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 PETITIONER

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QUESTION PRESENTED

Whether the court of appeals erred in holding that a private party cannot bring a Lanham Act claim challenging a product label regulated under the Food, Drug, and Cosmetic Act.

PARTIES TO THE PROCEEDINGS

The case caption contains the names of all parties who were parties in the court of appeals.

RULE 29.6 STATEMENT

Pom Wonderful LLC is directly owned by Pom Wonderful Holdings LLC, which is directly owned by Roll Global LLC and ultimately owned by Stewart and Lynda Resnick as trustees of the Stewart & Lynda Resnick Revocable Trust. No publicly held company holds any interest in the Stewart & Lynda Resnick Revocable Trust.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-14a) is reported at 679 F.3d 1170. The district court's motion to dismiss orders (Pet. App. 75a-101a) are unreported. The district court's summary judgment order (Pet. App. 21a-73a) is reported at 727 F. Supp. 2d 849.

JURISDICTION

The court of appeals entered judgment on May 17, 2012. The court denied rehearing and rehearing en

banc on August 8, 2012. Pet. App. 15a-16a. On October 31, 2012, Justice Kennedy extended the time within which to file a petition for a writ of certiorari to and including December 21, 2012. The petition was filed on that date and granted on January 10, 2014. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS AND REGULATIONS

The relevant provisions of the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*; the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*; and the Food and Drug Administration's regulations, 21 C.F.R. pts. 101 & 102, are set forth in the Appendix to this brief.

PRELIMINARY STATEMENT

Respondent Coca-Cola has designed its "Pomegranate Blueberry" juice product to mislead consumers. Over 99% of the product is apple and grape juice. The amounts of pomegranate and blueberry juice it contains—0.3% and 0.2% respectively—are so trivial that no consumer could perceive them. Yet every aspect of the product's appearance is tailored to convince consumers that it contains significant amounts of pomegranate and blueberry juice. The words "Pomegranate" and "Blueberry" appear in large font on the front of the bottle, each occupying a single line of the label. These words dwarf the FDA-required disclaimer, "Flavored Blend of 5 Juices," which is set in significantly smaller font on a separate line below the product name. The bottle prominently displays images of a pomegranate and oversized blueberries, which appear, respectively, in front of images of an apple and grapes. The product is colored deep purple to resemble pomegranate and blueberry juice. *See infra* p. 9 (image).

Petitioner Pom Wonderful LLC sells pomegranate juice and pomegranate juice blends that compete with Coca-Cola's product. A consumer survey conducted by Pom showed that consumers are misled in large numbers to believe that Coca-Cola's product actually has substantial amounts of pomegranate and blueberry juice. Having concluded that it was losing sales of its actual pomegranate juice products to Coca-Cola's deceptive product, Pom brought suit under the Lanham Act. An internal Coca-Cola document produced in discovery revealed that Coca-Cola knew its "Pomegranate Blueberry" product posed "a risk from a misleading standpoint as the product has less than 0.5% pomegranate and blueberry juices"—but was "willing to assume the risk."

The Ninth Circuit held that Pom's Lanham Act challenge must be dismissed as a matter of law. It concluded that no matter how misleading Coca-Cola's product is, the Food, Drug, and Cosmetic Act ("FDCA") impliedly bars Pom's suit. The court recognized that no provision of the FDCA precludes Lanham Act actions, and the court did not dispute that Coca-Cola could have complied with the requirements of both statutes. The court further acknowledged that FDA's regulations implementing the FDCA do not address all aspects of Coca-Cola's misleading label and that it was unclear whether Coca-Cola's product in fact complied with the regulations to the extent they applied. The Ninth Circuit nonetheless held that Lanham Act challenges to misleading food labels are impliedly precluded because FDA regulates food labeling under the FDCA. There is no support for that sweeping holding, which would shield a broad range of indisputably misleading statements from challenge, even by competitors directly harmed by those statements.

As a matter of separation of powers, the courts are duty bound to give effect to all federal statutes unless Congress has directed otherwise or the statutes irreconcilably conflict. Here, Congress did not create an exception to the Lanham Act for food labeling claims, and Coca-Cola could easily have complied with both the Lanham Act and the FDCA. Accordingly, the judgment should be reversed.

STATEMENT

A. Statutory And Regulatory Framework

1. The Lanham Act

In 1946 Congress enacted the Lanham Act to make "actionable the deceptive and misleading use of marks"; "protect persons engaged in [interstate] commerce against unfair competition"; and "provide rights and remedies stipulated by treaties and conventions respecting … unfair competition." Pub. L. No. 79-489, § 45, 60 Stat. 427, 444 (1946) (codified at 15 U.S.C. § 1127) (noting the "intent" of the Act); *see also Dastar Corp.* v. *Twentieth Century Fox Film Corp.*, 539 U.S. 23, 28-29 (2003). Congress intended the Act to secure to a business owner "the good will of his business and protect[] the public against spurious and falsely marked goods." S. Rep. No. 79-1333, at 3 (1946), *reprinted in* 1946 U.S.C.C.A.N. 1274; *see also, e.g.*, *Conte Bros. Automotive, Inc.* v. *Quaker State-Slick 50, Inc.*, 165 F.3d 221, 229 (3d Cir. 1998) (Alito, J.) (Lanham Act "focus[es] … on anti-competitive conduct in a commercial context.").

The Act protects businesses from unfair competitive acts by providing a private cause of action to a commercial plaintiff that has been harmed by a competitor's false advertising. 15 U.S.C. § 1125(a)(1)(B). As

amended, § 1125(a) imposes liability, in relevant part, on

> 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 or misleading description of fact, or false or misleading representation of fact, which … (B) … misrepresents the nature, characteristics, qualities, or geographic origin of his or her … goods[.]

Id. § 1125(a)(1)(B).[1] The Act thus provides a private remedy to a "commercial plaintiff" whose "commercial interests" have been harmed through false or misleading representations. *Sandoz Pharm. Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990).

2. The FDCA

Enacted in 1938 (*see* Pub. L. No. 75-717, 52 Stat. 1040 (1938)), the FDCA regulates (among many other things) the labeling of food and beverages. The statute prohibits the misbranding of "food," 21 U.S.C. § 331,

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[1] Section 1125 has been amended on several occasions since 1946, including when Congress enacted the Trademark Law Revision Act of 1988, Pub. L. No. 100-667, § 132, 102 Stat. 3935, 3946, which redrafted § 1125(a) and largely codified pre-1988 case law. *See* S. Rep. No. 100-515, at 40-41 (1988), *reprinted in* 1988 U.S.C.C.A.N. 5577, 5603-5604; *ALPO Petfoods, Inc.* v. *Ralston Purina Co.*, 913 F.2d 958, 964 n.6 (D.C. Cir. 1990); *see also, e.g.*, Trademark Remedy Clarification Act, Pub. L. No. 102-542, § 3(c), 106 Stat. 3567, 3568 (1992) (adding 15 U.S.C. § 1125(a)(2)); Trademark Amendments Act of 1999, Pub. L. No. 106-43, § 5, 113 Stat. 218, 220 (adding 15 U.S.C. § 1125(a)(3)).

which includes any "article[] used for food or drink for man," *id.* § 321(f). The statute then specifies circumstances in which a food is "deemed to be misbranded." *Id.* § 343. These include instances where "labeling is false or misleading in any particular"; where required information "is not prominently placed thereon with [sufficient] conspicuousness"; and where a label fails to "bear … the common or usual name of the food." *Id.* § 343(a), (f), (i)(1).

In 1990 Congress amended the FDCA's labeling provisions by enacting the Nutrition Labeling and Education Act ("NLEA"). Pub. L. No. 101-535, 104 Stat. 2353 (1990).[2] Among its reforms, the NLEA required nutritional labeling for most food products and regulated the manner in which food labels characterize the nutrients present in a product and the relationship between those nutrients and health conditions. *See, e.g.*, *id.* §§ 2-3 (codified at 21 U.S.C. § 343(q)-(r)).

Whereas the Lanham Act is intended to protect against unfair competition, the FDCA's misbranding provisions seek principally to protect public health and

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[2] In addition to enacting the NLEA in 1990, Congress has amended the FDCA's food misbranding provisions on several other occasions since 1938. *See, e.g.*, Color Additive Amendments of 1960, Pub. L. No. 86-618, § 102(a)(3), 74 Stat. 397, 398 (adding 21 U.S.C. § 343(m)); Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 7(a), 108 Stat. 4325, 4329-4330 (adding 21 U.S.C. § 343(s)); Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 308(b), 116 Stat. 594, 672-673 (adding 21 U.S.C. § 343(v)); Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, tit. 2, § 203(a), 118 Stat. 891, 906-908 (adding 21 U.S.C. § 343(w)-(x)).

safety. *See 62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951); *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331-332 (3d Cir. 2009). Presumably for that reason, the FDCA does not create a private cause of action to remedy noncompliance; the statute permits only government enforcement. *See* 21 U.S.C. § 337(a). In contrast to the Lanham Act's civil liability provisions, violations of the FDCA's prohibition on misbranding of food may be criminally prosecuted. *See id.* § 333(a).

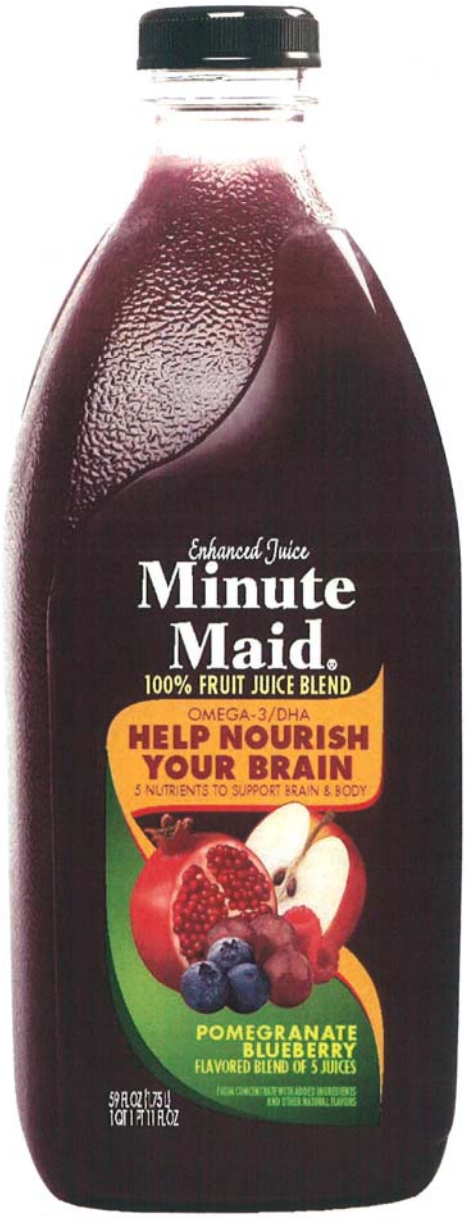
FDA has promulgated regulations that relate to various aspects of food labeling, including labeling of juice products. *See, e.g.*, 21 C.F.R. § 101.18(b) (misbranding of food by selective inclusion of ingredients in a product's name), § 102.5(b) (naming of food products where characterizing ingredients bear on price or consumer acceptance), § 102.33(b)-(d) (naming of beverages containing multiple juices). *See infra* pp. 22-24, 47-52.

Both as originally enacted and as amended by the NLEA, the FDCA's misbranding provisions do not purport to displace other provisions of federal law. By contrast, the NLEA does specifically address the FDCA's effect on state laws. *See* Pub. L. No. 101-535, § 6 (21 U.S.C. § 343-1 & note). The statute narrowly displaces only those state laws that purport to impose labeling requirements "of the type" imposed by certain enumerated provisions of the FDCA that are not "identical" to the requirements of those provisions. 21 U.S.C. § 343-1(a)(2), (3). In a parallel saving clause, Congress specified that no further preemption of state law should be implied from the NLEA's preemption provision. *See* Pub. L. No. 101-535, § 6(c)(1) (21 U.S.C. § 343-1 note).

B. Coca-Cola's Willful Deception

This is a classic Lanham Act false advertising case. Pom and Coca-Cola compete directly in the market for pomegranate juices. JA 25a, 27a-28a. Pom is the largest grower of pomegranates and distributor of pomegranate juice in the United States. JA 23a. It has been selling and marketing its juice products since 2002. *Id.* Through its POM WONDERFUL® brand, Pom produces, markets, and sells bottled pomegranate juice and various pomegranate juice blends, including a pomegranate-blueberry juice blend. *Id.* Pom has been a driving force in the development of the pomegranate and pomegranate juice market. *Id.* 23a-25a. Its efforts have propelled Pom to commercial success. *Id.* 24a.

Coca-Cola is one of Pom's primary competitors in the juice market. JA 25a, 27a-28a. Coca-Cola markets and sells various bottled juices and juice blends under its Minute Maid brand. Pet. App. 1a; JA 25a. In September 2007, Coca-Cola announced the launch of a new "Pomegranate Blueberry" juice product. *Id.* Unbeknownst to consumers, over 99% of Coca-Cola's "Pomegranate Blueberry" juice is actually apple and grape juice. Pet. App. 2a; *see also* JA 23a, 26a. It contains only trivial amounts of pomegranate juice (0.3%) and blueberry juice (0.2%). Pet. App. 2a, 30a. Notwithstanding the actual contents of the product, the front label of Coca-Cola's product is as follows:


Enhanced Juice
Minute Maid
100% FRUIT JUICE BLEND
OMEGA-3/DHA
HELP NOURISH YOUR BRAIN
5 NUTRIENTS TO SUPPORT BRAIN & BODY
POMEGRANATE BLUEBERRY
FLAVORED BLEND OF 5 JUICES

CA ER 112 (bottle); *see also* JA 38a (enlarged label).

The overall appearance of the product is unquestionably designed to emphasize pomegranate and blueberry juice. The name "Pomegranate Blueberry" appears in large font—with the words "Flavored Blend of 5 Juices" appearing only in smaller font on a different line below the name. The vignette on the bottle displays a pomegranate and blueberries at least as prominently as an apple and grapes. And Coca-Cola adds coloring so that the contents resemble pomegranate and blueberry juice. *See, e.g.*, JA 39a ("FRUIT AND VEGETABLE JUICES (FOR COLOR)"). Nowhere on Coca-Cola's label are the actual juice percentages disclosed. In fact, Coca-Cola's front label does not even mention the product's overwhelmingly dominant ingredients—apple juice or grape juice—by name.

The summary judgment record in this case confirms that Coca-Cola's "Pomegranate Blueberry" product is, in fact, misleading to consumers. A consumer survey conducted by E. Deborah Jay, President and CEO of the respected Field Research Corporation, revealed unsurprisingly that

> a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that [Coca-Cola's juice] mainly contains pomegranate and blueberry juice (and not other types of fruit juice) due to the packaging (the words "pomegranate blueberry" on the front of the bottle and in the product name on the back of the bottle).

JA 96a; *see also* Pet. App. 32a-33a. Indeed, 36% of the consumers who were shown the juice's bottle believed that the juice contains mainly pomegranate and blueberry juice. *See* JA 95a; Pet. App. 32a-33a n.8.

Coca-Cola "has received a record number of complaints" regarding its "Pomegranate Blueberry" product. Pet. App. 31a. A fourteen-year employee of Coca-Cola who has "field[ed] consumer complaints about many products" admitted in deposition testimony (which she later tried to recant) "that there have been no Minute Maid products about which consumers have complained more." *Id.* (internal quotation marks omitted). One consumer, for example, complained:

> Today I made the mistake of buying [the] Minute Maid product that you call "Pomegranate Blueberry[.]" What a crock. It's nothing but fancy apple grape juice. You people are scumbags for mislabeling your products. I'll never buy this product again. I'll never buy Minute Maid products again. And I'll tell all of my friends about this fraud. Thanks for wasting my time and money ….

Id. 31a-32a (alterations and omission in original) (footnote omitted).

None of this came as a surprise to Coca-Cola. To the contrary, prior to the launch of the product, Coca-Cola's Director of Scientific and Regulatory Affairs sent an internal email stating:

> As discussed here is a copy of the front label for the new MM Enhanced Juice Pomegrante [sic] Blueberry product. The product has a blend of apple, grape, pomegranate, blueberry & raspberry juices from conc. We are in compliance with the FDA regs related to the naming of juice containing products. *There is a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices.* [The President and General Manager of

> Minute Maid] is *aware of this issue & is willing to assume the risk*.

Pet. App. 34a-35a (emphases added).

C. Proceedings Below

1. In September 2008 Pom brought this lawsuit under the Lanham Act and California law. Pet. App. 3a. Pom alleged that it had lost sales because Coca-Cola's labeling, marketing, and advertising misled consumers to believe that Coca-Cola's "Pomegranate Blueberry" product consists primarily of pomegranate and blueberry juices, when in fact it consists almost entirely of the less expensive and less desirable apple and grape juices. *Id.*

Coca-Cola moved to dismiss Pom's Lanham Act claim on the ground that Coca-Cola's label complied with FDA juice-naming regulations permitting a beverage to be named after a non-predominant juice in certain circumstances. The district court granted Coca-Cola's motion in part. Pet. App. 83a. The court concluded that Pom's Lanham Act claim was barred by FDA juice-naming regulations to the extent it challenged the name and label of Coca-Cola's "Pomegranate Blueberry" product. *Id.* 89a-91a. The court permitted Pom to pursue its challenge to Coca-Cola's advertising and other marketing of the product. *Id.* 91a-92a. Pom subsequently filed an amended complaint, and, after the district court denied Coca-Cola's motion to dismiss that complaint, the parties conducted discovery. *Id.* 37a, 75a-81a.

The parties then cross-moved for summary judgment. Pet. App. 37a-38a. The district court granted partial summary judgment to Coca-Cola, reiterating its prior ruling that Pom's Lanham Act claim was barred

by FDA's regulations to the extent it challenged Coca-Cola's label. *See id.* 60a-69a.[3]

2. The Ninth Circuit affirmed, holding that "the FDCA and its regulations bar pursuit of both the name and labeling aspects of Pom's Lanham Act claim." Pet. App. 9a. The court of appeals recognized that FDA had never approved the label, *see* Pet. App. 11a-12a, and the court avoided making any definitive pronouncement about whether the label is in fact "authorized" by FDA's regulations. The court explained that it was "primarily guided" in its decision "not by Coca-Cola's apparent compliance with FDA regulations but by Congress' decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* 12a.

The Ninth Circuit acknowledged that FDA apparently had not made any judgment that Coca-Cola's label comports with the FDCA, *see* 21 U.S.C. § 343(a), noting that "FDA has apparently not taken a view on whether Coca-Cola's labeling misleads consumers." Pet. App. 11a-12a. That was true in particular of Coca-Cola's use of a significantly smaller font size for the words "Flavored Blend of 5 Juices" than for the words "Pomegranate Blueberry." The Ninth Circuit found it sufficient that "*so far as we can tell*," the agency had not "*required* that all words in a juice blend's name appear on the label in the same size …." *Id.* 10a (empha-

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[3] The parties subsequently agreed to entry of judgment with respect to Pom's challenges to Coca-Cola's advertising and other marketing, with Pom preserving its right to appeal the court's motion to dismiss and summary judgment orders. *See* Pet. App. 17a-19a.

ses added). On that view, the court found it sufficient that, "[i]f the FDA believes that [the relative font sizes used in the label] mislead[] consumers, it can act." *Id.* 11a; *see also id.* ("If the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act.").

The Ninth Circuit was similarly noncommittal in its discussion of the name of Coca-Cola's "Pomegranate Blueberry" product, again noting merely that "*as best we can tell*, FDA regulations authorize the name Coca-Cola has chosen." Pet. App. 9a (emphasis added). Indeed, while the Ninth Circuit explained that under FDA's regulations a product's name may reference non-predominant juices if they provide the product's flavor, *see id.*, nowhere did the court point to any evidence that the trace amounts of pomegranate juice and blueberry juice (.3% and .2%, respectively) in fact provide the product's flavor.

Having deemed it irrelevant as a matter of law whether Coca-Cola's label in fact complied with FDA's regulations, the Ninth Circuit expressly left any assessment of that kind to the agency: "[W]e must keep in mind that we lack the FDA's expertise …. In the circumstances here, the appropriate forum for [Pom's] complaints is the [FDA]." Pet. App. 12a (internal quotation marks omitted; second and third alterations in original). The court of appeals thus precluded application of the Lanham Act to a broad range of potentially misleading statements in a variety of diverse contexts solely on the ground that they are subject to "comprehensive" FDA regulation. *Id.*; *see also id.* 8a ("[T]he Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority."); *id.* 11a ("[F]or a court to act when the FDA has not—despite

regulating extensively in this area—would risk undercutting the FDA's expert judgments and authority.").

SUMMARY OF ARGUMENT

Neither the FDCA nor the Lanham Act contains any provision limiting application of the Lanham Act in challenges to misleading food labels. Because there is no textual basis for an FDA-compliance exception to the Lanham Act, such an exception may be adopted, if at all, only by implication. The presumption against such implied repeals is exceptionally strong: When two federal statutes overlap, both federal statutes must be given effect unless they are in "irreconcilable conflict."

Coca-Cola does not begin to satisfy that demanding standard. Coca-Cola could easily have complied with the FDCA, FDA's juice-naming regulations, and the Lanham Act. Nothing in the FDCA or FDA's regulations required Coca-Cola to design its product in the misleading way it chose. Nor is there any conflict between the purposes and remedies of the two statutes. The Lanham Act protects competitors and can be enforced in private actions by businesses harmed by their competitors' false labeling, including misleading food labels. The FDCA protects public health and safety. It can be enforced only by the government and imposes criminal penalties that must necessarily be construed narrowly. The statutes thus work in tandem to ensure that products are marketed in ways that are both safe for consumers and not unfair to competitors.

Indeed, the structure and history of the FDCA strongly indicate that Congress intended *not* to preclude Lanham Act claims in the realm of food labeling. The Lanham Act has been used to challenge food labeling for decades. Yet Congress has not enacted any

provision purporting to preclude those kinds of claims. The absence of any express preclusion is particularly conspicuous because in 1990 Congress *did* add an express state-law preemption provision to the FDCA's regulation of food labeling. Had Congress intended to foreclose Lanham Act suits challenging food labels, it easily could have done so as part of that enactment.

The conclusion that the FDCA does not preclude application of the Lanham Act to misleading juice labels follows inexorably from this Court's holding in *Wyeth* v. *Levine*, 555 U.S. 555 (2009), that FDA's approval of a drug label does not displace state failure-to-warn suits challenging the adequacy of the warning. *Wyeth* involved FDA's implementation of the FDCA in a manner that reflected the agency's substantive judgment about the label's adequacy. FDA specifically approved, and mandated use of, the precise wording on Wyeth's label; at that time, it was uncertain whether Wyeth was even permitted to alter the label without prior permission; and FDA contended that state tort law was preempted. This Court nonetheless concluded that the state-law challenge was not preempted, holding that the FDCA merely sets a floor upon which other laws can build. Following *Wyeth*, there can be no serious argument that the provisions of the FDCA at issue in this case are in "irreconcilable conflict" with the Lanham Act. FDA does not even generally *review*—much less approve—particular food labels; nothing even arguably prevented Coca-Cola from designing its label to avoid misleading consumers; and FDA has given no indication that its juice-naming rules set the outer bounds of labeling regulation. Moreover, as with respect to the claim at issue in *Wyeth*, Congress has declined to enact a provision precluding Lanham Act chal-

lenges to food labels despite decades of coexistence between the Lanham Act and the FDCA.

The Ninth Circuit's contrary holding did not apply this Court's "irreconcilable conflict" precedents or even acknowledge *Wyeth*. Instead, the court found that FDA's mere regulatory authority under the FDCA displaced the Lanham Act. To reach this conclusion, the court misapplied principles drawn from the doctrines of field preemption and primary jurisdiction—neither of which applies here.

Tellingly, Coca-Cola has not even attempted to defend the court of appeals' rationale. It has argued instead that Pom's claim is foreclosed because FDA's regulations allegedly "specifically authorize" Coca-Cola's label. This is beside the point because even if Coca-Cola's label is in compliance with those regulations, there is no irreconcilable conflict between the Lanham Act and the regulations. In any event, FDA's juice-naming regulations do not "specifically authorize" Coca-Cola's misleading product. It is undisputed that FDA has not reviewed and approved Coca-Cola's label. And FDA has stated unequivocally that the mere fact that the name of a juice comports with FDA's naming regulation does not mean that the label as a whole is not misleading. Here, Pom alleges that Coca-Cola's product and its label—taken as a whole—mislead consumers and damage Pom. Several features of the label are not addressed by FDA regulations. For example, as the Ninth Circuit itself recognized, no FDA regulation authorizes Coca-Cola to use markedly larger type for the words "Pomegranate" and "Blueberry" than the FDA-required phrase "Flavored Blend of 5 Juices." The regulations also do not approve the outsized image of the pomegranate and blueberry fruits or the use of coloration to reinforce these misleading elements. All

these features taken together mislead consumers and injure Pom, and none is addressed by FDA's juice-naming regulations. Finally, it is not at all clear that the name Coca-Cola has chosen in fact comports with FDA's regulations. Indeed, Coca-Cola's arguments in this Court strongly suggest it does not.

Congress could not have intended the far-reaching negative consequences of the Ninth Circuit's untethered and expansive holding. The Ninth Circuit's approach would leave regulation of misrepresentations made in connection with product labeling almost entirely in the hands of FDA. But it has long been understood that FDA does not have anywhere near the resources necessary to police food labeling. Precluding Lanham Act challenges to misleading food labels would thus create a significant enforcement gap that Congress could not have desired. Under the Ninth Circuit's approach, moreover, any time an agency has broad authority to regulate labeling or potentially misleading commercial practices, that regulation could preclude private actions under the Lanham Act. But Congress has recognized the importance of the Lanham Act's prohibition on false advertising in deterring unfair competition, and there is no reason to think Congress intended to repeal that prohibition *sub silentio*.

ARGUMENT

I. THE FOOD, DRUG, AND COSMETIC ACT DOES NOT PRECLUDE FALSE ADVERTISING CLAIMS BROUGHT UNDER THE LANHAM ACT

A. Lanham Act Challenges To Misleading Food Labels Are Not Expressly Precluded

The interpretation of a statute, of course, "begin[s] with the text." *Arlington Cent. Sch. Dist. Bd. of Educ.* v. *Murphy*, 548 U.S. 291, 296 (2006). "When the statutory 'language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.'" *Id.* at 296-297 (quoting *Hartford Underwriters Ins. Co.* v. *Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000)). Nothing in the Lanham Act or the FDCA provides any textual support for the conclusion that Pom's Lanham Act claim is precluded by the FDCA. The governing provision of the Lanham Act is unequivocal:

> 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 or misleading description of fact, or false or misleading representation of fact, which … in commercial advertising or promotion, *misrepresents the nature, characteristics, qualities, or geographic origin* of his or her or another person's goods, services, or commercial activities, shall be liable[.]

15 U.S.C. § 1125(a)(1), (B) (emphases added). Thus, by its plain terms, the Lanham Act mandates that Coca-Cola not misrepresent the nature or characteristics of its product. Nothing in the Lanham Act provides support for the FDA-compliance exception urged by Coca-

Cola—much less for the Ninth Circuit's sweeping exception based on FDA's mere regulatory authority or purportedly "comprehensive regulation." Pet App. 12a.

Nor can any textual support for preclusion be found in the FDCA. The FDCA provides that food is "deemed to be misbranded" in a variety of circumstances. 21 U.S.C. § 343. But it nowhere purports to displace the Lanham Act. The same goes for FDA's implementing regulations, which Coca-Cola invokes in its defense. Those regulations address various aspects of food labeling, including labeling of juice products. *See, e.g.*, 21 C.F.R. § 102.33(b)-(d). But nowhere do they contain any provision purporting to bar Lanham Act claims. *See Cottrell, Ltd.* v. *Biotrol Int'l, Inc.*, 191 F.3d 1248, 1256 (10th Cir. 1999) (refusing to dismiss Lanham Act claim that "touches on issues covered by" the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) because "nowhere" does FIFRA "explicitly preclude Lanham Act coverage").

B. There Is No Conflict—Much Less The Required Irreconcilable Conflict—Between The Lanham Act And The FDCA

This Court has repeatedly instructed that "absent 'a clearly expressed congressional intention,'" courts must give full effect to allegedly competing federal statutes unless they are "in 'irreconcilable conflict,' or where the latter Act covers the whole subject of the earlier one and 'is clearly intended as a substitute.'" *Carcieri* v. *Salazar*, 555 U.S. 379, 395 (2009); *see also Branch* v. *Smith*, 538 U.S. 254, 273 (2003) (plurality opinion) (quoting *Morton* v. *Mancari*, 417 U.S. 535, 551 (1974), and *Posadas* v. *National City Bank*, 296 U.S. 497, 503 (1936)).

Thus, when considering two federal statutes that contain no express preclusion but are nonetheless claimed to be in conflict, "it is the duty of the courts … to regard each as effective" if they "are capable of coexistence." *Morton*, 417 U.S. at 551. This Court will "not infer a statutory repeal 'unless the later statute "expressly contradict[s] the original act"' or unless such a construction 'is absolutely necessary ... in order that [the] words [of the later statute] shall have any meaning at all.'" *National Ass'n of Home Builders* v. *Defenders of Wildlife*, 551 U.S. 644, 662-663 (2007) (quoting *Traynor* v. *Turnage*, 485 U.S. 535, 548 (1988) (alterations in original)). Even statutes that "overlap" or may appear to be somewhat "redundan[t]" can be "fully capable of coexisting" and should be given full effect so long as no irreconcilable conflict exists. *United States* v. *Batchelder*, 442 U.S. 114, 118 (1979) (overlapping criminal statutes imposing different maximum terms of imprisonment for nearly identical conduct held "fully capable of coexisting").

This high bar for implied preclusion is rooted in separation of powers principles. As the Court has explained, the rule against implied repeals is dictated by two "superior values": In addition to "harmonizing different statutes," this rule "constrain[s] judicial discretion in the interpretation of the laws." *Astoria Fed. Sav. Loan Ass'n* v. *Solimino*, 501 U.S. 104, 109 (1991). Without a strong presumption that potentially competing federal laws should be given full effect whenever possible, courts would be "at liberty to pick and choose among congressional enactments" whenever two federal statutes happen to overlap. *Morton*, 417 U.S. at 551. This Court has categorically rejected that approach. *Id.*

1. Coca-Cola can easily comply with both the Lanham Act and the FDCA and FDA's regulations

The Lanham Act and the FDCA's regulation of food labeling "are fully capable of coexisting," *Batchelder*, 442 U.S. at 122, because Coca-Cola "can easily satisfy both mandates," *Department of Transp.* v. *Public Citizen*, 541 U.S. 752, 767 (2004): It can refrain from harming competitors through its deceptive product label (as required by the Lanham Act) while at the same time selling a product that is not misbranded (as required by the FDCA). As applied here, the Lanham Act simply prohibits Coca-Cola from making false or misleading descriptions or representations regarding its juice product. 15 U.S.C. § 1125(a)(1). Certainly, neither the FDCA's statutory provisions on food labeling nor FDA's implementing regulations require Coca-Cola to engage in such conduct.

Coca-Cola was not required to use the misleading name it selected for its product. The FDCA's provision relating to food-naming, 21 U.S.C. § 343(i), states in relevant part that, for a food not to be misbranded, the label must "bear[] (1) the common or usual name of the food, if any there be"; and, (2) if the food is "fabricated from two or more ingredients, the common or usual name of each such ingredient." *Id.* Nothing in § 343(i) required Coca-Cola to omit the beverage's two predominant juices and name the product "Pomegranate Blueberry"—even though the product contains 99.4% apple juice and grape juice and .5% pomegranate and blueberry juice combined. Pet. App. 2a.

Likewise, Coca-Cola does not—and cannot—argue that anything in FDA's juice-naming regulation, 21 C.F.R. § 102.33, required it to give its product the mis-

leading name it chose. Section 102.33 specifies ways in which a juice product's label *can* satisfy the statutory requirement set forth in 21 U.S.C. § 343(i). In some circumstances, the regulation permits a product containing multiple juices to be labeled using the name of a non-predominant juice if the label indicates that the product is a "blend" of juices and is "flavored" with the non-predominant juice. *See* 21 C.F.R. § 102.33(c), (d)(1). But this is merely an option. The regulations do not mandate that the name of a juice blend omit reference to the juices comprising more than 99% of the beverage—as Coca-Cola chose to do here. *See id.* § 102.33(c) ("*If* a … blend of single-strength juices contains … a juice other than the named or implied juice …. (emphasis added)), (d) ("*where* one or more, but not all, of the juices are named on the label … and *where* the named juice is not the predominant juice …" (emphases added)). Nor do they mandate that Coca-Cola's label omit reference to the minimal percentage contribution of pomegranate and blueberry juices. In fact, § 102.33(d)(2) specifically provides that, if a party elects to name its product after a non-predominant juice, it *can* choose to indicate on the label the percentage of the drink comprised by that juice, so as not to mislead consumers. Coca-Cola chose not to do so.

Similarly, nothing in the FDCA or FDA's regulations required Coca-Cola to craft an overall product label that is grossly misleading. It was not required to shrink the font size of the words "Flavored Blend of 5 Juices" relative to the size of the product name "Pomegranate Blueberry." It was not required to include a vignette on the bottle that displays a pomegranate and blueberries at least as prominently as an apple and grapes. And it was not required to color the beverage a deep purple so that it resembles blueberry-

pomegranate juice. Coca-Cola did not do any of these things to comply with an FDA regulation; it did them because it wanted consumers falsely to believe that the company's "Pomegranate Blueberry" juice was made with appreciable amounts of pomegranate and blueberry juice.

Nothing in the FDCA purports to protect misleading labels from challenge. To the contrary, the FDCA addresses attempts to exploit gaps in the regulation of specific aspects of food labeling by broadly *prohibiting* labeling that is "false or misleading in any particular." 21 U.S.C. § 343(a); *see also id.* § 321(n) (in "determining whether the labeling … is misleading there shall be taken into account (among other things) not only representations made or suggested … , but also the extent to which the labeling … fails to reveal facts material in the light of such representations"). The FDCA also separately *prohibits* obscuring any required label material by strategically shrinking its font size. *See id.* § 343(f) (required label material must be displayed "prominently" on the label "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").

In short, nothing in the FDCA or FDA's regulations prevented Coca-Cola from making its label nonmisleading—and thus compliant with the Lanham Act. "Without a conflict," Coca-Cola "must comply with all of its statutory mandates." *Public Citizen*, 541 U.S. at 767; *see also Wyeth*, 555 U.S. at 573 ("Impossibility preemption is a demanding defense" that is not met where defendant "has failed to demonstrate that it was impossible for it to comply with both federal and state re-

quirements."); *Nader* v. *Allegheny Airlines, Inc.*, 426 U.S. 290, 299-300 (1976) (finding no "irreconcilable conflict between the statutory scheme [then in force] and the persistence of common-law remedies" where "[t]here is no [statutory or regulatory] *requirement* that [defendant] engage in" the actionable conduct (emphasis added)).

2. The Lanham Act's and FDCA's purposes and remedies confirm that the two laws can and do coexist

The distinct—but complementary—purposes of the Lanham Act and FDCA confirm that the two statutes easily coexist. *See, e.g.*, *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 144 (2001) (two overlapping laws with "different requirements and protections" should both be regarded as effective); *Board of Supervisors* v. *Lackawana Iron & Coal Co.*, 93 U.S. 619, 623 (1876) (no irreconcilable conflict where the statutes' "scope and purposes are distinct and different").

The Lanham Act aims to "protect persons engaged in [interstate] commerce against unfair competition." 15 U.S.C. § 1127. It advances this objective by "provid[ing] a private remedy to a commercial plaintiff" whose "commercial interests" have been harmed by another party's false advertising. *Sandoz*, 902 F.2d at 230. Consumers, by contrast, lack prudential standing to bring such actions. *See, e.g.*, *Made in the USA Found.* v. *Phillips Foods, Inc.*, 365 F.3d 278, 279-280 (4th Cir. 2004) (collecting cases); *Conte Bros. Auto., Inc.* v. *Quaker State-Slick 50, Inc.*, 165 F.3d 221, 229 (3d Cir. 1998) (Alito, J.); *Seven-Up Co.* v. *Coca-Cola Co.*, 86 F.3d 1379, 1383 n.5 (5th Cir. 1996); *Colligan* v. *Activities Club of New York, Ltd.*, 442 F.2d 686 (2d Cir. 1971).

Thus, while the Lanham Act's prohibition on false advertising undoubtedly benefits both consumers and commercial entities, the statute is "primarily intended to protect commercial interests." *Sandoz*, 902 F.2d at 230.

The FDCA's misbranding provisions serve a different purpose: They are designed to protect the public's health and safety. *See 62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951) ("The purposes of this legislation … 'touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.'"); *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331-332 (3d Cir. 2009) (FDCA motivated by "[m]ounting public concern over unsafe food and drugs" in the 1930s). The responsibility for enforcing noncompliance with the statute, as such, has remained with FDA, not private parties. 21 U.S.C. § 337(a) ("[A]ll … proceedings for the enforcement, or to restrain violations, of this [Act] shall be by and in the name of the United States.").[4]

The statutes' purposes are therefore distinct, albeit overlapping and complementary. FDA enforcement of the FDCA's public health goals is not undermined by private competitors' efforts to prevent unfair competition under the Lanham Act. To the contrary, the statutes' respective purposes and requirements work in tandem to ensure that products are marketed in ways

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[4] In the NLEA, Congress authorized state authorities to enforce noncompliance with certain misbranding provisions of the FDCA through civil enforcement and injunctive proceedings if certain circumstances are satisfied. Pub. L. No. 101-535, § 4, 104 Stat. 2353, 2362 (1990) (21 U.S.C. § 337(b)).

that are *both* safe for consumers and not unfair to competitors.

There is likewise no basis to believe that the availability of private remedies under the Lanham Act in the food labeling context could interfere with FDA's enforcement of the FDCA itself. As discussed *infra* pp. 29-32, in enacting the NLEA, Congress preempted state laws only to a limited extent, and expressly disclaimed preemption as to all other state-law claims. Under this provision, States are free to impose civil liability for violations of the FDCA's misbranding provisions. It necessarily follows that the availability of nationally uniform private remedies under the Lanham Act poses no conflict with FDA's enforcement of the FDCA.

Even aside from the NLEA's preemption provision, moreover, there is no tension—much less conflict—between the respective remedial schemes of the FDCA and Lanham Act. In the public health context of the FDCA, Congress determined that enforcement of the FDCA's "floor" requirements should include criminal liability and other regulatory penalties. *See* 21 U.S.C. § 343 (defining misbranding), § 331 (prohibiting misbranding), § 333(a) (criminal penalties), § 334(a)(1) (seizure). By contrast, in the commercial context of the Lanham Act, Congress opted to rely on private parties and traditional civil remedies to address the commercial wrong of false advertising. *See, e.g.*, 15 U.S.C. § 1116(a) (injunctive relief), § 1117(a) (profits, damages, and costs); *see also Coca-Cola Co.* v. *Procter & Gamble Co.*, 822 F.2d 28, 31 (6th Cir. 1987) ("[C]ompetitors have the greatest interest in stopping misleading advertising, and a private cause of action under section 43(a) allows those parties with the greatest interest in enforcement … to enforce the statute rigorously.").

The two statutes' respective remedial schemes thus properly reflect the distinct purposes of each: The Lanham Act's less severe civil remedies preserve integrity in competition, whereas the FDCA's criminal and other public sanctions provide a backdrop deterrent intended to ensure minimum levels of public health, safety, and understanding in the food industry. *See Batchelder*, 442 U.S. at 122 (no conflict where different maximum penalties applied to convictions under different, albeit overlapping, statutes). Indeed, as the Court explained in *Wyeth*, civil remedies through private actions can be a fully "complementary form of … regulation" that compensates in part for FDA's own "limited resources." 555 U.S. at 578-579; *see also infra* pp. 52-54.

3. Congress has declined to preclude Lanham Act challenges to misleading food labels

Congress has given no indication whatsoever that it believes application of the Lanham Act to misleading food labels conflicts with the FDCA. The FDCA was enacted in 1938. Pub. L. No. 75-717, 52 Stat. 1040 (1938). Eight years later, Congress enacted the Lanham Act's prohibition on false advertising. Pub. L. No. 79-489, § 43, 60 Stat. 427, 441 (1946). In the subsequent sixty years, Congress has repeatedly amended both. These amendments have included both a redrafting of § 1125(a) as part of the Trademark Law Revision Act of 1988, *see* Pub. L. No. 100-667, § 132, 102 Stat. 3935, and enactment of the NLEA in 1990. *See also supra* nn.1, 2. To paraphrase this Court's observation in *Wyeth*, 555 U.S. at 574: "If Congress thought [Lanham Act] suits posed an obstacle to its objectives, it surely would have enacted an express [preclusion] provision at some point during the FDCA's 70-year history."

Indeed, quite to the contrary, Congress has declined to preclude application of the Lanham Act to food-labeling claims despite expressly defining the preemptive reach of the FDCA. When Congress amended the FDCA in the NLEA in 1990, it enacted detailed provisions explicitly governing the preemptive scope of the FDCA's food-labeling requirements. *See* Pub. L. No. 101-535, § 6, 104 Stat. 2353, 2362-2364 (21 U.S.C. § 343-1 & note). In doing so, however, Congress limited the effect of those provisions to *state*-law requirements (and only certain of those). It did not displace Lanham Act challenges to food labels.[5]

Congress was well aware that the Lanham Act applied to misleading food labels when it decided to displace only state-law labeling requirements. The NLEA was enacted against the backdrop of cases challenging food labels under the Lanham Act's prohibition on false advertising. *See, e.g.*, *Hesmer Foods, Inc.* v. *Campbell Soup Co.*, 346 F.2d 356, 359 (7th Cir. 1965) (Lanham Act challenge to product named "Barbecue Beans" despite the fact it neither contains meat nor was cooked over an open fire); *Potato Chip Inst.* v. *General Mills, Inc.*, 333 F. Supp. 173 (D. Neb. 1971) (challenge to package label describing dehydrated potato product "CHIPOS" as potato chips), *aff'd*, 461 F.2d 1088 (8th Cir. 1972) (per curiam). Indeed, testimony at the hearings that ultimately led to enactment of the NLEA made clear that

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[5] Indeed, the legislative history of the NLEA confirms what is apparent on the face of § 343-1: the NLEA's preemption provision was a "carefully crafted" provision that was "limited in scope" and represented the result of congressional "compromise." 136 Cong. Rec. 33,425, 33,429 (1990) (Sen. Hatch); *see also* 136 Cong. Rec. 20,414, 20,418 (1990) (Rep. Waxman).

the Lanham Act was available—and in fact being used—to challenge food claims:

> There is also the Lanham Act, which says that if you … create a false impression about your product versus some other product, you can be sued by other companies that say that this is injuring them. There have been a number of food Lanham Act suits where millions of dollars of penalties have been brought forward.

Health and Nutrition Claims in Food Advertising and Labeling, Hearing Before the S. Comm. on Gov't Affairs, 101st Cong. 74 (1990) (statement of Daniel L. Jaffe, Executive Vice President, Ass'n of Nat'l Advertisers) ("1990 Senate Hearings"); *see also FDA's Continuing Failure to Regulate Health Claims for Foods, Hearings Before the Subcomm. on Human Res. and Intergov'tl Relations of the H. Comm. on Gov't Operations*, 101st Cong. 157, 431 (1989) (testimony by OIRA officials regarding OMB memorandum stating, in connection with regulation of health claims on food products, that "manufacturers have strong incentives to avoid costly product liability and Lanham Act exposure"). Congress was thus well aware of the use of the Lanham Act to combat deceptive food labeling. *See United States* v. *Rutherford*, 442 U.S. 544, 554 & n.10 (1979) ("That Congress is aware of the [agency's] policy … is evident from Senate Subcommittee hearings").

Congress' decision to preempt only certain types of state labeling requirements further confirms that Congress did not intend to displace laws, like the Lanham Act, that generally prohibit misleading labeling. In the NLEA, Congress enacted a saving clause that makes clear that the NLEA does not preempt state laws falling outside of the law's express preemption provision:

"The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1]." NLEA § 6(c)(1) (21 U.S.C. § 343-1 note). And the NLEA's express preemption provision, by its terms, displaces only a specified class of state laws: those state laws that purport to impose food labeling requirements "of the type" imposed by *certain* enumerated provisions of the FDCA that are not "identical" to the requirements in those provisions. *See* 21 U.S.C. § 343-1(a)(2), (3). Critically, in enumerating the FDCA provisions that trigger this (qualified) preemption, Congress *omitted* the FDCA's prohibition of labeling that is "false or misleading in any particular," *id.* § 343(a).

Congress' exclusion of § 343(a) from the list of provisions set forth in § 343-1 makes plain its determination that even the application of *state* laws imposing requirements "of the type" of § 343(a)—*i.e.*, provisions that generally prohibit the "false or misleading" labeling of food—would be consistent with the FDCA's food-labeling framework. The NLEA's limited preemption provision was motivated by the need for "[n]ational uniform[ity]" across the 50 states in certain technical aspects of food labeling. 21 U.S.C. § 343-1 (section title); *see also* 136 Cong. Rec. at 20,418 (Rep. Waxman) ("A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws."). Laws that generally prohibit false or misleading labeling, however, do not impose inconsistent technical labeling mandates across jurisdictions; they make actionable misleading conduct that has no redeeming value by applying a "'single, uniform'" standard. *Altria Group, Inc.* v. *Good*, 555 U.S. 70, 79-80 (2008); *see also id.* at 82.

This statutory scheme renders implausible any contention that, after specifically *preserving* from preemption by the NLEA state-law claims "of the type" generally prohibiting false or misleading labeling, 21 U.S.C. §§ 343(a), 343-1(a) & note, Congress could have intended to displace the Lanham Act—a uniformly applicable *federal* counterpart to those un-preempted state laws.

4. As in *Wyeth*, the FDCA and FDA's regulations set only a "floor" upon which other laws can build

Nothing in the FDCA, the NLEA, FDA's regulations, or the preambles to those regulations suggests that, through its regulations, FDA was tasked or even intended to define the outer contours of what makes a juice label misleading. Rather, even more so than in *Wyeth*, FDA's regulations bespeak an intent to set a floor—but not a ceiling—on the adequacy of labeling.

Wyeth involved a state tort failure-to-warn claim against a drug manufacturer alleging that certain safety information should have been included on the warning label but was not. *See* 555 U.S. at 558. The Court acknowledged that "FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." *Id.* at 568. Although the Court determined that under a particular regulation, Wyeth could have provisionally altered the approved label to strengthen the warning at issue, that issue was contested by FDA itself. *See id.* at 569-572; Brief for the United States as Amicus Curiae Supporting Petitioner ("U.S. Br."), *Wyeth* v. *Levine*, 555 U.S. 555, 2008 WL 2308908, at *21-25 (June 2, 2008). The Court held that despite FDA's specific approval of the precise label being challenged, the plaintiff's tort claim was not preempted. *Wyeth*, 555 U.S. at 581. In reaching this

holding, the Court rejected Wyeth's argument that "requiring it to comply with [state law] … would obstruct the purposes and objectives of federal drug labeling regulations." *Id.* at 573.

The Court's analysis in *Wyeth* confirms that there is no conflict between the FDCA and the Lanham Act in this case. Although *Wyeth* involved preemption, not preclusion of another federal statute, the teachings of *Wyeth* apply here. In *Wyeth*, the Court asked whether state law "creates an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" 555 U.S. at 563-564 (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). The standard in this preclusion case is the more demanding "irreconcilable conflict" standard. *See, e.g.*, *Morton*, 417 U.S. at 550-551. For the same reasons the lower standard for obstacle preemption could not be met in *Wyeth*, so too here there is no irreconcilable conflict between the Lanham Act and the FDCA.

a. In *Wyeth*, the Court first reviewed the history of federal regulation of drugs and drug labeling in order to discern "Congress' purposes" with respect to preemption in enacting the FDCA. 555 U.S. at 574. Relying heavily on Congress' "silence," *id.* at 575, on the issue despite the availability of state tort law "during the FDCA's 70-year history," *id.* at 574, the Court concluded that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," *id.* at 575. In this case, the evidence on this score is at least as powerful. As noted, the Lanham Act and the FDCA have coexisted for over sixty years, and at no point during this history did Congress preclude Lanham Act claims, despite multiple amendments of both statutes and enactment of a detailed provision preempting state law. *See supra* pp. 28-30.

b. Unlike with respect to the prescription drug at issue in *Wyeth*, FDA does *not* approve or disapprove food and beverage labels. *See* Pet. App. 12a ("The FDA has not established a general mechanism to review juice beverage labels before they reach consumers."). Further, as the Solicitor General has confirmed, there is no basis for Coca-Cola to construe the absence of pending FDA proceedings as tacit FDA approval of its product label. *See* Brief of the United States As Amicus Curiae ("U.S. Pet. Br.") 16; *Heckler* v. *Chaney*, 470 U.S. 821, 831 (1985) (listing "many" reasons why an agency may decide not to pursue enforcement action); *Altria Group*, 555 U.S. at 89-90. To the contrary, inferring approval from lack of enforcement would be particularly unwarranted, as FDA's enforcement for misbranding of food and beverages is nearly nonexistent. *See infra* pp. 52-54.

Thus, the case for preclusion here is far weaker than the (unsuccessful) case for preemption in *Wyeth*. There, the Court refused to find "obstacle" preemption—a standard that is itself *less* stringent for defendants than the one applicable here—even where the applicable FDCA provisions and FDA regulations *did* require affirmative FDA approval of Wyeth's prescription drug label and Wyeth had repeatedly secured the required approval. *See* 555 U.S. at 561-563. That even mandatory, affirmative FDA approval was held in *Wyeth* to set only a regulatory "floor" is fatal to Coca-Cola's claims.

c. The Court in *Wyeth* found no preemption even though FDA had taken the position that "'FDA approval of labeling … preempt[ed] conflicting or contrary State law.'" 555 U.S. at 575. Here, FDA has made clear that compliance with one aspect of its juice-

naming regulations does not, by itself, render a juice label non-misleading.

In the preamble to its 1993 rulemaking, FDA explained that the general juice-naming scheme it was adopting—*e.g.*, allowing multiple-juice blends in some circumstances to be named after non-predominant juices if they provide the characterizing flavor and the name included the phrases "blend of juices"—"would provide adequately descriptive labeling *for some products*." 58 Fed. Reg. 2897, 2920 (Jan. 6, 1993) (emphasis added). But it stressed that the agency "does not agree that this scheme would ensure that *all* multiple-juice beverages would bear labels that are not misleading." *Id.* (emphasis added); *see also id.* ("FDA agrees with those comments that expressed concern that consumers are being misled into believing that named juices are present in greater amounts than is actually the case. The agency is aware of a number of products currently on the market for which the suggested labeling would not inform the consumer that the named juice is present in only a minor amount."). Similarly, although 21 C.F.R. § 102.33(b) permits a non-predominant juice to appear first in a product name if that juice provides a characterizing flavor, FDA has cautioned that "there is great potential for [such a] label to misrepresent the contribution of the named juice to the product" and that "this provision *does not relieve the manufacturer* of the obligation to label the product in a truthful and nonmisleading manner." 58 Fed. Reg. at 2920 (emphasis added).

FDA stressed that, in some circumstances, "the disclosure of the amount of a characterizing ingredient is a material fact." 58 Fed. Reg. at 2921. FDA explained:

> The agency notes that the regulation on the general principles for common and usual names provides in § 102.5(b) (21 CFR 102.5(b)) that when the proportion of a characterizing ingredient in a food has a material bearing on price or consumer acceptance, or when the label or labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient is present in an amount greater than is actually the case, the percentage [of] such characterizing ingredient shall be declared as a part of the common or usual name of the food.

Id. at 2920. Likewise, FDA noted that the use of vignettes on an otherwise-appropriate label can also raise misbranding concerns. *See id.* at 2922 ("[FDA] will determine on a case-by-case basis whether a vignette is misleading because it is not consistent with other label information *or for other reasons*." (emphasis added)); *id.* ("[F]or a beverage label to not be misleading, it is necessary that the vignette and other label statements on the beverage not conflict in any way."). Indeed, in this case, FDA confirms that it has *not* "marked the metes and bounds of all possible misleading material on juice labels." U.S. Pet. Br. 11-12.

FDA also made clear in the 1993 preamble that its regulations are not intended to prevent juice manufacturers from providing more information than they require. Although FDA's regulation permits a juice product in some circumstances to omit from its name some of the juices it contains, FDA stated that it affirmatively "encourage[s]" that "each juice in a beverage be declared in the name of the product." 58 Fed. Reg. at 2919.

FDA's enforcement positions confirm that FDA regulations merely set a floor on the requisites of food labeling. In 2009, for example, FDA issued a warning letter to a juice manufacturer asserting that two of its juice blend products were "misbranded under section 403(a)(1) of the Act [21 USC 343(a)(1)] because their labels [we]re misleading."[6] Each label used a non-predominant juice in the product name and included the caveat that the product was "flavored" and a "blend." Nonetheless, FDA invoked 21 U.S.C. § 343(a)(1)—which generally prohibits "labeling … [that] is false or misleading in any particular"—and found the labels misleading because they were "designed to imply that the product[s] [were] 100% [non-predominant] juice."

In support of its conclusion, FDA relied on several aspects of the label without ever pointing to a specific FDA regulation. The agency first pointed to the labels' emphasis on the non-predominant juices: "The principal display panels identify the products as 'Orange Tangerine' and 'Grape,' respectively, in large, bold lettering outlined in black; however, neither orange/tangerine juice nor grape juice is the predominant juice in the products." Then, FDA identified additional factors supporting its conclusion—the "close proximity" of the words "All Natural 100% Juice" to the named juices and the fact that the "flavored" and "blend" caveats were at the bottom of the labels in small, white font. FDA's targeting of juice labels that seemingly comply with FDA's discrete juice-naming regulations confirms

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[6] *See* Warning Letter from Roberta F. Wagner, FDA, to Brad Alford, Nestle U.S.A., Dec. 4, 2009, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122. htm.

that FDA has not viewed its regulations as setting a limit on the ways in which juice labels can be misleading.

d. Adjudication of Pom's Lanham Act claim poses no risk of frustrating the policy objectives reflected in FDA's regulations. As just explained, FDA has disclaimed that compliance with 21 C.F.R. § 102.33 will assure that a product's label or even its name will be non-misleading. Thus, a finding in this action that Coca-Cola's product name is in fact misleading would not be in tension with FDA's position reflected in the 1993 preamble and 2009 Warning Letter referenced above. Moreover, as the Solicitor General recognizes, Pom's challenge to the non-naming aspects of Coca-Cola's label is not even arguably in tension with FDA's policy judgments because FDA has not issued regulations relating to those aspects of Coca-Cola's label. *See* U.S. Pet. Br. 18-19; Pet. App. 10a-11a; *see also infra* pp. 47-49.

In any event, even if FDA had determined that *all* labels complying with § 102.33(d)(1) are necessarily non-misleading, permitting Pom's claim to go forward still would not thwart FDA's policy objectives. This is not a situation in which an agency has sought to encourage the conduct being challenged in order to advance the ultimate purpose of the regulation. For example, in *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000), the Court found preempted a state-law duty to install airbags in all new vehicles where the Department of Transportation had rejected the "'all airbag'" standard in favor of a "gradual phase-in of a mix of passive restraints" instead. *Wyeth*, 555 U.S. at 580 (citing *Geier*, 529 U.S. at 879). The Court reasoned that, in opting for a phased-in approach, the agency had balanced the safety advantages of an immediate "'all air-

bag'" standard against a phase-in strategy that "would … lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance—all of which … promoted[d] [the regulation']s safety objectives." *Geier*, 529 U.S. at 875; *id.* at 881 (adopting view that regulation "'embodie[d] the Secretary's policy judgment that safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car.'"). Imposing an all-airbag standard under state law would have upset that balance. *Id.*

Nothing remotely equivalent is at issue in this case. FDA does not have a policy of encouraging manufacturers to name their blended juices after ingredients that are present only in trace amounts. To the contrary, consistent with the FDCA's goal of fostering public health through consumer understanding, FDA has "*encourage[d]*" that "each juice in a beverage be declared in the name of the product." 58 Fed. Reg. at 2919 (emphasis added). Thus, at most, FDA provided § 102.33(d)(1) as an option while still encouraging manufacturers to provide more information to consumers in their juice products' names. There is no basis to conclude in these circumstances that FDA believed that allowing labels like Coca-Cola's was necessary to pursue "a significant regulatory objective." *See Williamson* v. *Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1137 (2011).

Indeed, the coexistence of Lanham Act claims and the FDCA in the context of misleading food labels poses a much easier question than even the one confronted in *Wyeth*. There, the continued availability of failure-to-warn claims under state law raised a risk of "overwarning" and thus a plausible need by the agency to

balance potentially countervailing policy interests. *See, e.g.*, U.S. Br., *Wyeth* v. *Levine*, *supra*, 2008 WL 2308908, at *17 ("[L]abeling must strike a balance between notifying users of potential dangers and not unnecessarily deterring beneficial uses through overwarning."); *see also id.* at *8, *16-17. Here, there is no such offsetting concern. If the legitimate countervailing interest in *Wyeth* did not turn FDA's judgments into a regulatory "ceiling," it is impossible to conclude that FDA's food labeling regulations do so here. In the same way that state laws offer "an additional, and important, layer of consumer protection that complements FDA regulation," *Wyeth*, 555 U.S. at 579, the Lanham Act provides a layer of competitor and consumer protection that the FDCA does not address. This case follows *a fortiori* from *Wyeth*.

C. There Is No Support For The Ninth Circuit's Sweeping Theory Of Field Preclusion

The Ninth Circuit did not conduct an "irreconcilable conflict" analysis or consider any of the many indications discussed above that the two statutes do not irreconcilably conflict. The court did not identify a single provision of the FDCA that is even arguably in tension with the Lanham Act. Nor did the court acknowledge this Court's holding in *Wyeth* that the FDCA merely sets a "floor" for regulation of labels on which other laws can build. 555 U.S. at 577-578. Rather, the court rested principally on its perception that Congress had "entrust[ed] matters of juice beverage labeling to the FDA" and on what it misperceived as "FDA's comprehensive regulation of that labeling." Pet. App. 12a. The Ninth Circuit thus appeared to apply concepts more akin to field preemption and primary jurisdiction. Neither doctrine, however, supports the court's conclusion. Indeed, in opposing certiorari, Coca-

Cola did not even attempt to defend the Ninth Circuit's actual rationale. *See* Br. in Opp. 1, 6, 7, 15; *see also infra* p. 45.

1. By relying heavily on FDA's regulatory authority and assertedly "comprehensive regulation," Pet. App. 12a, the Ninth Circuit appeared to apply considerations that might be relevant in the context of a *field* preemption analysis, where courts are tasked with discerning whether "'the scope of a [federal] statute indicates that Congress intended federal law to occupy a field exclusively.'" *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1266 (2012) (quoting *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995)) (alterations in *Kurns*). But field preemption is not the relevant analog in considering whether one federal statute impliedly repealed another federal statute. Rather, the relevant preemption counterpart is the strongest form of conflict preemption—"impossibility" preemption. *Wyeth*, 555 U.S. at 573. That standard, like the standard applicable in the implied-repeal context, requires the defendant to show an "irreconcilable conflict" between the allegedly conflicting statutes. *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984). For the reasons set forth above, Coca-Cola does not come close to satisfying that "demanding" standard. *Wyeth*, 555 U.S. at 573.

In any event, the Ninth Circuit's analysis would be wrong even if field preemption principles applied. The Court has warned against too easily "infer[ring] preemption from the comprehensiveness of [agencies'] regulations." *Hillsborough Cnty., Fla.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985). "To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." *Id.* This is precisely

what the Ninth Circuit purported to do in this case: Relying on FDA's supposed "comprehensive regulation" and little else, it concluded that "'the appropriate forum for [Pom's] complaints is the [FDA].'" Pet. App. 12a (alterations in original).

The Third Circuit's decision in *Holk* v. *Snapple Beverage Corp.* is instructive. 575 F.3d 329. Adhering to this Court's teachings in *English* v. *General Electric Co.*, 496 U.S. 72 (1990), and *Hillsborough County*, the Third Circuit properly expressed "reluctan[ce] to find field preemption predicated solely on the comprehensiveness of federal regulation." 575 F.3d at 338. After careful review of Congress' and FDA's relevant pronouncements, the court concluded that "neither Congress nor the FDA intended to occupy the fields of food and beverage labeling and juice products." *Id.* at 339. Other lower courts have reached the same conclusion,[7] as has the United States. U.S. Pet. Br. 10-11. Moreover, as discussed below, the premise that FDA has comprehensively regulated juice labels is incorrect. *See infra* pp. 47-49, 52-54.

2. The Ninth Circuit also invoked notions of agency deference, making repeated reference to FDA's "expertise" in juice labeling and concluding that "'the appropriate forum for [Pom's] complaints is the [FDA].'" Pet. App. 12a (alterations in original); *see id.* 8a (FDA's "apparent determination[s]"), 10a (FDA's "expert

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[7] *See Pom Wonderful LLC* v. *Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1123 (C.D. Cal. 2009); *Hitt* v. *Arizona Beverage Co.*, No. 08-cv-809, 2009 WL 449190, at *5 (S.D. Cal. Feb. 4, 2009); *Lockwood* v. *Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009).

judgment[]"), 11a (same), 12a ("[T]he agency may act if it believes that a label in the market is deceptive"). The deference principles invoked by the Ninth Circuit—which underpin the separate doctrine of primary jurisdiction—are also inapposite here. Indeed, Coca-Cola did not seek dismissal on primary jurisdiction grounds.

First, because primary jurisdiction is grounded in principles of deference, it necessarily presupposes that the parties are able at least to apply to the agency for a ruling. *See Reiter* v. *Cooper*, 507 U.S. 258, 268 & n.3 (1993) (citing *Mitchell Coal & Coke Co.* v. *Pennsylvania R.R. Co.*, 230 U.S. 247, 267 (1913)). But FDA "does not accept formal petitions to take a discretionary enforcement action" and any enforcement decision by FDA "would not be subject to judicial review." U.S. Pet. Br. 15 (citing 21 C.F.R. § 10.30(k); *Heckler* v. *Chaney*, 470 U.S. 821, 837-838 (1985)). Against this backdrop, the Ninth Circuit's conclusion that "'the appropriate forum for [Pom's] complaint is the [FDA]'" is not so much an invocation of abstention as a declaration of abdication. Pet. App. 12a.[8]

Second, the primary jurisdiction doctrine permits a court "to enable a 'referral' to [an] agency … to seek an administrative ruling" only under limited circumstanc-

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[8] Additionally, any dismissal under the primary jurisdiction doctrine must be *without* prejudice. *See Reiter*, 507 U.S. at 268-269 ("Referral of the issue to the administrative agency does not deprive the court of jurisdiction; it has discretion either to retain jurisdiction or, if the parties would not be unfairly disadvantaged, to dismiss the case without prejudice."). Here, however, the court of appeals affirmed judgment for Coca-Cola *with* prejudice. Pet. App. 14a.

es—i.e., where the relevant "claims … *contain some issue within the special competence* of [the] administrative agency." *Reiter*, 507 U.S. at 268 (emphasis added). Pom's claim, however, arises under the Lanham Act, and its outcome is independent of the application or interpretation of the FDCA or FDA's regulations. JA 28a-30a. The Solicitor General properly acknowledged that FDA "does not administer the Lanham Act" and expressly disavows any "authority to resolve [Pom]'s claim of competitive injury due to a misleading label." U.S. Pet. Br. 14. This case thus lacks the core precondition of cases warranting administrative deference: the "issue" in dispute—whether Coca-Cola's product is misleading under the Lanham Act—is *not* "within the special competence of [the] agency." *Reiter*, 507 U.S. at 268; *see also Nader*, 426 U.S. at 305-306 (declining to apply primary jurisdiction where "[t]he standards to be applied … are within the conventional competence of the courts, and the judgment of a technically expert body is not likely to be helpful in the application of th[o]se standards.").

Third, importing primary-jurisdiction-like principles into the preclusion context would perpetuate the needless doctrinal confusion that the Ninth Circuit's decision has already created. *See Watkins* v. *Vital Pharm., Inc.*, No. 12-cv-9374, 2013 WL 5972174, at *3 (C.D. Cal. Nov. 7, 2013) ("Although the precise issue before the court in *Pom Wonderful* was whether the FDCA barred the plaintiff's Lanham Act claim, courts have interpreted the decision as 'based on the idea of deference to the FDA' and 'implicitly relying on the primary jurisdiction doctrine.'"); *Won Kyung Hwang* v. *Ohso Clean, Inc.*, No. 12-cv-6355, 2013 WL 1632697, at *16, *18 (N.D. Cal. Apr. 16, 2013); *Ivie* v. *Kraft Foods Global, Inc.*, No. 12-cv-2554, 2013 WL 685372, at *6-7

(N.D. Cal. Feb. 25, 2013); *Astiana* v. *Hain Celestial Grp., Inc.*, 905 F. Supp. 2d 1013, 1015 (N.D. Cal. 2012); *All One God Faith, Inc.* v. *Hain Celestial Grp., Inc.*, No. 09-cv-3517, 2012 WL 3257660, at *9 (N.D. Cal. Aug. 8, 2012).

* * *

The unbounded scope of the court of appeals' decision magnifies its adverse impact. Under the Ninth Circuit's ruling, so long as products meet FDA's minimum requirements "as best [one] can tell," Pet. App. 9a, manufacturers can label them in any manner, without regard to whether their labeling deceives consumers and unfairly injures competitors. The ruling thus displaces even Lanham Act claims that allege, as Pom did in this case, that a manufacturer has *knowingly* used a label that is misleading. *See id.* 35a (quoting internal email admitting "a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices" but deciding to "assume the risk."). Nothing in the Lanham Act, the FDCA, or FDA's regulations tolerates—much less dictates—such a result.

D. Coca-Cola's Misleading Product Does Not Comply With The FDCA And FDA's Regulations

In this Court, Coca-Cola has not defended the "regulatory authority" rationale employed by the Ninth Circuit. Instead, Coca-Cola has argued that the Lanham Act does not apply because its product label allegedly complies with FDA's juice-naming regulations. *See* Br. in Opp. 1, 6, 10, 12. For all of the reasons set forth above, application of the Lanham Act to Coca-Cola's misleading label is not precluded even if that label did fully comply with the FDCA and FDA's juice-

naming regulations because Coca-Cola cannot satisfy the "irreconcilable conflict" standard. But in any event, Coca-Cola's label does *not* comply.

1. Coca-Cola's product is misleading as a whole and thus violates the FDCA

FDA has cautioned that its juice-naming provision "does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner." 58 Fed. Reg. at 2920.[9] *See supra* pp. 35-36. Consistent with this position, FDA has deemed misbranded under the FDCA's catch-all provision, 21 U.S.C. § 343(a)—and taken action against—juice products that seemingly comply with FDA's discrete labeling regulations but remain misleading in the aggregate. *See supra* pp. 37-38. In short, there is no compliance with the FDCA if a label is misleading in the aggregate.

That is the case here. Pom's complaint challenges Coca-Cola's presentation of its *entire* product as misleading, not merely discrete aspects of the label. *See* JA 61a, 26a. In this Court, Coca-Cola disaggregates certain components of its product's label—primarily, the common name and the font size used by Coca-Cola for certain required language on the label—and argues that Pom's claim should be precluded because those components, in isolation, allegedly comply with certain FDA regulations. *See, e.g.*, Br. in Opp. 5-6. But consumers see the entire label (along with the color of the juice, which Coca-Cola intentionally colors deep pur-

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[9] *See also id.* ("[F]or multiple-juice beverages that name one or more but not all of the juices [in the product's name], there is great potential for the label to misrepresent the contribution of the named juice to the product."); U.S. Pet. Br. 12 & n.3.

ple), not merely the product's name or strings of words in differing font sizes. Thus, even assuming that some elements of Coca-Cola's label did comply with narrow regulations addressing particular labeling requirements, such selective compliance would be irrelevant. So long as the label as a whole is misleading, it does not comply with 21 U.S.C. § 343(a) as interpreted by FDA, *see supra* pp. 35-38, and there is no reason—even under Coca-Cola's own theory—why Pom should be barred from pursuing its Lanham Act claim. *See also* 21 U.S.C. § 321(n) (inquiry into whether label is misleading must take into account failure to reveal facts material in light of representations suggested on label).

2. The misleading aspects of Coca-Cola's product are not in compliance with specific FDA regulations

In any event, Coca-Cola has not shown that the various misleading elements of its product comply with specific FDA regulations applicable to those elements.

Font Sizes. In its product label, Coca-Cola elected to use much smaller print for some of the words required to be part of the "name" of its product under FDA's regulations ("Flavored Blend of 5 Juices") than for the words in its product name that Coca-Cola wants customers to focus on ("Pomegranate" and "Blueberry"). Pet. App. 11a. In considering that aspect of Pom's challenge, the Ninth Circuit acknowledged that there is no FDA regulation on point. *See id.* ("If the FDA thought such a regulation were necessary 'to render [that information] likely to be read and understood by the ordinary individual,' it could have said so.'" (citing 21 U.S.C. § 343(f) (alteration in original)). And FDA itself confirms that "the FDCA and FDA have not specifically addressed 'how [Coca-Cola] presents

the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label.'" U.S. Pet. Br. 19 (quoting Pet. App. 10a).

Undeterred, Coca-Cola now argues that the "FDA has specifically addressed the font-size issue in 21 C.F.R. § 101.22(i)(1)(i)." Resp. Supp. Br. 3. That is doubly wrong.

First, § 101.22(i)(1)(i) applies only if "the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in 'strawberry shortcake.'" 21 C.F.R. § 101.22(i)(1)(i). The food at issue here is a blend of juices consisting of "99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice." Pet. App. 2a. To the extent such a blend of juices is "commonly expected to contain a characterizing food ingredient," it surely is not pomegranate juice or blueberry juice.

Second, if § 101.22(i)(1)(i) is at all relevant, at most it addresses the font size of the single word "Flavored." *See* 21 C.F.R. § 101.22(i)(1)(i) ("[T]he name of the characterizing flavor [here, "Pomegranate Blueberry"] … 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" (emphasis added)).[10] It does not authorize Coca-Cola to shrink the words "Blend of 5 Juices" as it has done. That language is required to be included in the product's "common or usual name" by a different regulation, 21 C.F.R.

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[10] A product's "characterizing flavor(s)" includes any flavor that the producer elects to highlight as the primary flavor through labeling, advertising, or by other means. *See* 21 C.F.R. § 101.22(i).

§ 102.33(c), which addresses a product's basic nature—not added flavoring—and does not address the font size of the language it requires.

By attempting to insert § 101.22(i)(1)(i)'s provision into § 102.33(c), Coca-Cola ignores the different purposes of these two regulations. FDA stressed these distinct purposes in refusing to exempt juice products that must use the term "flavor" or "flavored" under § 101.22(i) from § 102.33's "common or usual name" requirement. *See* 58 Fed. Reg. at 2920. A commenter arguing for that exemption contended that use of the word "flavor" following the characterizing ingredient would "adequately inform[] the consumer in accordance with § 101.22." *Id.* But FDA refused to permit parties to omit the phrase "blend of ---- other juices" required by § 102.33, noting that § 101.22 "informs the consumer when flavoring substances have been added to the product," while § 102.33 "describes other aspects of the basic nature of the product." *Id.*

The Product Name. Coca-Cola claims that the name of its product complies with FDA's juice-naming regulation set forth in 21 C.F.R. § 102.33(d). That regulation permits a product to be named after a juice that "is not the predominant juice" if the name of the product "[i]ndicate[s] that the named juice is present as a flavor or flavoring." 21 C.F.R. § 102.33(d)(1). But Coca-Cola's own contentions in this Court indicate that its product does not, in fact, comply with § 102.33(d) because the traces of pomegranate and blueberry juices in its product are not "present as a flavor or flavoring."

Coca-Cola's reliance on 21 C.F.R. § 101.22(i)(1)(i) demonstrates as much. That provision, which sets minimum font sizes for the mandatory disclosure that a food contains *added* natural flavoring, applies only

where "the food contains … an amount of characterizing ingredient *insufficient to independently characterize the food*, or the food contains *no such ingredient*." 21 C.F.R. § 101.22(i)(1)(i) (emphases added). Coca-Cola's reliance on this provision is thus a telling admission that its product contains so little pomegranate and blueberry juice that those juices do *not* independently characterize the product. It is added "natural flavoring"[11]—not actual pomegranate and blueberry *juice*—that (allegedly) gives the product a pomegranate-blueberry flavor. Because pomegranate juice and blueberry juice are not "present as a flavor" as required by § 102.33(d), Coca-Cola cannot invoke that provision to show that its product's name complies with FDA's juice-naming regulations.

Notably, Coca-Cola does not invoke § 101.22(i)(1)(iii), which applies if a 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" (emphasis added). That provision—not § 101.22(i)(1)(i)—would apply if Coca-Cola were relying on both the trace amounts of pomegranate and blueberry juice and added natural flavoring to generate the claimed flavor of the product. But if that provision were applicable, then Coca-Cola would not be in compliance with its requirement that "the name of the food shall be *immediately*

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[11] The term "natural flavor" (or "natural flavoring") is an FDA term of art that refers to certain substances, such as essential oils and extractives, which contain "flavoring constituents derived from" items like "fruit or fruit juice" and "whose significant function in food is flavoring rather than nutritional." 21 C.F.R. § 101.22(a)(3).

followed by the words 'with other natural flavor.'" 21 C.F.R. § 101.22(i)(1)(iii) (emphasis added). Those words appear on Coca-Cola's label only after the words "From Concentrate With Added Ingredient," which themselves are separated from the phrase "Pomegranate Blueberry Flavored Blend of 5 Juices" by an empty line. *See* JA 38a; CA ER 108, 112.

Coca-Cola's own arguments in this case thus cast significant doubt on whether the miniscule quantities of pomegranate juice and blueberry juice in its product suffice to provide the product's "flavor or flavoring." And even if they did, it would still remain far from clear that Coca-Cola could rely on §102.33(d)(1) in light of the restriction imposed by 21 C.F.R. § 102.5(b), which mandates that

> [t]he 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.[12]

21 C.F.R. § 102.5(b). Pomegranate juice and blueberry juice are far more expensive than the juices that comprise over 99% of Coca-Cola's "Pomegranate Blueberry" juice product, Pet. App. 2a, and the proportion of

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[12] *See* 58 Fed. Reg. at 2920, 2921 (noting the application of § 102.5(b) to multiple-juice blends).

pomegranate and blueberry juice obviously has a bearing on consumer acceptance of Coca-Cola's product, JA 24a-26a. Yet, Coca-Cola's label does not include—or even hint at—the trivial percentage of pomegranate and blueberry juice in the product.

The Vignette. The fruit "vignette" on Coca-Cola's label is also misleading. It prominently features a large pomegranate that is placed in front of an apple of roughly the same size. *See* JA 38a. It also features outsized blueberries that sit in front of the grapes pictured on the label. Nothing in this display suggests that pomegranate and blueberry juice together make up just 0.5% of the product, while apple and grape juice make up over 99%. Although FDA discussed fruit vignettes in the 1993 rulemaking (*see* 58 Fed. Reg. at 2921-2922), Coca-Cola has never pointed to a regulation "authorizing" its misleading vignette.

II. CONGRESS COULD NOT HAVE INTENDED THE RESULT REACHED BY THE NINTH CIRCUIT OR URGED BY COCA-COLA

A. FDA Lacks The Resources To Regulate False And Misleading Food Labels

Congress could not have intended to leave all regulation of misleading food labels to FDA, which lacks the resources to handle that critical task. As Congress has long understood, FDA woefully lacks the resources necessary to police misleading food labels. In *Wyeth*, this Court noted that the "FDA has limited resources" to conduct even what might be its most critical mission: to ensure the safety and effectiveness of pharmaceuticals. 555 U.S. at 578 & n.11. For this reason, even in that area of significant scientific complexity, FDA "long maintained that state law offers an additional, and im-

portant, layer of consumer protection that complements FDA regulation." *Id.* at 579.

In the realm of food labeling, the agency's resources are even more markedly inadequate to its mission. As the Government Accountability Office explained in a 2008 report, FDA's efforts to regulate food labeling leave significant gaps. *See* U.S. Gov't Accountability Office, GAO 08-597, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods* (2008) ("GAO Report"), *available at* http://www.gao.gov/assets/290/280466.pdf. The Report's overall conclusion was summarized as follows: "FDA has limited assurance that domestic and imported foods comply with food labeling requirements, such as those prohibiting false or misleading labeling." *Id.* at 5.

More specifically, the Report explained that: "FDA has reported that limited resources and authorities significantly challenge its efforts to carry out food safety responsibilities—challenges that also impact efforts to administer and enforce labeling requirements." GAO Report 6. In 2007, over 65,000 firms were subject to FDA's food regulations. *See id.* at 51, tbl. 9. These firms, of course, manufacture countless numbers of different food products. But from 2005 to 2007, the portion of the FDA Office of Nutrition, Labeling, and Dietary Supplements "dedicated to food labeling activities" had an annual budget of only "$1.1 million to $1.3 million" and had only "from 9.0 to 10.5" full-time equivalent employees. *Id.* at 7. From 1998 through 2006, FDA obtained only *two* injunctions against firms for food-related mislabeling. *See id.* at 22. For the most part, the agency simply issued warning letters, if it did anything at all. *See id.* at 18-21. Indeed, FDA has

acknowledged that it generally does not even attempt to police misleading food labels:

> [A]ccording to FDA officials, the agency generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need to legally demonstrate that a label is misleading[.]

Id. at 30.

FDA's inadequate resources create a gap that the Lanham Act plays a crucial role in filling. The threat of liability under the Lanham Act provides a substantial economic disincentive vital to offsetting the monetary incentives that exist for certain producers to create inaccurate or misleading labeling. Indeed, in the hearings leading up to enactment of the NLEA, Congress heard from the advertising industry that the danger of a Lanham Act suit is a "step" in "deciding" whether a consumer will be misled by a food label or advertisement. *See* 1990 Senate Hearing, at 74 ("There is also the Lanham Act, which says that if you … create a false impression about your product versus some other product, you can be sued by other companies that say that this is injuring them. There have been a number of food Lanham Act suits where millions of dollars of penalties have been brought forward."). There is no reason to believe Congress intended to eliminate this essential constraint.

B. The Ninth Circuit's Reasoning Would Apply To A Range Of Other Regulatory Regimes

The Ninth Circuit's reasoning reaches beyond food labeling regulated by FDA. It has been applied to other products regulated by FDA. *See Astiana*, 905 F.

Supp. 2d at 1014-1017 (FDA's authority to regulate cosmetics barred state-law mislabeling challenge to cosmetics labeled "all natural," "pure natural," and "pure, natural & organic"). And it extends to other federal statutes that empower other agencies to police false and misleading statements through regulation. Indeed, one court has already applied the Ninth Circuit's decision to preclude a Lanham Act claim challenging the labeling of personal care and cosmetic products as "organic" in light of the USDA's regulation of such products under the Organic Food Products Act of 1990. *See All One God Faith*, 2012 WL 3257660, at *1-11.

Perhaps most significantly, the FTC is broadly charged with preventing "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1)-(2). To that end, the FTC has issued regulatory guides for a variety of sectors, from plant nurseries to auto parts, from jewelry to private vocational and distance schools. *See* 16 C.F.R. §§ 18.0-18.8, 20.0-20.3, 23.0-23.26, 254.0-254.7. Under the Ninth Circuit's reasoning, the FTC's expansive regulatory authority would preclude a Lanham Act suit against demonstrably misleading statements in any regulated field.

Congress enacted the prohibition on false advertising in the Lanham Act to prevent competitive injury based on misleading product claims. It has made clear that robust private enforcement of that provision is necessary to further "the public policy of deterring acts of unfair competition." S. Rep. No. 100-515, at 38 (1988), *reprinted in* 1988 U.S.C.C.A.N. 5577, 5603. That purpose is directly served in this case. Coca-Cola was not required to use a misleading label—it did so to unfairly lure customers away from Pom. Nothing in the FDCA or FDA's regulations bar Pom's claim. The

Ninth Circuit's contrary conclusion finds no basis in this Court's precedents and would significantly undermine the Lanham Act. Where Congress has enacted two statutes that apply to the same underlying conduct, it is the role of the courts to apply both of those laws to the fullest extent possible. Here, both the Lanham Act and the FDCA can and should be given effect.

CONCLUSION

The judgment should be reversed.

Respectfully submitted.

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APPENDICES

15 U.S.C. § 1116: Injunctive relief

(a) Jurisdiction; service

The several courts vested with jurisdiction of civil actions arising under this chapter shall have power to grant injunctions, according to the principles of equity and upon such terms as the court may deem reasonable, to prevent the violation of any right of the registrant of a mark registered in the Patent and Trademark Office or to prevent a violation under subsection (a), (c), or (d) of section 1125 of this title. Any such injunction may include a provision directing the defendant to file with the court and serve on the plaintiff within thirty days after the service on the defendant of such injunction, or such extended period as the court may direct, a report in writing under oath setting forth in detail the manner and form in which the defendant has complied with the injunction. Any such injunction granted upon hearing, after notice to the defendant, by any district court of the United States, may be served on the parties against whom such injunction is granted anywhere in the United States where they may be found, and shall be operative and may be enforced by proceedings to punish for contempt, or otherwise, by the court by which such injunction was granted, or by any other United States district court in whose jurisdiction the defendant may be found.

* * *

15 U.S.C. § 1117: Recovery for violation of rights

(a) Profits; damages and costs; attorney fees

When a violation of any right of the registrant of a mark registered in the Patent and Trademark Office, a violation under section 1125(a) or (d) of this title, or a willful violation under section 1125(c) of this title, shall have been established in any civil action arising under this chapter, the plaintiff shall be entitled, subject to the provisions of sections 1111 and 1114 of this title, and subject to the principles of equity, to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action. The court shall assess such profits and damages or cause the same to be assessed under its direction. In assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed. In assessing damages the court may enter judgment, according to the circumstances of the case, for any sum above the amount found as actual damages, not exceeding three times such amount. If the court shall find that the amount of the recovery based on profits is either inadequate or excessive the court may in its discretion enter judgment for such sum as the court shall find to be just, according to the circumstances of the case. Such sum in either of the above circumstances shall constitute compensation and not a penalty. The court in exceptional cases may award reasonable attorney fees to the prevailing party.

* * *

15 U.S.C. § 1125: False designations of origin, false descriptions, and dilution forbidden

(a) Civil action

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

> (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

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

(2) As used in this subsection, the term "any person" includes any State, instrumentality of a State or employee of a State or instrumentality of a State acting in his or her official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this chapter in the same manner and to the same extent as any nongovernmental entity.

(3) In a civil action for trade dress infringement under this chapter for trade dress not registered on the principal register, the person who asserts trade dress pro-

tection has the burden of proving that the matter sought to be protected is not functional.

* * *

15 U.S.C. § 1127: Construction and definitions; intent of chapter

* * *

The intent of this chapter is to regulate commerce within the control of Congress by making actionable the deceptive and misleading use of marks in such commerce; to protect registered marks used in such commerce from interference by State, or territorial legislation; to protect persons engaged in such commerce against unfair competition; to prevent fraud and deception in such commerce by the use of reproductions, copies, counterfeits, or colorable imitations of registered marks; and to provide rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the United States and foreign nations.

21 U.S.C. § 321: 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 determin-

ing 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.

* * *

21 U.S.C. § 331: Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

* * *

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

* * *

21 U.S.C. § 333: Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

* * *

21 U.S.C. § 337: 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.

21 U.S.C. § 343: 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, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.

* * *

(f) Prominence of information on label

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

* * *

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

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title 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.

* * *

21 U.S.C. § 343-1: 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.

* * *

21 U.S.C. § 343-1 Note (Construction of Pub. L. No. 101-535)

Pub. L. 101–535, § 6(c), Nov. 8, 1990, 104 Stat. 2364, provided that:

(1) The Nutrition Labeling and Education Act of 1990 [Pub. L. 101–535, see Short Title of 1990 Amendment note set out under section 301 of this title] 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 [this section].

(2) The amendment made by subsection (a) [enacting this section] and the provisions of subsection (b) [set out as a note above] 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 [this chapter] 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."

21 C.F.R. § 101.18: Misbranding of food

* * *

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

* * *

21 C.F.R. § 101.22: 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 charac-

terizing 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.

* * *

21 C.F.R. § 102.5: General principles

* * *

(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 im-

mediately 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.

* * *

21 C.F.R. § 102.33: Beverages that contain fruit or vegetable juice

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

such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice (e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). In accordance with § 101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.

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

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

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

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

(e) The common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "acid-reduced cranberry juice," "deflavored, decolored grape juice").

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

(g)(1) If one or more juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such terms must be included in the name of each individual juice or it may be stated once adjacent to the product name so that it applies to all the juices, (e.g., "cherry juice (from concentrate) in a blend of two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a type size no less than one-half the height of the letters in the name of the juice.

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