(d)(1)). The court found that the name of Coca-Cola's product—insofar as it includes "Pomegranate Blueberry Flavored Blend of 5 Juices …"—complies with FDA's regulation, and therefore that "Pom's challenge to the name … would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading." *Ibid*.

Turning to the font sizes on the label, the court described Pom's claim as "focuse[d] on how Coca-Cola presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label. … Pom apparently wants to force Coca-Cola to alter the size of the words on its labeling so that the words 'Pomegranate Blueberry' no longer appear in larger, more conspicuous type on Coca-Cola's label than do the words 'Flavored Blend of 5 Juices.'" Pet. App. 10a. The court found this claim precluded by the FDCA because "allowing Pom to achieve this result would again undermine the … FDCA and its implementing regulations[, which] have identified the words and statements that must or may be included on labeling

and have specified how prominently and conspicuously those words and statements must appear." *Ibid*.[5]

The court of appeals did not address the merits of Pom's contentions in this Court that Coca-Cola's product is misleading in other respects. The court specifically found that Pom waived its assertion (Br. 2, 52) that, taking into account the percentage make-up of the beverage, the pomegranate and the blueberries depicted in the vignette should have been much smaller relative to the apple and the grapes; the court explained that Pom had not "meaningfully" raised this argument on appeal. Pet. App. 10a.[6] The court did not address, and thus also presumably found waived, Pom's perfunctory assertion (Br. 2, 51) as to Coca-Cola's division of the product's name onto multiple lines.[7] The court did not address Pom's current arguments that Coca-Cola's product's color is mis-leading (Br. 2) or that pomegranate juice and blue-berry juice do not provide the product's flavor (Br. 51), arguments that Pom did not raise in even a perfunctory fashion before the court of appeals.

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[5] Pom (Br. 40) and the United States (Br. 24) ignore these passages of the court of appeals' decision concerning the divergence between Pom's proposed requirements and the FDA regulations in asserting that the court relied on a field preemption/preclusion theory. To the extent the court's decision may be so characterized, Coca-Cola does not rely on that theory in this Court.

[6] Pom made the argument only in a footnote in its opening brief. See Br. for Appellant at 28 n.11, *Pom Wonderful LLC* v. *The Coca-Cola Co.*, 679 F.3d 1170 (9th Cir. 2012) (No. 10-55861). The district court had earlier found that the vignette "clearly complies with FDA requirements relating to the depiction of vignettes." Pet. App. 67a (citing 58 Fed. Reg. 2897, 2918-21 (Jan. 6, 1993)).

[7] See Br. for Appellant, *supra* n.6, at 28 n.11.

4. Given the district court's and court of appeals' threshold ruling that Pom's Lanham Act claim is precluded, those courts did not reach the question whether reasonable jurors could find Coca-Cola's product's name and label misleading. Pom nonetheless discusses (Br. 10-12) that question, omitting any mention of the contrary evidence, which we summarize here.

First, Pom invokes (Br. 10) a survey by its expert, E. Deborah Jay, that found that many potential purchasers of pomegranate and blueberry juice blends are likely to conclude from Coca-Cola's label that its product contains mainly pomegranate and blueberry juices. But Coca-Cola's expert, Ran Kivetz, a professor at Columbia Business School, explained that Ms. Jay's survey suffered from numerous flaws, including use of "highly biased" questions and "an inadequate, commercially unviable, and suspicious control package." JA 173a.

Second, Pom claims that Coca-Cola received a "'record number of complaints'" regarding the product. Pet. Br. 11 (quoting Pet. App. 31a (district court's description of what "Pom contends")). But Pom's assertion distorts the testimony of a Coca-Cola consumer affairs employee, who in fact testified that Coca-Cola had received only a very small number of complaints, most of which had nothing to do with the name or label. See JA 176a ("[l]ess than 1% of the comments, approximately 20 in total, were complaints regarding the Juice's name or labeling").[8]

[8] There was evidence that Pom itself had directed an employee to "call [Coca-Cola's] customer service numbers and ask what % pomegranate juice is in their blends … [and] [i]f they won't give her an answer, please have her call back several times …." Ex.

Third, Pom quotes an internal Coca-Cola email stating that, although "'[w]e are in compliance with the FDA regs related to the naming of juice containing products[,] *[t]here is a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices*.'" Pet. Br. 11-12 (quoting Pet. App. 34a-35a) (emphasis Pom's). But the "risk" to which the e-mail referred was the risk of an unmeritorious lawsuit, not the risk that consumers would actually be misled by a juice name and label that comply fully with FDA's detailed regulations on these subjects. See Deft. Reply St. To Pltf. St. Of Genuine Issues at 27, No. 08-06237, Dkt. No. 239 (C.D. Cal. Jan. 15, 2010). In any event, the email was not written by a lawyer and did not purport to address the legal issues resolved by the courts below in Coca-Cola's favor.

SUMMARY OF ARGUMENT

I

Interpreting a later, more specific law to narrow the scope of an earlier, more general law is a "classic judicial task," *United States* v. *Fausto*, 484 U.S. 439, 453 (1988), not an implied repeal. In such circumstances, this Court has rejected the implied-repeal framework and instead has sought to reconcile the two federal laws based on the usual statutory-interpretation indicia of "text, structure, and purpose," *Elgin*, 132 S. Ct. at 2133. This approach recognizes that it is unrealistic to expect that Congress, in enacting one federal law, is aware of and should address every possible impact of that enactment on older federal laws.

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18 To Decl. Of S. Zalesin ISO Mot. In Limine, No. 08-06237, Dkt. No. 198 (C.D. Cal. Feb. 2, 2010).

This framework applies here. The Lanham Act was enacted in 1946 and applies to "goods and services" of all types. The NLEA was enacted in 1990 and seeks "national uniform[ity]" on certain aspects of food naming and labeling. The question thus is not whether the NLEA impliedly repeals Lanham Act § 43(a), but whether the NLEA narrows the scope of that Lanham Act section in the circumstances here.

II

The answer is yes. The text, structure, and purpose of the NLEA (and FDCA) demonstrate, *first*, an overriding congressional intent to achieve national uniformity in food/juice naming and labeling and to bar private lawsuits that undermine that goal; and *second*, a comprehensive federal regulatory scheme in the FDCA (and regulations thereunder) that is far more specific than Lanham Act § 43(a) as to food/juice naming and labeling.

Where one federal law discloses Congress's intent to achieve national uniformity, this Court has readily inferred Congress's intent to narrow the scope of (or bar altogether) a private cause of action under a second federal law that would undermine Congress's uniformity goal. The courts of appeals have consistently followed that approach where Congress's uniformity goal is revealed by a provision that expressly preempts state-law suits but is silent as to narrowing or preclusion of private federal-law suits.

Here, even before the NLEA's enactment, Congress's intent that there be national uniformity in food and juice naming and labeling was evident from 21 U.S.C. § 337(a), the FDCA's provision barring private enforcement of the FDCA's provisions. The NLEA confirmed and further implemented the national-

uniformity goal. Its "National Uniform Nutrition Labeling" provision expressly preempts state requirements that are "not identical" to the requirements in certain FDCA provisions. Congress's evident purpose was to allow food and juice manufacturers to comply with a single standard nationwide. Private state-law suits would disrupt that national uniformity by exposing manufacturers to an array of different standards proposed by the plaintiffs.

Accordingly, it is appropriate to infer that Congress intended to preclude a Lanham Act § 43(a) suit that poses the same threat to national uniformity as that posed by a state-law suit within the express terms of the preemption clause. Petitioner's claims, if pleaded as a state-law suit, would be squarely within the preemption clause. Each of petitioner's assertions is covered by an FDCA requirement that is given preemptive force by the NLEA, and petitioner has conceded that its proposed requirements seek to heighten (and thus are "not identical to") the requirements prescribed by the FDCA.

The specificity of the food/juice naming and labeling provisions of the FDCA/NLEA (and FDA's regulations thereunder) relative to the broad and general language of Lanham Act § 43(a) further shows that Congress intended to preclude a Lanham Act claim in the circumstances here. FDA's regulations authorize the name and label of respondent's product in every respect challenged by petitioner. For example, the name "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES" is authorized by 21 C.F.R. § 102.33(b)-(d). And because "FLAVORED BLEND OF 5 JUICES" is more than one-half the height of "POMEGRANATE BLUEBERRY," the font size

satisfies the cross-referenced requirement, *id*. § 101.22(i)(1)(iii), that these words be "not less than one-half the height of the letters used in the name of the characterizing flavor," as well as the more general requirement that the name "shall be in a size reasonably related to the most prominent printed matter," *id.* § 101.3(d).

The existence of some manufacturer discretion (within the bounds of these requirements) to choose its own nationally-uniform label does not indicate Congress's or FDA's intent to allow private plaintiffs to invoke Lanham Act § 43(a), under the guise of more stringent enforcement, to urge a host of different requirements on food manufacturers. To the contrary, as Congress and FDA recognized, such a regime would undermine Congress's overriding goal of national uniformity.

III

Petitioner's remaining arguments are unpersuasive. *First*, the suggestion that FDA lacks adequate resources to regulate food labels for potential to mislead is belied by FDA's certification that the relevant FDCA provisions were "adequately implemented," and in any event the answer to any asserted resources problem is not to allow private Lanham Act lawsuits at the expense of national uniformity. *Second*, petitioner overstates the extent to which Lanham Act § 43(a) would be curtailed in other sectors by a holding that the claims in this case are precluded by the FDCA and NLEA. Petitioner's examples involve neither the express preemption clause nor the detailed set of regulations at issue here. The judgment of the court of appeals should be affirmed.

ARGUMENT

I. A SPECIFIC FEDERAL LAW CAN NARROW THE SCOPE OF A GENERAL FEDERAL LAW EVEN IF IT DOES NOT EXPRESSLY SO INDICATE AND EVEN IF THE TWO LAWS ARE NOT IN IRRECONCILABLE CONFLICT

As the United States agrees (Br. 11-12, 16-18), petitioner is incorrect to invoke (Br. 20-21) the canon against implied repeal as barring FDCA/NLEA's preclusion of its Lanham Act claim. This Court has repeatedly held that the implied-repeal canon does not apply where, as here, a later, more specific law clarifies or narrows the otherwise broad scope of an earlier law.[9] And contrary to petitioner's suggestion (Br. 19-20), this Court has never put Congress to the burden of *explicitly* addressing the impact of one law on every other corner of the U.S. Code.

In *Fausto*, for example, this Court considered whether the Civil Service Reform Act's ("CSRA") "elaborate 'new framework for evaluating adverse personnel actions against [federal employees],'" 484 U.S. at 443 (quoting *Lindahl* v. *OPM*, 470 U.S. 768, 774 (1985)) (bracket in original), precluded a federal employee "from seeking the Claims Court review

[9] A specific law may narrow the scope of a general law even if the general law comes later in time. *See, e.g.*, *Morton* v. *Mancari*, 417 U.S. 535, 550-51 (1974) ("Where 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*.") (emphasis added). For example, in *Morton*, 417 U.S. at 550-51, the Court found the general anti-discrimination provision of Title VII narrowed by an exception (based on the Indian Reorganization Act) allowing the Bureau of Indian Affairs to grant preferences to Indians in the Bureau's hiring and promotion process.

traditionally available under the [earlier-enacted] Tucker Act … [and] Back Pay Act," *id*. The CSRA did not explicitly address its impact upon those earlier statutes. See *id.* at 456 (Stevens, J., dissenting). This Court nonetheless asked whether Congress's intent to effect such preclusion through the CSRA was "fairly discernible," and found that it was. *Id.* at 452 (majority opinion). The Court deemed inapposite "the doctrine that repeals by implication are strongly disfavored," *ibid.*, explaining:

> Repeal by implication of an express statutory text is one thing; it can be strongly presumed that Congress will specifically address language on the statute books that it wishes to change. But repeal by implication of a legal disposition implied by a statutory text is something else. The courts frequently find Congress to have done this—whenever, in fact, they interpret a statutory text in the light of surrounding texts that happen to have been subsequently enacted. This classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.

Id. at 453 (internal citation omitted). See also, *e.g.*, *Elgin*, 132 S. Ct. at 2133 (holding, without reference to implied repeal, that CSRA impliedly narrows the ability of certain litigants to sue in federal district court under 28 U.S.C. § 1331); *United States* v. *Estate of Romani*, 523 U.S. 517, 530 (1998) ("Given the fact that this basic question of interpretation [of a 1797 statute] remains unresolved, it does not seem appropriate to view the issue in this case as whether the Tax

Lien Act of 1966 implicitly amended or repealed the [1797] statute. Instead, we think the proper inquiry is how best to harmonize the impact of the two statutes ….”); *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000) (“At the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings. … This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand.”) (internal citation omitted); *Bhd. of R.R. Trainmen* v. *Chicago River & Ind. R. R. Co.*, 353 U.S. 30, 42 (1957) (“the specific provisions of the Railway Labor Act take precedence over the more general provisions of the Norris-LaGuardia Act”).

Indeed, this Court has taken such an approach to Lanham Act § 43(a), the general statutory provision at issue here, in *Dastar Corp.* v. *Twentieth Century Fox Film Corp.*, 539 U.S. 23 (2003). *Dastar* involved the scope of that section’s cause of action against a defendant who makes “a ‘false designation of origin.’” *Id.* at 31 (quoting 15 U.S.C. § 1125(a)). This Court observed that “‘origin’” could conceivably “include not merely the producer of the physical item … but also the creator of the content that the physical item conveys.” *Id*. at 33. But this Court, without discussing implied repeal, found Congress’s subsequent enactment of copyright statutes (which did not expressly mention the Lanham Act) to narrow that otherwise broad scope. *Id.* at 33-34. Those copyright statutes addressed the matter more “specifically,” *id.* at 33, than did Lanham Act § 43(a).[10]

[10] As *Dastar* demonstrates, one federal law can narrow specific words in another federal law. See also *Fausto*, 484 U.S. at 454 (CSRA narrowed scope of the words “appropriate authority” in

This case presents a similar scenario: Years after enacting the broad and general provisions of the 1946 Lanham Act, Congress enacted the 1990 NLEA recognizing that certain specific FDCA provisions governing food naming and labeling should be "national[ly] uniform." NLEA § 6. The implied-repeal framework does not apply, and the proper inquiry instead is "how best to harmonize the impact of the two statutes," *Estate of Romani*, 523 U.S. at 530, in keeping with "Congress' intent," *id.* at 533. As explained in Point II, *infra*, Congress intended to preclude a Lanham Act § 43(a) claim in the circumstances here.[11]

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the Back Pay Act to no longer include the Court of Claims); *Keogh* v. *Chicago & N.W. Ry. Co.*, 260 U.S. 156, 163 (1922) (Brandeis, J.) (once Interstate Commerce Commission fixed carriers' rates, shippers could not complain that the rates constituted "violation of … [their] legal rights," and hence could not assert that they had been "'injured in [their] business or property'" as required to bring a cause of action under the Anti-Trust Act) (quoting Anti-Trust Act of July 2, 1890, c. 647, 26 Stat. 209). Similarly here, for the reasons discussed in Point II, *infra*, the NLEA and FDCA narrow the words "false or misleading" in Lanham Act § 43(a) so that they do not reach aspects of a nationally-uniform juice label that have been chosen in compliance with the FDCA and FDA's regulations. Accord, U.S. Br. 18.

[11] Even if the implied-repeal framework did apply (which it does not), petitioner overstates (Br. 21) its requirements. By definition, an *implied* repeal does not require an express statement in the later law, even when an earlier Congress purported to require one. See *Lockhart* v. *United States*, 546 U.S. 142, 148 (2005) (Scalia, J., concurring). Moreover, the implied-repeal framework does not require that it is impossible to comply with both laws. See *Credit Suisse Secs. (USA) LLC* v. *Billing*, 551 U.S. 264, 273 (2007) (a conflict may be found where one statute "forbid[s] the very thing that the [other statute] … *permit[s]*") (emphasis added). Accordingly, it is irrelevant that "neither the

II. THE FDCA AND NLEA NARROW THE SCOPE OF LANHAM ACT § 43(A) IN THE CIRCUMSTANCES HERE

Under the appropriate analytic framework, which involves "reconciling … laws enacted over time, and getting them to 'make sense' in combination," *Fausto*, 484 U.S. at 453, the FDCA and NLEA preclude petitioner's proposed Lanham Act § 43(a) claim against respondent's juice-blend name and label. The touchstone is "Congress' intent," *Estate of Romani*, 523 U.S. at 533, as revealed by the relevant statutes' "text, structure, and purpose," *Elgin*, 132 S. Ct. at 2133.

The text, structure, and purpose of the FDCA and NLEA demonstrate Congress's clear intent to achieve national uniformity in food and juice naming and labeling that would be defeated by Lanham Act claims like petitioner's. The relevant textual provisions here include, *first*, the FDCA's delegation of authority to enforce its provisions exclusively to the federal government (and in certain limited instances the States), rather than private parties, 21 U.S.C. § 337; *second*, the NLEA's "national uniform[ity]" provision, which expressly preempts private state-law actions that seek to impose requirements "not identical" to enumerated FDCA provisions, NLEA § 6; and *third*, the FDCA's

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FDCA's statutory provisions on food labeling nor FDA's implementing regulations *require* Coca-Cola" (Pet. Br. 22) (emphasis added) to use a name or label that petitioner contends is misleading. Although *Department of Transportation* v. *Public Citizen*, 541 U.S. 752 (2004) (cited at Pet. Br. 24), observed that the "irreconcilable conflict" standard would be satisfied where the regulated entity cannot comply with both statutes, *id.* at 766-67, the Court did not address or decide whether the standard could be satisfied in the *Credit Suisse* scenario where one statute forbids, and a second statute permits, certain conduct.

substantive provisions (and FDA regulations thereunder), which are substantially more specific than is Lanham Act § 43(a) as to food and juice naming and labeling. These provisions together reveal a comprehensive regulatory structure whose purpose is to make food and juice naming and labeling nationally uniform, relieving manufacturers of the difficulties of complying with an array of divergent standards proposed by private plaintiffs. The legislative history of the NLEA confirms this overriding national-uniformity goal.

A. The FDCA Delegates Enforcement Authority To The Federal Government Rather Than To Private Plaintiffs

Even before the NLEA's enactment, Congress's desire for national uniformity was apparent from the FDCA's delegation of enforcement authority exclusively to the federal government rather than to private plaintiffs (subject to certain limited enforcement rights for the States). See 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (§ 337 is "clear evidence" that the FDCA is to "be enforced exclusively by the Federal Government"). Cf. *Astra USA, Inc.* v. *Santa Clara Cnty.*, 131 S. Ct. 1342, 1347, 1349 (2011) ("Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities," and thus enabled HHS "to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis").

B. The NLEA Further Implemented The National-Uniformity Goal Through An Express Preemption Clause

The NLEA confirmed and further implemented Congress's national-uniformity goal. Specifically, NLEA § 6, entitled "National Uniform Nutrition Labeling," preempts, *inter alia*, any state-law "requirement for the labeling of food of the type required by section … 403(f) [regarding conspicuousness] … [and] 403(i)(1) [regarding common or usual name] … that is not identical to the requirement of such section." NLEA § 6(a)(3) (codified in part at 21 U.S.C. § 343-1(a)(3)). This provision supports a strong inference that Congress intended to preclude private suits under Lanham Act § 43(a) that pose the same threat to national uniformity as do private state-law suits.

In *Fausto*, *Elgin*, and other decisions, this Court has inferred a congressional intent to achieve national uniformity from the comprehensive structure of the federal law at issue, and has then held that this national-uniformity goal requires narrowing the scope of an earlier-enacted law. In *Fausto*, for example, this Court observed that "[a] leading purpose of the CSRA was to replace the haphazard arrangements for administrative and judicial review of personnel action," 484 U.S. at 444, with a scheme of Merit Systems Protection Board ("MSPB") "administrative review … followed by judicial review in the Federal Circuit," *id.* at 447. *Fausto* held that the CSRA impliedly precluded certain suits under the Tucker Act and Back Pay Act because such suits would undermine national uniformity. *Id.* at 451 (instead of being directed to the MSPB and in turn the Federal Circuit, certain "employees would be able to obtain review in the district courts and the regional courts of appeals

throughout the country, undermining the consistency of interpretation by the Federal Circuit"). See also *Elgin*, 132 S. Ct. at 2135 (similar); *Keogh* v. *Chicago & N.W. Ry. Co.*, 260 U.S. 156, 163 (1922) (Brandeis, J.) (law entrusting to a federal agency the task of approving carriers' rates required preclusion of private antitrust suits because, if such suits were allowed, "[u]niform treatment would not result … unless the highly improbable happened, and the several juries and courts gave to each the same measure of relief").

The courts of appeals have applied that principle in the specific context of a provision, like the NLEA's, that expressly preempts state law and is silent on preclusion of an earlier-enacted federal law. These courts have consistently inferred from such a provision that Congress intended to preclude private suits under the "other" federal law because they would pose the same threat to national uniformity as would the expressly-preempted private suits under state law. See *Lane* v. *R.A. Sims, Jr., Inc.*, 241 F.3d 439, 443 (5th Cir. 2001) (inferring from Federal Railroad Safety Act's ("FRSA") provision expressly preempting state-law negligence claims that Congress also intended to preclude Federal Employers' Liability Act ("FELA")-based negligence claims). As the court of appeals explained in *Lane*:

> [U]niformity can be achieved only if the regulations … are applied similarly to a FELA plaintiff's negligence claim and a … state law negligence claim. ... [A]llowing juries in FELA cases to find negligence … even though [the railroad complied with] the FRSA regulations, would further undermine uniformity, because it would result in the

> establishment, through such verdicts, of varying, uncertain [requirements].

Id. at 443-44. Accord, *Waymire* v. *Norfolk & W. Ry. Co.*, 218 F.3d 773, 777 (7th Cir. 2000); *Nickels* v. *Grand Trunk W. R.R., Inc*., 560 F.3d 426, 430 (6th Cir. 2009).[12]

Similarly here, there is a strong basis to infer that Congress intended to preclude federal Lanham Act suits at least to the same extent that it intended to preempt state-law suits that fall within the express preemption clause. The legislative history confirms the inference, as NLEA's sponsors elaborated on why national uniformity was needed in this area. For example, Senator Hatch explained:

> [I]nconsistent State and local laws seriously disrupt food manufacturing and distribution, resulting in higher prices for consumers. Moreover, they frustrate food safety and nutrition education efforts by presenting

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[12] *Lane* also noted that, absent preclusion of FELA suits, there would be an inequality between railroad employees (who could sue under FELA) and others (who lack standing under FELA and who are expressly preempted from suing under state law). 241 F.3d at 443. Petitioner's proposed regime would create a similar inequality by allowing business entities to sue under the Lanham Act while depriving consumers of any corresponding ability to sue (because they lack standing under the Lanham Act and are expressly preempted by the NLEA from suing under state law).

Courts of appeals that have declined to find FELA claims precluded, see *Cowden* v. *BNSF Ry. Co*., 690 F.3d 884, 893-94 (8th Cir. 2012); *Tufariello* v. *Long Island R.R. Co*., 458 F.3d 80, 86 (2d Cir. 2006), reasoned that the FRSA regulations at issue in those cases (unlike those at issue in the cases cited in text) did not address the circumstances underlying the FELA claim.

> consumers with varying and inconsistent information and warnings.

136 Cong. Rec. S16607, 16611 (Oct. 24, 1990). See also, *e.g.*, 136 Cong. Rec. H5836, 5840 (July 30, 1990) (statement of Rep. Waxman) ("A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws."); *id.* at 5843 (statement of Rep. Madigan) (similar);[13] 58 Fed. Reg. at 2462 ("[I]n enacting the 1990 amendments, Congress decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result.") (citing statement of Rep. Madigan).[14]

Petitioner's proposed requirements would be within the express terms of the NLEA's preemption clause if asserted in a state-law suit.[15] *First*, petitioner has conceded that it seeks to enforce Lanham Act requirements above any "floor" set by the FDCA, and thus that its proposed requirements are necessarily "not identical" to those imposed by the FDCA. See,

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[13] There was no Senate Report on the NLEA, and the House Report, H.R. Rep. No. 101-538 (June 13, 1990), preceded the July 30, 1990, addition to the bill of preemption as to the FDCA provisions at issue here.

[14] From the standpoint of consumer deception as well, it would make little sense to preempt consumers from suing under state law, but to allow business entities to sue under the Lanham Act on a theory that deception caused the consumers to buy from the defendant rather than the plaintiff.

[15] The district court below indeed held that petitioner's state-law claims challenging the name and label of respondent's product are preempted. See *supra*, n.4.

e.g., Opp. To Mot. To Dismiss First Amended Compl. at 10, No. 08-06237 (C.D. Cal. Aug. 26, 2009) ("Pom's claim is based on the fact that the product's naming and labeling is misleading even if they comply with the minimum requirements set forth by the FDA regulations."); Pet. Br. 32 ("FDA's regulations bespeak an intent to set a floor—but not a ceiling—on the adequacy of labeling."). That concession is appropriate, for as shown in detail in Point II.C, *infra*, each of petitioner's proposed requirements diverges from the relevant provisions of the FDCA and FDA's regulations thereunder.

Second, petitioner's claims are covered by FDCA provisions enumerated in the NLEA's preemption clause. Specifically, petitioner contends in this Court that respondent's product is misleading with regard to (1) name (Br. 22-23, 49-52); (2) font size (Br. 23, 47); (3) vignette (Br. 52); (4) division of the name onto multiple lines (Br. 10, 51); and (5) coloring (Br. 2).[16] But the name and the vignette are covered by FDCA § 403(i)(1), which addresses "the common or usual name" of a juice. 21 U.S.C. § 343(i)(1).[17] Petitioner's assertions concerning the height of the words on the label and the division of the product's name onto multiple lines are addressed by FDCA § 403(f), which requires that words be placed on the label "with such conspicuousness (as compared with other words …) … as to render [them] likely to be read and understood by the ordinary individual under customary conditions

[16] As explained *infra*, at 45-47, petitioner's arguments as to the vignette, the division of the name onto multiple lines, and the color are waived.

[17] FDA has treated vignettes under FDCA § 403(i)(1) on the theory that a vignette bears on the product's name. See 56 Fed. Reg. at 30462.

of purchase and use." 21 U.S.C. § 343(f). And any issue of supposedly misleading purple coloration is covered by FDCA § 403(i)(2), which provides in relevant part that "colors not required to be certified under section 379e(c) of this title unless sold as … such colors[] may be designated as … colorings without naming each." 21 U.S.C. § 343(i)(2) (footnote omitted).

These FDCA provisions allow the manufacturer to employ a single name and label nationwide—rather than be subjected to "a multitude of dispersed and uncoordinated lawsuits," *Astra*, 131 S. Ct. at 1349, proposing a range of different requirements. For example, as to relative conspicuousness of the words on the label, one plaintiff might insist that "FLAVORED BLEND OF 5 JUICES" be three-quarters the height of "POMEGRANATE" and "BLUEBERRY"; another might insist on equal height; another might insist on equal height and bold font; and so on. See also *supra*, at 2. "Uniform treatment would not result … unless the highly improbable happened, and the several juries and courts gave to each [plaintiff] the same measure of relief." *Keogh*, 260 U.S. at 163. That is the antithesis of what Congress intended when it enacted a "national uniform[ity]" provision to solve the problem that, as one sponsor put it, "[a] national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws," 136 Cong. Rec. at 5840 (statement of Rep. Waxman).

The NLEA's preemption clause undermines petitioner's reliance (Br. 32-34) on *Wyeth* v. *Levine*. In that case, in finding that the FDCA did not preempt a state-law claim, this Court emphasized that Congress had *not* "enacted an express pre-emption provision" for

prescription drugs. 555 U.S. at 574. Here, with the goal of providing a nationally-uniform standard for the food industry, Congress *did* enact an express preemption clause for certain food naming and labeling issues. Under *Fausto* and other cases discussed above, it is appropriate to infer from such textual and structural evidence Congress's intent to preclude private suits brought under the generally-worded Lanham Act § 43(a) if (as here) they would be expressly preempted if brought as state-law claims.[18]

Petitioner's and the United States' attempts to escape the NLEA's preemption clause and the inference it supports are unpersuasive. They ignore the purpose of the clause and the fact that petitioner seeks to do through the Lanham Act what it could not do through a state-law claim—namely, enforce requirements for blended fruit-juice naming and labeling that are "not identical" to the relevant FDCA provisions (or its implementing regulations).

Petitioner's Arguments. *First*, petitioner speculates that Congress considered but declined to enact a clause expressly precluding private suits under non-FDCA federal statutes. See Br. 29 n.5 (noting legislative history's description of NLEA's preemption

[18] The NLEA's preemption clause, in exempting safety requirements, see § 6(c)(2), highlights another reason why *Wyeth* v. *Levine* is inapposite. Whereas *Wyeth* involved a tragic side-effect from a drug that required amputation of the plaintiff's forearm, 555 U.S. at 559, this case involves no such safety issue, but rather an allegation that FDA's regulations are inadequate to prevent consumers from being misled and thus have harmed petitioner. *Wyeth*'s calculus that the uniformity benefit of preemption did not outweigh the cost there (eliminating a source of redress for a physically-injured plaintiff) hardly supports the same conclusion here.

clause as "carefully crafted," "limited in scope," and a "compromise") (internal quotation marks omitted). But these references do not show that Congress considered private suits under non-FDCA federal statutes, or whether to preclude such suits.[19] Rather, they pertain to Congress's decision to limit the express preemption clause to the FDCA provisions referenced therein (which, as discussed above, cover petitioner's assertions), and to provide explicitly that courts should not use implied-preemption analysis to go beyond the scope of that clause. See NLEA § 6(c)(1) ("The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the [FDCA] [which was added by NLEA § 6(a)]."). That Congress prohibited courts from holding impliedly preempted state-law suits that fall *outside* the scope of the express preemption clause does not suggest that Congress prohibited courts from inferring that Congress intended to preclude suits under the Lanham Act that would fall *within* the express preemption clause if asserted under state law.

Second, petitioner asserts (Br. 29) that "Congress was well aware that the Lanham Act applied to misleading food labels when it decided to displace only state-law labeling requirements." But petitioner offers scant support, principally citing (*ibid.*) two lower-court decisions over the 44-year period between 1946 (the Lanham Act) and 1990 (the NLEA). See Pet. Br. 29 (citing *Hesmer Foods, Inc.* v. *Campbell Soup Co.*, 346 F.2d 356, 359 (7th Cir. 1965); *Potato Chip Inst.* v. *General Mills, Inc.*, 333 F. Supp. 173 (D.

[19] As shown in Point I, *supra*, the lack of an *express* preclusion of other federal laws is not dispositive. This Court routinely finds *implied* preclusion based on indicia of Congress's intent.

Neb. 1971), aff'd, 461 F.2d 1088 (8th Cir. 1972) (per curiam)).[20] Compare *Wyeth*, 555 U.S. at 575 (Congress was aware of "*prevalen[t]* … state tort litigation") (emphasis added). Petitioner's reliance (Br. 30) on two snippets of legislative history that made passing reference to the Lanham Act[21] is equally unavailing.

Third, while appearing to concede (Br. 31) that its claims are regulated by FDCA subsections 403(i)(1), (i)(2), and (f) (each of which has preemptive force under the NLEA's preemption clause), petitioner argues that its claim is akin to a claim under subsection 403(a) (which does not). But Congress cannot have contemplated that the preemption clause could be nullified simply because a plaintiff invokes subsection 403(a) rather than one or more of the subsections that have preemptive effect under the NLEA's preemption clause. Subsection 403(a), an obviously general provision, instead covers circumstances that are *not* covered by one or more of the subsections that have preemptive effect. See, *e.g.*, 56 Fed. Reg. 60528, 60530 (Nov. 27, 1991) ("State requirements that would not be subject to the preemption provisions of the 1990 amendments … includ[e] *State laws pertaining to issues for which there is no*

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[20] Notably, unlike here, see Point II.C, *infra*, neither case involved an FDA regulation addressing the challenged labeling aspect, *i.e.*, "the word 'barbecue' in the name Campbell's Barbecue Beans," *Hesmer Foods*, 346 F.2d at 359, and the "use of 'potato chip' for a product of dehydrated potatoes," *Potato Chip Inst.*, 333 F. Supp. at 180 (discussing non-binding FDA policy guideline).

[21] See *Health & Nutrition Claims in Food Advertising & Labeling, Hearing Before the S. Comm. on Gov't Affairs*, 101st Cong. 74 (1990); *FDA's Continuing Failure to Regulate Health Claims for Foods, Hearings Before the Subcomm. on Human Res. & Intergov'tl Relations of the H. Comm. on Gov't Operations*, 101st Cong. 157 (1989).

national framework, such as open date labeling, unit price labeling, container deposit labeling, religious dietary labeling, and previously frozen labeling") (emphasis added); 58 Fed. Reg. 2478, 2484 (Jan. 6, 1993) (labeling issue "outside the coverage of section 403(r)(1)(B) … would be subject to section 403(a)").[22] So understood, the NLEA's preemption clause works as intended. Private plaintiffs are prohibited from disrupting the FDCA's nationally-uniform standard where a specific standard exists—*i.e.*, in situations covered by one or more of the § 403 subsections that have preemptive effect. But private plaintiffs can bring suit under state law or the Lanham Act where no such specific FDCA standard exists—*i.e.*, in the situation covered by subsection 403(a).[23]

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[22] Although FDA has occasionally used subsection (a) as a shorthand for other subsections, see, *e.g.*, Warning Letter from FDA to Brad Alford, dated December 4, 2009, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm (cited at Pet. Br. 37 n.6), those documents were more informal than the rulemaking statements (cited in text) in which FDA focused on the issue.

[23] As noted *supra*, at 27, petitioner has described its suit as seeking to go above the FDCA provisions that have preemptive effect. Any attempt by petitioner to enforce those provisions would be barred by 21 U.S.C. § 337(a). See II.A, *supra*. And § 337(a) cannot be avoided by the end run of purporting to enforce an identical state-law or Lanham Act equivalent of one of the covered FDCA provisions. Cf. *Astra*, 131 S. Ct. at 1348 (in context of analogous statutory scheme, rejecting a plaintiff's attempted end run around the lack of a private cause of action). The NLEA's preemption clause, whose goal was "national uniform[ity]," cannot sensibly be construed to have endorsed such an end run by preempting only "not identical" state requirements (without addressing "identical" ones). Instead, Congress assumed that "identical" requirements were already, and would remain, impliedly preempted by § 337(a). Precedent is not to the contrary. Although *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), and *Riegel*

The United States' arguments. The United States acknowledges (Br. 20) that the NLEA's preemption clause distinguishes this case from *Wyeth* v. *Levine*, but then declines (Br. 25) to infer from that clause that Congress intended to preclude all private suits under the Lanham Act that would fall within the express terms of the preemption clause if they were state-law suits. The United States' reasons for refusing to draw that inference, set forth in a brief rather than a regulation or rulemaking statement, do not warrant deference. See, *e.g.*, *Republic of Austria* v. *Altmann*, 541 U.S. 677, 701 (2004) (United States' views in an *amicus* brief on "a 'pure question of statutory construction' … merit no special deference") (quoting *INS* v. *Cardoza-Fonseca*, 480 U.S. 421, 446 (1987)). Moreover, they are unpersuasive:

First, the United States argues (Br. 25) that the preemption clause, because not completely exhaustive, proves that Congress was not interested in national uniformity after all. Specifically, the United States notes that the NLEA's preemption clause does not apply to "*all* misbranding provisions" (*ibid*. (emphasis added) (citing 21 U.S.C. § 343(a)(1))),[24] and allows States to obtain exemptions as to non-identical state-law requirements that otherwise would be preempted

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v. *Medtronic, Inc.*, 552 U.S. 312 (2008), involved the FDCA, neither addressed § 337(a). The federal law at issue in *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), did not contain any equivalent to § 337(a).

[24] The United States does not endorse petitioner's argument that its suit can be characterized as akin to a suit to enforce FDCA § 403(a), and hence outside the scope of the NLEA's preemption clause. The United States thus appears to agree that Lanham Act claims like petitioner's, if asserted under state law, would come within that clause's scope.

by the preemption clause (*ibid*. (citing 21 U.S.C. § 343-1(b))). But the United States does not contend that either of those carve-outs applies here,[25] and it provides no explanation why the existence of the carve-outs means that Congress abandoned its national-uniformity goal in circumstances (like those here) that *are* within the preemption clause's scope.

Second, the United States mischaracterizes respondent as seeking a "total displacement of a federal remedy" (Br. 25), which the United States views (*ibid.*) as inconsistent with Congress's partial limitation of state remedies through the preemption clause. In fact, respondent seeks the *same* preclusion of federal Lanham Act claims as there would be preemption of analogous state-law suits under the NLEA's preemption clause. Again, the United States does not contest that petitioner's claims here would be squarely within the preemption clause if asserted as state-law claims.

Finally, the United States argues (Br. 25-26 n.10) that the NLEA preemption clause's explicit mention of state-law suits and not federal-law suits suggests that Congress did not view the latter as undermining national uniformity. But cases like *Fausto*, *Elgin*, *Keogh*, *Lane*, *Waymire*, and *Nickels*—none of which the United States addresses—demonstrate that Congress's silence on precluding federal-law suits is not dispositive where other textual or structural indicia reveal Congress's intent to preclude such suits.

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[25] The United States further observes (Br. 25 (citing 21 U.S.C. § 337(b))) that States may enforce FDCA's provisions under certain circumstances. But only States, not private parties, can avail themselves of this provision, and then only after allowing FDA to pursue enforcement first. This provision thus is more consistent with national uniformity than opposed to it.

And in this context, unlike in the preemption context where considerations of federalism are at stake, there is no presumption against preclusion. Compare, *e.g.*, *Elgin*, 132 S. Ct. at 2133 ("we examine the [federal law's] text, structure, and purpose"), with *Altria Group, Inc.* v. *Good*, 555 U.S. 70, 77 (2008) ("When addressing questions of express or implied pre-emption, we begin our analysis 'with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'") (bracket in original) (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Accord, Brief Of Alaska *et al.* As *Amici Curiae* In Support Of Petitioner ("Alaska Br.") 3, 5. The remainder of the United States' argument (Br. 25-26 n.10) simply relies on petitioner's argument (Br. 29-31) and is unpersuasive for the reasons set forth *supra*, at 30-33.

C. Congress Regulated Food And Juice Naming And Labeling With Far More Specificity In The FDCA And NLEA Than In Lanham Act § 43(a)

As discussed in Point I, *supra*, a key consideration in determining whether one federal law narrows the scope of another federal law is whether the former is more specific than the latter regarding the subject at hand. See, *e.g.*, *Dastar*, 539 U.S. at 34; *Fausto*, 484 U.S. at 454. The FDCA provisions discussed above are plainly more specific regarding juice naming and labeling than is Lanham Act § 43(a), which speaks broadly to goods and services of any type. The FDA's regulations implementing the FDCA provisions are yet more specific. This specificity provides an additional ground for finding petitioner's Lanham Act claim precluded here.

Those regulations should be understood against the backdrop of FDA's certification, pursuant to the NLEA, that FDA's regulations "adequately implement" the FDCA subsections covered by the preemption clause. Congress postponed the effectiveness of the preemption clause until FDA determined that FDCA subsections 403(i)(1) and 403(f) were "adequately implemented." NLEA § 6(b)(3)(B).[26] FDA subsequently made that determination. See 58 Fed. Reg. at 2473 ("FDA finds that [its regulatory] requirements adequately implement section 403(f) of the act."); *id.* at 2474 ("FDA concludes that it does have a strong and adequate regulatory system in place to implement section 403(i)(1) of the act."). Thus, this is not, as in *Wyeth*, a circumstance where "FDA ha[d] paid very little attention to the issues raised," *Wyeth*, 555 U.S. at 581 n.14 (internal quotation marks omitted), and petitioner and the United States are incorrect to ignore FDA's certification of adequate implementation in arguing that FDA has not yet given adequate attention to certain aspects of juice naming and labeling.

As shown below, the regulations specifically authorize each aspect of the name and label of respondent's product. Petitioner's and the United States' arguments to the contrary are unpersuasive. Nor does the United States' interpretation of the regulations deserve deference here, for it ignores, *inter alia*, FDA's recognition of Congress's national-uniformity goal, 58 Fed. Reg. at 2462, and departs from FDA's formal

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[26] The portion of the preemption clause giving preemptive force to FDCA § 403(i)(2) went into effect immediately. See NLEA § 6(a) (making only FDCA § 403A(a)(3) (which covers, *inter alia*, § 403(f) and (i)(1)), not § 403A(a)(2) (which covers, *inter alia*, § 403(i)(2)), subject to the postponement measure in NLEA § 6(b)).

declaration that FDCA § 403(f) and (i)(1) were adequately implemented. See *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2575 (2011) (FDA's interpretation of its regulations in a brief filed by the United States is "'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") (quoting *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997)) (bracket in original).[27]

Name. 21 C.F.R. § 102.33 addresses how a juice manufacturer can name a multi-juice beverage.[28] Under paragraph (b), the name need not include the individual juices in descending order by volume if "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)." Under paragraph (c), the name need not include all the single-strength juices if the name "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.')." And under paragraph (d), the named single-

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[27] Even if FDA is entitled to deference concerning interpretation of its regulations, it is not entitled to deference concerning the interplay between those regulations and a separate federal law (the Lanham Act) that FDA does not administer, see, *e.g.*, *U.S. Air Tour Ass'n* v. *FAA*, 298 F.3d 997, 1015-16 (D.C. Cir. 2002), or the ultimate question whether the FDCA provisions and/or FDA regulations preclude a Lanham Act claim, cf. *PLIVA*, 131 S. Ct. at 2575 n.3 ("we do not defer to an agency's ultimate conclusion about whether state law should be pre-empted").

[28] 21 C.F.R. § 102.5(b) (discussed at Pet. Br. 51) precedes § 102.33 and sets forth "[g]eneral principles" for Part 102 of 21 C.F.R. Chapter I, Subchapter B. Section 102.5(b) makes clear that its general principles apply "unless modified by a specific regulation in subpart B of this part," 21 C.F.R. § 102.5(b), such as § 102.33.

strength juices need not be the predominant one if the name either "(1) [i]ndicate[s] that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink); or (2) [i]nclude[s] the amount of the named juice, declared in a 5-percent range …."

Each of these paragraphs applies here and authorizes the name respondent chose: "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES …" JA 38a. The name is a precise aggregation of the cited example names in § 102.33(b)-(d), using the term "flavored," the term "blend of _ juices," and the names of the minority juices.[29]

To be sure, § 102.33(d) allows a manufacturer to choose between using a name like "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES …" and disclosing the percentage contribution of the named single-strength juice to the beverage as a whole. See Pet. Br. 23. And FDA stated in the rulemaking statement that it "affirmatively 'encourage[s]' that 'each juice in a beverage be declared in the name of the product.'" Pet. Br. 36 (quoting 58 Fed. Reg. 2897, 2919 (Jan. 6, 1993)) (alteration in original). But FDA did not *require* such a declaration and instead left the choice to the manufacturer, cf. *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 874-75 (2000), in keeping with FDA's recognition, in a rulemaking statement issued on the same day § 102.33 was adopted, that, "even though Federal requirements may preempt

[29] Even if the product's label did not satisfy § 102.33 or the other regulatory provisions discussed below, it would not follow that petitioner's Lanham Act claim should be allowed. Rather, any non-compliance by respondent with that FDCA scheme is a matter for FDA (or in limited instances the States) to enforce under 21 U.S.C. § 337.

more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result." 58 Fed. Reg. at 2462. Petitioner's proposed regime in which private plaintiffs across the country can seek divergent standards would destroy the national uniformity that Congress sought to attain. See *supra*, at 2.

Nor, contrary to petitioner's suggestion (Br. 23), is there any *de minimis* exception to the naming rules of § 102.33, such that where the percentage contribution of the named single-strength juice is quite small, those rules no longer apply. Not only is such an exception absent from the text of § 102.33, but that text actually contemplates, see § 102.33(b) (citing 21 C.F.R. § 101.22(i)(1)(iii)), the situation where the percentage contribution of the named juice is so small that it does not itself suffice to be the characterizing flavor without the addition of additional flavoring that "simulates, resembles or reinforces the characterizing flavor." 21 C.F.R. § 101.22(i)(1)(iii). See also 58 Fed. Reg. at 2921 (recognizing that § 102.33(d)'s option of using "flavored" to indicate presence of non-named fruit juices would apply even where the named juice that precedes "flavored" is "less than 2 percent" of the beverage).

Petitioner finally argues that, "[b]ecause pomegranate juice and blueberry juice are not 'present as a flavor' as required by § 102.33(d), respondent cannot invoke that provision to show that its product's name complies with FDA's juice-naming regulations." Br. 50 (quoting 21 C.F.R. § 102.33(d)(1)). As an initial matter, this argument is waived because petitioner did not raise it in the courts below. See, *e.g.*, *Cutter* v.

Wilkinson, 544 U.S. 709, 718 n.7 (2005). In any event, the argument is incorrect because it assumes that the relevant regulation, § 102.33(d)(1), allows the name to include a non-predominant juice only if the *juice* (here, .3% and .2% pomegranate and blueberry juice concentrates, respectively) is *the* dispositive, characterizing flavoring agent. In fact, § 102.33(d)(1) does not so require; rather, the "juice" need only be "present as *a* flavor or flavoring," 21 C.F.R. § 102.33(d)(1) (emphasis added), and can be reinforced by added flavors (such as "essential oil[s]" or "extractive[s]," *id.* § 101.22(a)(3)) that, together with the juice(s), make the product taste like the named fruits.[30]

As to whether the juices-plus-added-flavors in fact make the product here taste like pomegranate and blueberry, a question raised by § 102.33(b) (where "the declared juices alone do not characterize the product before the addition of … added [natural] flavors," "the presence of added natural flavors is … required to be declared"), respondent answered "yes" through the words "AND OTHER NATURAL FLAVORS" (JA 38a),

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[30] The United States suggests (Br. 23, expressly departing from its certiorari-stage brief, see *id.* at 23 n.8 (so acknowledging)) that there may be a remaining factual question "whether pomegranate and blueberry juices in respondent's product are present as flavors or flavoring," but the United States should not be allowed to overcome petitioner's waiver of this issue. See *FTC* v. *Phoebe Putney Health Sys., Inc.*, 568 U.S. __, 133 S. Ct. 1003, 1010 n.4 (2013). In any event, pomegranate and blueberry juices (without added flavors) need not be *the* crucial flavoring agents as a matter of law for the reasons discussed in text, and that pomegranate juice and blueberry juice are each *a* flavor is clear from the absence of any statement on the label that these juices have been "deflavored," 21 C.F.R. § 102.33(e). Thus, contrary to the United States' suggestion, there is no need for remand for any factual development on this question.

and petitioner appears to agree, see Br. 50 ("It is added 'natural flavoring'—not actual pomegranate and blueberry *juice*—that (allegedly) gives the product a pomegranate-blueberry flavor.") (footnote omitted). At the very least, petitioner does not affirmatively dispute that factual proposition; the word "(allegedly)" surely cannot be enough to do so, especially where petitioner never asserted such an argument below.

Font sizes. Section 102.33(b)'s cross-reference to § 101.22(i)(1)(iii), which both petitioner and the United States ignore, specifically authorizes the sizes respondent chose for "POMEGRANATE" and "BLUEBERRY," on the one hand, and "FLAVORED BLEND OF 5 JUICES," on the other. As discussed above, § 102.33(b) allows the name to omit any list of single-strength juices in descending order by volume, and instead to declare a minority juice first, "e.g., raspberry-flavored apple and pear juice drink." 21 C.F.R. § 102.33(b). Section 102.33(b) then cross-references § 101.22(i)(1)(iii) as follows: "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." *Id.* § 102.33(b). And § 101.22(i)(1)(iii) in turn provides that, where the manufacturer *does* need to add such added flavors, "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*." *Id.* § 101.22(i)(1)(iii) (emphasis added). Section 102.33(b)'s cross-reference to § 101.22(i)(1)(iii) thus instructs that the words "flavored apple and pear juice drink" in the § 102.33(b) example must be not less than one-half the height of the word "raspberry," and, here, that

"FLAVORED BLEND OF FIVE JUICES" must be not less than one-half the height of "POMEGRANATE" and "BLUEBERRY."[31] As is evident from JA 38a, respondent's label meets this requirement.[32]

Even aside from § 102.33(b)'s cross-reference to § 101.22(i)(1)(iii), the "not less than one-half the height" requirement applies to the word "FLAVORED" (and hence logically to the words "BLEND OF 5 JUICES" that appear on the same line as "FLAVORED") by virtue of § 101.22(i)(1)(i). That regulation, it will be recalled, applies where "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[.]" 21 C.F.R. § 101.22(i)(1)(i). It further provides that, in such a circumstance, "the name of the characterizing flavor … 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., … 'strawberry flavored shortcake.'" *Ibid.* It applies here because, in

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[31] The cross-reference makes sense. The added flavors addressed by § 101.22(i)(1)(iii), like the non-named single-strength juices (here, apple, grape, and raspberry) addressed by § 102.33, are ingredients other than pomegranate and blueberry that need not be disclosed individually and instead may be referenced through words that follow "POMEGRANATE BLUEBERRY"—namely, through the words "FLAVORED BLEND OF 5 JUICES" (to satisfy § 102.33) and "OTHER NATURAL FLAVORS" (to satisfy § 101.22(i)(1)(iii)).

[32] Only by ignoring § 102.33(b)'s cross-reference to § 101.22(i)(1)(iii) is the United States able to assert (Br. 33) that the regulations at most provide the required height size for the word "FLAVORED" and not the words "BLEND OF 5 JUICES."

addition to the pomegranate juice concentrate and blueberry juice concentrate ingredients, the beverage contains natural pomegranate flavoring and natural blueberry flavoring. See JA 39a. As noted above, the words "FLAVORED BLEND OF 5 JUICES" are more than half the height of the words "POMEGRANATE BLUEBERRY" and hence comply with § 101.22(i)(1)(i).[33]

Finally, even if the "not less than one-half the height" requirement does not apply to § 102.33, it does not follow that FDA's regulations are silent on the issue. To the contrary, respondent's label would still be governed by (and comply with) 21 C.F.R. § 101.3(d): "This statement of identity"—here, the name, see § 101.3(b)—"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

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[33] Section 101.22(i)(1)(iii) also directly applies here (*i.e.*, even aside from the fact that it is cross-referenced by § 102.33(b)) because, in addition to the pomegranate juice concentrate and blueberry juice concentrate ingredients, the beverage contains other (*i.e.*, not pomegranate or blueberry) natural flavoring that simulates, resembles, or reinforces the overall pomegranate and blueberry flavors. See JA 39a. In keeping with § 101.22(i)(1)(iii), the "name of the food" is "immediately followed by the words 'with … other natural flavor[s]' [in caps, JA 38a] in letters not less than one-half the height of the letters used in the name of the characterizing flavor [*i.e.*, pomegranate and blueberry, in caps, JA 38a]." *Id.* § 101.22(i)(1)(iii). The "immediately followed" requirement is met because the name of the product consists not only of the words "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES" but also the words "FROM CONCENTRATE WITH ADDED INGREDIENTS," see *id.* §§ 102.33(g)(1), 101.30(b)(3), and those words are immediately followed by "AND OTHER NATURAL FLAVORS." Petitioner's contrary argument (Br. 50-51) ignores these regulations.

base on which the package rests as it is designed to be displayed."

As with the naming rules, the font-size rules—the "not less than one-half the height" requirement and/or the "size reasonably related to the most prominent printed matter" requirement—allow the manufacturer to choose its own nationally-uniform label within the bounds set by these requirements. The contrary regime proposed by petitioner and the United States again would allow private plaintiffs across the nation to seek a phalanx of divergent standards, disrupting Congress's national-uniformity goal. See *supra*, at 2. The United States' brief ignores FDA's recognition and endorsement, see 58 Fed. Reg. at 2462, of that national-uniformity goal.

Vignette. Petitioner waived this issue by raising it only in a footnote in its opening brief in the court of appeals, see Br. for Appellant, *supra* n. 6, at 28 n.11, after which the court specifically declined to address it because it was "not meaningfully" (Pet. App. 10a) raised. See, *e.g.*, *Sosa* v. *Alvarez-Machain*, 542 U.S. 692, 735 n.24 (2004) (A "footnote … is not enough to raise the question fairly, and we do not consider it.").[34]

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[34] The United States acknowledges the waiver but, contrary to its position in other cases, does not affirmatively argue that this Court should find the vignette issue waived. Compare U.S. Br. 30 n.14, with Brief for the United States as *Amicus Curiae* Supporting Respondent at 29, *Robertson* v. *United States*, 560 U.S. 272 (2010) (No. 08-6261), 2010 WL 783666 ("[I]t would be particularly inappropriate [to consider an argument waived by petitioner] because petitioner's waiver … means that the D.C. Court of Appeals never had an opportunity to answer key questions about the [relevant facts]."). The United States should not be allowed to inject this waived argument into the case. See *Phoebe Putney Health Sys*., 133 S. Ct. at 1010 n.4.

In any event, FDA's rulemaking authorizes this aspect of respondent's label as well. Specifically, some commenters (to FDA's proposed rule) requested "that the fruits … be depicted in proportion to the amount of each juice present." 58 Fed. Reg. at 2922. FDA rejected that proposal because, *inter alia*, "the relative size and the quantity of those fruits … are difficult to represent in a manner that would allow the consumer to readily recognize the quantity relationship." *Ibid.*

FDA thus again left manufacturers with the ability to include a vignette of their choosing that could be employed nationwide. Private Lanham Act suits seeking to impose idiosyncratic vignette requirements would disrupt national uniformity in contravention of Congress's intent. Petitioner might want a vignette that depicts a tiny pomegranate and blueberries relative to a larger apple and grapes; another plaintiff might insist on including percentage components below the vignette; another plaintiff might seek a ban on vignettes altogether. To the extent FDA left open the possibility of "case-by-case" analysis, 58 Fed. Reg. at 2922, it meant analysis by "*[t]he agency*," *ibid.* (emphasis added), not by private Lanham Act plaintiffs. Moreover, respondent's vignette actually serves to make the label less, not more, misleading insofar as it depicts all five fruits, and thus underscores to consumers the message sent by "FLAVORED BLEND OF 5 JUICES," JA 38a, *i.e.*, that pomegranate and blueberry are not the only juices present. See 58 Fed. Reg. at 2921-22 (refusing to require that vignette depict all fruits, but noting that doing so "would provide useful information").

Division of name onto multiple lines. Petitioner waived this argument (Br. 23) as well, raising the argument only in a footnote in its opening brief in the

court of appeals, see Br. for Appellant, *supra* n. 6, at 28 n.11, and the court of appeals did not address it. See *Cutter*, 544 U.S. at 718 n.7 ("Because these [arguments] were not addressed by the Court of Appeals, and mindful that we are a court of review, not of first view, we do not consider them here.").[35]

In any event, this aspect of respondent's label is authorized by FDA's regulation acknowledging that the name may appear "in *lines*." 21 C.F.R. § 101.3(d) (emphasis added). FDA could have but did not mandate that the name appear on a single line, a requirement that would be impractical because "[s]ome juice beverages will have very complex common or usual names." FDA, *A Food Labeling Guide* 11 (Jan. 2013), *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf. Again, if private Lanham Act suits are allowed on this issue, the potential for divergent standards is manifest: One plaintiff might seek to require that the entire name appear on the same line, another plaintiff might be amenable to having the name on two but not more lines, yet another plaintiff might be indifferent as to the number of lines so long as they appear within a bold highlighted box.

Coloring. Petitioner waived this argument (Br. 2, 23-24) by failing to raise it in any fashion before the court of appeals panel, which consequently did not

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[35] While the United States at least acknowledges petitioner's waiver problem regarding the vignette, *see supra* at 45 n. 34, the United States (Br. 33) fails to recognize that the same problem exists as to petitioner's "division onto multiple lines" argument, and indeed the United States affirmatively advances (*ibid.*) this argument on the merits. The United States again should not be allowed to inject this waived argument into the case. See *Phoebe Putney Health Sys.*, 133 S. Ct. at 1010 n.4.

address it.[36] In any event, FDA's regulation specifies that the "statement of ingredients," 21 C.F.R. § 101.22(k)—as opposed to the front label—must declare color additives of the type here using terms such as "'Color Added,'" "'Colored with __,'" or "an equally informative term that makes clear that a color additive has been used in the food," *id.* § 101.22(k)(2). Respondent's statement of ingredients complies by including "FRUIT AND VEGETABLE JUICES (FOR COLOR)." JA 39a. Petitioner and other private plaintiffs may not impose different standards.

It is evident from the foregoing discussion that the FDCA and FDA regulations, on the one hand, and a Lanham Act suit like petitioner's, on the other, seek to regulate the same thing—the name and label of a juice beverage—in non-identical ways. Petitioner's argument (Br. 25-26) that the supposedly distinct purposes of the FDCA/NLEA and the Lanham Act eliminate this tension is incorrect. To begin with, both the FDCA and the Lanham Act share the goal of preventing consumers from being deceived. Compare, *e.g.*, 21 U.S.C. § 341 (FDCA "promote[s] honesty and fair dealing in the interest of consumers"), with *Am. Home Prods. Corp.* v. *Johnson & Johnson*, 577 F.2d 160, 165 (2d Cir. 1978) (Lanham Act § 43(a) seeks to "protect[] against … sophisticated deception" as "tested by the reactions of the public").[37] Moreover,

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[36] The United States discusses neither the waiver nor the merits aspects of petitioner's coloring argument.

[37] In contrast, the different laws in the cases cited by petitioner (Br. 25) did not regulate the same subject matter. See, *e.g.*, *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 144 (2001) (laws only "partial[ly]" "overlap[ped]"); *Bd. of Sup'rs of Wood Cnty.* v. *Lackawana Iron & Coal Co.*, 93 U.S. 619, 622

regardless of the Lanham Act's underlying policies, the greater stringency that private plaintiffs might seek under that Act directly undermines Congress's intent in the FDCA/NLEA. As FDA recognized, "in enacting the [NLEA], Congress decided that even though Federal requirements might preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result." 58 Fed. Reg. at 2462.

III. PETITIONER'S REMAINING ARGUMENTS ARE UNPERSUASIVE

Petitioner concludes (Br. 52-56) with a plea that its Lanham Act claim should be allowed because, *first*, FDA supposedly lacks resources to regulate food naming and labeling, and *second*, finding the Lanham Act claim precluded here will allegedly require the same outcome in numerous non-food sectors. Neither argument has merit.

A. FDA Determined That The Relevant FDCA Provisions Were Adequately Implemented, And In Any Event National Uniformity Was Congress's Overriding Goal

Petitioner asserts (without basis) that FDA lacks adequate resources without explaining why that issue is legally relevant. For several reasons, it is not.

First, as discussed *supra*, at 7, in 1993, FDA certified that FDCA § 403(f) and (i)(1) were "adequately implemented." 58 Fed. Reg. at 2473-74. The NLEA

(1876) (laws applied to different companies and geographic areas).

does not prescribe any mechanism for FDA to retract that determination. Accordingly, it is that determination, and not the reports cited by petitioner (Br. 53-54) and its *amicus* Donald Kennedy (Br. 7-11), that is dispositive here. Tellingly, the United States' brief (signed by several officials of HHS (of which FDA is a part)) does not suggest that FDA's resources are inadequate.

Second, FDA, even aside from its "adequately implemented" certification, has engaged in robust enforcement of the FDCA's food naming/labeling provisions, issuing numerous warning letters relating to food each year. See FDA, Inspections, Compliance, Enforcement, and Criminal Investigations: Warning Letters, http://www.fda.gov/iceci/enforcementactions/WarningLetters/default.htm (search for "food labeling").[38] Mr. Kennedy diminishes such letters as "typically the extent of [FDA's] enforcement activity" (Kennedy Br. 9 (internal quotation marks omitted)), but he does not explain why they are insufficient. In fact, according to FDA, they are highly successful. See Office of Inspector General, Dep't of Health and Human Services, FDA Warning Letters—Timeliness and Effectiveness 2 (Feb. 1999), *available at* https://oig.hhs.gov/oei/reports/oei-09-97-00381.pdf ("When FDA conducts follow-up activities, it finds that firms have either corrected the violations cited in warning letters or have made significant progress toward doing so. Almost 90 percent of firms respond in writing to warning letters within 15 days of receiving them,

[38] Petitioner itself has been a recipient. See Letter from FDA to Matt Tupper, dated February 23, 2010, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202785.htm.

detailing corrective actions that they intend to take.").[39]

Third, even if FDA lacked resources to regulate food naming and labeling, it does not follow that allowing private Lanham Act claims is the solution Congress intended. To the contrary, Congress recognized that private suits would beget a worse problem by subjecting food manufacturers to a patchwork of constantly shifting standards across the country. And it was *that* problem that Congress deemed paramount and sought to resolve in enacting the NLEA's "national uniform[ity]" provision. In FDA's words, "Congress decided that … the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result." 58 Fed. Reg. at 2462.[40] Cf. *Astra*, 131 S. Ct. at 1350 (despite reports "of inadequate [agency] enforcement," "Congress did not respond … by inviting 340B entities to launch lawsuits in district courts across the country").

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[39] *Amici curiae* Public Citizen *et al.* incorrectly assert (Br. 21) that FDA issued only one warning letter from February 1, 2013 to February 1, 2014 regarding food labeled in a misleading manner. See also Letter from FDA to Cheryl Stewart, dated March 28, 2013, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm346316.htm; Letter from FDA to Riad Shatila, dated March 6, 2013, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm354203.htm. Moreover, *amici* have not shown that additional instances occurred that escaped a warning letter.

[40] *Amici* States, in dismissing national uniformity as a "sub-goal" (Alaska Br. 21), ignore this FDA statement, the title of the NLEA's preemption clause, and the legislative history. *Amici* States, unlike private plaintiffs, enjoy certain rights to enforce the FDCA, 21 U.S.C. § 337(b), and to seek exemptions from the NLEA's preemption clause, *id.* § 343-1(b).

B. Preclusion Of Petitioner's Lanham Act Claim As To The Juice Naming And Labeling Issues Here Will Not Curtail The Lanham Act In Other Circumstances

Contrary to petitioner's exaggerated assertion (Br. 55), a holding that its Lanham Act claim is precluded under the circumstances here will not "preclude a Lanham Act suit … in any regulated field." As an initial matter, a Lanham Act § 43(a) claim would not even be precluded in all circumstances involving food labeling. For example, because there is no FDCA provision on religious dietary labeling, see 56 Fed. Reg. at 60530, and certainly no such provision that has preemptive force under the NLEA's pre-emption clause, a private plaintiff could sue under Lanham Act § 43(a) if its competitor falsely labeled its product "kosher" or "halal."

Nor will Lanham Act § 43(a) suits be precluded in the other areas that petitioner cites (Br. 54-55) as examples, apart perhaps from cosmetics labeling. See Br. 54-55 (citing *Astiana* v. *Hain Celestial Group, Inc.*, 905 F. Supp. 2d 1013, 1014 (N.D. Cal. 2012)). Although that court did not address the question, the portion of the FDCA at issue contains an express preemption clause, 21 U.S.C. § 379s, similar to the NLEA's, such that the analysis in Point II.B, *supra*, may suggest preclusion of a Lanham Act claim.[41]

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[41] On the other hand, unlike in 21 U.S.C. § 343-1, Congress did not postpone the effectiveness of 21 U.S.C. § 379s until the agency had determined that the provisions to be given preemptive force were adequately implemented. Additionally, the analysis in Point II.C, *supra*, would not apply because FDA had not engaged in any detailed regulation of use of the words "all natural," "pure

As to petitioner's second example (Br. 55), the Organic Food Products Act does not contain an express preemption clause, rendering inapplicable the analysis in Point II.B, *supra*, and the agency had not yet issued a regulation authorizing the use of the ingredients in the product, rendering inapplicable the analysis in Point II.C, *supra*.

Petitioner's final example (Br. 55) is easily dispatched. The FTC Act, unlike the FDCA, contains an explicit provision that the FTC Act should not "be construed to prevent or interfere with the enforcement of the provisions of," or "to alter, modify or repeal," "the antitrust Acts or the Acts to regulate commerce." 15 U.S.C. § 51. See also *id.* § 1127 (Lanham Act "regulate[s] commerce"). Congress has thus directed that the FTC Act should *not* foreclose a claim under the Lanham Act.[42] By contrast, the FDCA and NLEA contain no such savings clause, and they do contain an express preemption clause that reveals Congress's intent to promote national uniformity and to bar suits by private plaintiffs that would undermine national uniformity.

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natural," and "pure, natural & organic," and thus the defendant could not argue that its product label was authorized by FDA's regulations.

[42] Moreover, the "regulatory guides" petitioner cites (Br. 55), unlike the FDCA provisions and FDA regulations at issue, provide the basis for "*voluntary* [compliance]," 16 C.F.R. pt. 17 (emphasis added), and thus "lack the force of law," *Christensen* v. *Harris Cnty.*, 529 U.S. 576, 587 (2000).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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APPENDIX

APPENDIX

1. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6, 104 Stat. 2353, 2362-64 provides:

Sec. 6. NATIONAL UNIFORM NUTRITION LABELING.

(a) PREEMPTION.—Chapter IV is amended by adding after section 403 the following new section:

SEC. 403A. (a) Except as provided in subsection (b), 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 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g),

(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), or 403(i)(2) that is not identical to the requirement of such section,

(3) any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) that is not identical to the requirement of such section,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q), except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A), or

(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label

or labeling of food that is not identical to the requirement of section 403(r), except a requirement respecting a claim made in the label or labeling of food which is exempt under clause (B) of such section.

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), 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).

(b) STUDY AND REGULATIONS.—

(1) For the purpose of implementing section 403A(a)(3), the Secretary of Health and Human Services shall enter into a contract with a public or nonprofit private entity to conduct a study of—

(A) State and local laws which require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act, and

(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to

enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

(2) The contract under paragraph (1) shall provide that the study required by such paragraph shall be completed within 6 months of the date of the enactment of this Act.

(3)(A) Within 9 months of the date of the enactment of this Act, the Secretary shall publish a proposed list of sections which are adequately being implemented by regulations as determined under paragraph (1)(B) and sections which are not adequately being implemented by regulations as so determined. After publication of the lists, the Secretary shall provide 60 days for comments on such lists.

(B) Within 24 months of the date of the enactment of this Act, the Secretary shall publish a final list of sections which are adequately being implemented by regulations and a list of sections which are not adequately being implemented by regulations. With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to the requirement of such section.

(C) Within 24 months of the date of the enactment of this Act, the Secretary shall publish proposed revisions to the regulations found to be inadequate under subparagraph (B) and within 30 months of such date shall issue final revisions. Upon the effective date of such final revisions, no State or political subdivision may establish or continue in

effect any requirement which is not identical to the requirement of the section which had its regulations revised in accordance with this subparagraph.

(D)(i) If the Secretary does not issue a final list in accordance with subparagraph (B), the proposed list issued under subparagraph (A) shall be considered the final list and States and political subdivisions shall be preempted with respect to sections found to be adequate in such proposed list in accordance with subparagraph (B).

(ii) If the Secretary does not issue final revisions of regulations in accordance with subparagraph (C), the proposed revisions issued under such subparagraph shall be considered the final revisions and States and political subdivisions shall be preempted with respect to sections the regulations of which are revised by the proposed revisions.

(E) Subsection (b) of section 403A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the prohibition prescribed by subparagraphs (B) and (C).

(c) CONSTRUCTION.—

(1) The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act.

(2) The amendment made by subsection (a) and the provisions of subsection (b) shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.

(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code.

2. 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 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 substantially 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.

3. 21 U.S.C. § 321 provides in pertinent part:

Definitions; generally

* * * * *

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the

labeling or advertising thereof or under such conditions of use as are customary or usual.

* * * * *

4. 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 settled 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.

5. 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)[1] of this title 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.

* * * * *

6. 15 U.S.C. § 1125 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

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

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.

* * * * *

7. 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.

* * * * *

8. 21 C.F.R. § 101.4 provides in pertinent part:

Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that

comply with standards of identity, except those ingredients exempted by 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with 101.36 need not be repeated in the ingredient list. * * *

* * * * *

9. **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 natural 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.

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(k) The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings added to foods subject to 105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.

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(2) Color additives not subject to certification and not otherwise required by applicable regulations in part 73 of this chapter to be declared by their respective common or usual names may be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as "Colored with _____" or "_____ color," the blank to be filled in with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

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10. 21 C.F.R. § 102.5 provides in pertinent part:

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.

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11. 21 C.F.R. § 102.33 provides in pertinent part:

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").

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(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.

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