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 THE GENERIC PHARMACEUTICAL ASSOCIATION AS AMICUS CURIAE SUPPORTING NEITHER PARTY

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BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS AMICUS CURIAE SUPPORTING NEITHER PARTY

INTEREST OF THE AMICUS CURIAE[1]

The Generic Pharmaceutical Association (GPhA) is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, but substantially less expensive. GPhA members' products account for roughly 80% of all prescriptions dispensed in the United States but only 27% of the money spent on prescriptions. In this way, the products sold by GPhA members save consumers nearly $200 billion each year. GPhA's core mission is to improve the lives of consumers by providing timely access to affordable pharmaceuticals. GPhA regularly participates in litigation as *amicus curiae*, taking legal positions that are adopted by GPhA's Board of Directors and reflect the position of GPhA as an organization. Most recently, GPhA participated as *amicus curiae* on the merits in

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[1] All parties have consented to the filing of this brief. Letters reflecting the parties' consent are being lodged with the Clerk. No counsel for a party authored any portion of this brief. No party and no other entity, except *amicus*, its members, and its counsel, made any monetary contribution toward the preparation or submission of this brief.

this Court in *FTC v. Actavis, Inc.*, No. 12-416; *Mut. Pharm. Co. v. Bartlett*, No. 12-142; and *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844.

Generic drug companies are periodically targeted by brand-name competitors seeking to use broad, general federal statutes, including the Lanham Act, to thwart generic competition even once a generic drug has been approved by the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA). *See, e.g.*, *Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 WL 746394 (E.D. Mich. Mar. 2, 2010) (Lanham Act); *see also SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc.,* 211 F.3d 21 (2d Cir. 2000) (Copyright Act). Federal courts have generally rejected such attempts to circumvent FDA approval decisions.

This case concerns the intersection between the Lanham Act and one particular area of the FDCA, food labeling. The FDCA contains a number of different regulatory structures, *e.g.*, for food, drugs, and medical devices. GPhA files this brief as *amicus curiae* to highlight the need to distinguish carefully among the relevant aspects of the FDCA: while a number of the elements on which respondent Coca-Cola and the court below relied are common to all regulatory structures under the FDCA, petitioner Pom relies principally on aspects of the FDCA that are specific to food labeling. In its decision, this Court should be cognizant of the differences. Even if petitioner is allowed to proceed with certain aspects of its claim, the Court should make clear that such a decision does not license second-guessing explicit FDA approvals, and in particular FDA approvals un-

der the agency's authority to review and approve the licensing, labeling, and marketing of pharmaceuticals.

SUMMARY OF ARGUMENT

The FDCA expressly forbids private enforcement of its requirements. *See* 21 U.S.C. § 337(a). As this Court has recognized, the statute is to "be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Accepting the broadest version of petitioner's argument would render that proposition a nullity, because virtually every misbranding claim a private party might wish to bring under the FDCA can be repackaged as a "false or misleading advertising" claim under the Lanham Act. That reading is unsustainable.

While the Lanham Act may have a valid role to play with respect to FDCA-regulated products, it cannot be used to second-guess the FDA directly. That second-guessing takes two principal forms: contending that a particular label, advertisement, or similar communication is "false" or "misleading" when the FDA has specifically reviewed the communication and determined that it is neither, and contending that a particular statement in labeling, advertising, or similar communication is false when the FDA has specifically determined that it is true. In those contexts, Congress has given primacy to the FDA and specified that private plaintiffs may not substitute their own judgment under the FDCA.

A number of petitioner's arguments are drawn not from the FDCA as a whole, but from aspects of the FDCA that are specific to food-labeling regulation.

Should this Court adopt any of those arguments, it is essential that the Court make clear that the analysis would differ under other subparts of the FDCA, such as those regulating prescription drugs or medical devices. Petitioner contends that the FDA did not review respondent's juice label individually, and so did not pass on the question whether the label as a whole (as opposed to the name) was misleading. But the FDA does review other products, such as drugs and devices, in great depth, including to ensure that their labeling and, in some cases, other advertising is not false or misleading. And petitioner repeatedly emphasizes that Congress has saved state-law suits *over food labeling* from preemption, inviting the Court to infer that Congress must therefore have had no problem with a Lanham Act action in this context as well. To the extent that inference is a valid one, by its own terms it does not extend beyond the food-labeling context. Other parts of the FDCA, such as the one relating to generic-drug labeling, have quite different preemption regimes. To the extent this Court holds that Lanham Act claims can coexist with some portion of the FDCA, this Court should be precise in identifying *which* portion of the FDCA, and what aspects of that portion inform the preclusion analysis.

To say the least, allowing a Lanham Act claim to proceed on these facts would not authorize a Lanham Act claim that depends on second-guessing the FDA in a context where Congress has done nothing to signal tolerance of private lawsuits.

ARGUMENT

The Lanham Act imposes strict liability on defendants for making statements in advertising that a jury finds to be either "false" or "misleading." But when that statement has been approved by the FDA pursuant to its responsibilities under the FDCA, a lay jury cannot be allowed to second-guess the agency's expert determinations—by holding that a statement is false when the FDA says it is true, or that labeling or advertising is misleading when the FDA says it is not. Many of the FDA's decisions are judicially reviewable, under a deferential standard that takes due account of the agency's expertise. A litigant cannot dodge the principle of agency deference by using the Lanham Act to litigate the accuracy of the agency's determinations.

I. Plaintiffs Cannot Use the Lanham Act To Undo Congress's Decision To Bar Private Actions Enforcing the FDCA

This case involves the Lanham Act's intersection with a key provision of the FDCA: 21 U.S.C. § 337(a), which "leaves no doubt" that the FDCA is to "be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 349 n.4, 352. Section 337(a) provides that "proceedings for the enforcement . . . of [the FDCA] shall be by and in the name of the United States," not in the name of private individuals. Following *Buckman*, it is universally understood that the FDCA "forbids private rights of action,"[2] whether for food, drugs, devices, or cosmetics.

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[2] *E.g.*, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010); *accord, e.g.*, *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236

Congress's omission of a private right of action was no accident. To the contrary, Congress entertained the possibility of allowing private parties to enforce the FDCA themselves, but it ultimately did not include such a provision in the FDCA. *See, e.g.*, *Bailey v. Johnson*, 48 F.3d 965, 967 (6th Cir. 1995) (citing legislative history).

Rather, Congress provided that violations of the FDCA's myriad requirements, from obtaining a required FDA approval to advertising truthfully, would be punished by the federal government itself. FDCA violations involving drugs and devices can be remedied by injunction, 21 U.S.C. § 332(a), and by criminal prosecution, *id.* § 333(a). And *only* the federal government can initiate those proceedings.[3]

For instance, only the government may enforce the prohibition on "misbranding" and seek to punish those who violate it. *See id.* § 331(a), (b). A product can be "misbranded" for a number of reasons, many of them relating to how the product is labeled. Food, for example, is misbranded if "its labeling is false or misleading in any particular." *Id.* § 343(a)(1). Similarly, in the drug and device context, misbranding includes both using "labeling [that] is false or misleading in any particular" and advertising a prescription drug in a manner that is not "true" in every particular that FDA requires to be included in the ad.

(6th Cir. 2000); *Bailey v. Johnson*, 48 F.3d 965, 967 (6th Cir. 1995) (citing cases); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997).

[3] By contrast, violations of the rules for food advertising carry no criminal or civil penalties. *See* 21 U.S.C. § 333(d). In addition, state governments may under some circumstances bring suit to enforce the FDCA. *Id.* § 337(b).

Id. § 352 (a), (n). Many products also cannot be sold without the FDA's approval, and for both drugs and devices, the approval process considers whether the proposed labeling is "false or misleading." *Id.* §§ 355(d)(7), 360e(d)(1)(A).

A. The FDCA Bars Lawsuits Second-Guessing the Agency's Determination That Labeling Is Not False or Misleading

Section 337(a) precludes a private party from bringing a lawsuit alleging that a prescription drug is labeled in a false or misleading way, and therefore that it is misbranded or that it is being marketed in violation of the FDCA notwithstanding the FDA's approval, because its labeling is false or misleading. And that prohibition goes beyond lawsuits seeking to invoke a (nonexistent) private right of action under the FDCA. As this Court held in *Buckman*, the FDCA itself precludes a State from creating a cause of action based on violation of the FDCA. 531 U.S. at 352-53. Such state causes of action are impermissible because they exert an "extraneous pull" on the FDA's enforcement discretion. *Id.* It stands to reason that Congress would not have wanted to allow a *federal* cause of action to exert precisely the same "extraneous pull."

Yet that is precisely what a Lanham Act cause of action does when it overlaps with the FDCA. A private lawsuit challenging the labeling of a food, drug, or device as "false" or "misleading" under the Lanham Act, when the FDA has approved that specific labeling as *not* false or misleading under the FDCA, undermines Congress's judgment that the federal

government enforce the FDCA's requirements and prohibitions.

For that reason, the court of appeals was correct to hold, in line with numerous other appellate decisions, "that the FDCA limits claims under the Lanham Act, . . . because allowing such a suit would undermine Congress's decision to limit enforcement of the FDCA to the federal government." Pet. App. 6a-7a. The specificity with which Congress declared that private parties may not enforce the FDCA in court is enough to "preclude a construction of the [Lanham Act] that permits the instant suit." *Argentine Republic v. Amerada Hess Shipping Corp.*, 488 U.S. 428, 438 (1989).

Challenging that holding, petitioner misapplies this Court's cases concerning how to reconcile two overlapping, potentially contradictory federal statutes. Petitioner has repeatedly contended that the court of appeals failed to follow the principle that each of the two statutes must be given effect. *E.g.*, Pet'r Br. 20-21; Pet'r Cert.-Stage Supp. Br. 6. But in the strongest form of its argument, petitioner appears to insist that the Lanham Act cannot yield to the FDCA *at all*. *See* Pet'r Br. 24. Nothing in this Court's cases requires that the Lanham Act be given the maximum possible effect in all cases, heedless of the potential impact on the FDCA. Rather, given the specific prohibition on private enforcement in Section 337(a), the statutes are easily construed *in pari materia* so that the Lanham Act does not apply to statements whose allegedly "false" or "misleading" nature has already been reviewed by the FDA. *See, e.g.*, *Crawford Fitting Co. v. J.T. Gibbons, Inc.*, 482 U.S. 437, 445 (1987). "To eliminate the contradic-

tion" between the specific FDCA and the general Lanham Act, "the specific provision is construed as an exception to the general one." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012).

That construction does not impliedly repeal the Lanham Act, or deprive it of effect; the Lanham Act "of course has the same effect . . . with respect to" claims not precluded by the FDCA, an overwhelming majority. *Amerada Hess*, 488 U.S. at 438. By contrast, Section 337(a) does *not* have the same effect if the Lanham Act may be used to circumvent it. A statute specifying that there be *no* private enforcement is rendered ineffective by *any* private enforcement. Put another way, Congress has not insisted that everyone must have a Lanham Act remedy, but it *has* insisted that no one may bring a private lawsuit to enforce the FDCA.

B. The FDCA Bars Lawsuits Seeking To Declare False What the Agency Has Declared True

The same rationale applies with equal force where the FDA's decision does not turn on the statutory terms "false" or "misleading," but where the Lanham Act cause of action seeks to declare "false"—and actionable—a proposition that the agency has specifically declared to be true. *See, e.g.*, *Wyeth*, 2010 WL 746394, at *4-5 (contention that generic drug was not bioequivalent to brand-name drug). As the government correctly states, a Lanham Act claim is precluded "if that claim rest[s] on grounds that would conflict with a determination underlying the agency's approval." U.S. Cert.-Stage Amicus Br. 16. The

agency is in a far superior position to make the judgments of scientific fact that underlie the approvals of specific products. And regulated parties understandably place significant, investment-backed reliance on the FDA's approval decisions. To the extent those decisions are challenged, it must be under the deferential standard of the Administrative Procedure Act, not before a jury being asked to award treble damages under the Lanham Act, *see* 15 U.S.C. § 1117(a).

The sort of scientific judgment made by the FDA is not suitable for second-guessing in a Lanham Act case. The Lanham Act allows lay juries to decide the truth or falsity of statements in advertising that rest on complex science. "If the advertising involves medical, scientific, or technical matters, expert witnesses will be necessary to unravel truth from falsity." 5 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 27:56, at 27-138 (4th ed. 2013). Where there is competing expert testimony, the question whether the advertising is true or false will likely go to the jury, with the jury's verdict reviewable only deferentially. *See, e.g.*, *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 500 & n.10 (5th Cir. 2000) (sustaining jury verdict based on expert evidence). And a Lanham Act judgment may even result in an injunction against the use of the false advertising—in other words, a jury may bar what the FDA has expressly authorized. Where the allegedly false statement pertains to compliance with the FDCA, its requirements, and the requirements thereunder, the Lanham Act suit amounts to enforcement of the FDCA.

Bioequivalence is a useful example of an FDA determination that cannot properly be litigated in a Lanham Act case. The FDA cannot approve a generic drug unless it is "bioequivalent" to another drug that has already gone through the FDA's approval process for new drugs, and its active ingredient or ingredients are the same as those of the brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(C); *see also, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* 132 S. Ct. 1670, 1676 (2012). The FDA has considerable "discretion to determine what tests or studies would provide it with appropriate information from which to determine" bioequivalence or the identity of active ingredients, *Schering Corp. v. FDA*, 51 F.3d 390, 399-400 (3d Cir. 1995); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1319 (D.C. Cir. 1998). That is because "the statute does not restrict applicants to a specific method for demonstrating bioequivalence." 57 Fed. Reg. 17,950, 17,977 (Apr. 28, 1992). Indeed, the statute expressly allows the FDA to decide on a drug-by-drug basis whether bioequivalence must be established through "in vitro" bioequivalence studies (laboratory testing), "in vivo" studies (testing on human subjects), "or both such studies." 21 U.S.C. § 355(j)(7)(A)(i)(III). The FDA has promulgated detailed regulations on that subject as well. See, *e.g.*, 21 C.F.R. §§ 320.21(b), (f), 320.22. Ultimately, the FDA has discretion to adopt "[a]ny . . . approach" that it "deem[s] adequate" to "establish bioequivalence," *id.* § 320.24(b)(6), and "[t]he preferred method . . . is determined on a case-by-case basis, depending on the drug under study." 57 Fed. Reg. at 17,972.

Once the FDA determines that a proposed generic drug is bioequivalent to an approved drug and meets

the other criteria necessary for approval, competitors and others with standing are free to challenge that conclusion. *See, e.g.*, *Serono*, 158 F.3d at 1318-19 (discussing challenge to FDA's conclusion that active ingredients were the same). That challenge proceeds under the familiar standard of the APA: it is brought against the agency or its head, not the generic drug maker; money damages are not available; review is limited to the administrative record; and the reviewing court grants a "high level of deference" to the FDA's interpretation of "scientific data within its area of expertise." *Id.* at 1320 (citation omitted).

A competitor would have no reason to proceed through that administrative challenge, however, if it could achieve the same result (or better) by suing under the Lanham Act. Alleging that the generic product was falsely marketed as "bioequivalent" to another drug, or as containing the same active ingredient, would allow the plaintiff to seek a jury trial and potentially win not just an injunction, but a substantial sum of money damages. But the import of such a lawsuit is that the FDA has allowed a drug onto the market that does not meet the FDCA's criteria for approval, even where the FDA has made an explicit determination that the drug does meet those criteria and the jury is being asked to disagree. That is an impermissible attempt to enforce the FDCA privately, and it is barred by Section 337(a) on the reasoning discussed above. *See, e.g.*, *Wyeth*, 2010 WL 746394, at *4.

If accepting a plaintiff's Lanham Act theory of falsity would compel the conclusion that the product violates the FDCA, *e.g.*, because it should not have

been approved or its labeling is false or misleading, then the Lanham Act claim is barred.

C. Considerations of Agency Deference and Fair Notice Preclude Punishing a Defendant Who Relies on the FDA

In this highly regulated area, the FDA often "does not give . . . words their ordinary English meanings." *United States v. 50 Boxes More or Less*, 909 F.2d 24, 25-26 (1st Cir. 1990) (Breyer, C.J.). And indeed, regulated parties need to comply with FDA's administratively-defined meanings rather than with terms' plain meaning. *See, e.g.*, 21 C.F.R. § 101.60(b)(1) ("zero calories" describes food with less than 5 calories in a specified portion).

Substituting a private civil action under the Lanham Act creates the risk that two rival meanings of the relevant legal terms will emerge: the meaning that FDA uses, and on which it is entitled to deference, and the ordinary-English meaning of those terms, on which a Lanham Act jury will premise liability. That result runs directly against two bedrock rules: that an agency deserves primacy in interpreting its own regulations, and that the government will not direct regulated parties to do one thing and then punish it for not doing something else.

That principle is particularly important where Congress has given the FDA authority not only to answer a certain scientific question, but also to specify *how* it is to be answered. For instance, in deciding whether a generic drug is "bioequivalent" to a brand-name drug, the FDA is authorized to decide what kind of scientific studies to require (laboratory testing versus testing in human subjects) and what con-

stitutes a "significant" difference in bioavailability. 21 U.S.C. § 355(j)(7)(A)(i)(III), (j)(8)(B)-(C). Allowing Lanham Act plaintiffs to use their own standards, their own science, and their own scientists to prove the falsity of a claim of bioequivalence would upset that delegation. Recognizing the need for clear and predictable rules, Congress directed the FDA to write them—fully intending that the regulated community would rely on them. *See, e.g.*, *id.* § 355(j)(3)(C) (recognizing reliance interest in study design). Allowing a Lanham Act plaintiff to come along later and convince a jury to adopt *his* experts' hindsight approach is altogether incompatible with that congressionally-conferred reliance interest. Petitioner does not meaningfully disagree. *See, e.g.*, Pet'r Br. 38 (acknowledging that a different rule could apply if the "agency . . . sought to encourage the conduct being challenged").

II. In Deciding This Case, This Court Should Be Cognizant of the Differences Within the FDCA

This Court should decide this case with careful attention to the varying procedures that the FDA applies to food, drugs, and devices, and to the corresponding differences in the provisions of the FDCA. Petitioner's briefing suggests a willingness to obscure those important differences.

Petitioner brought this case here asserting a conflict in the courts of appeals over the intersection between the Lanham Act and the FDCA (as well as other statutes such as the pesticide-regulation statute). The government correctly explained that this case was a rarity because it involved the FDCA pro-

visions governing food, whereas most of the cases in the courts of appeals involved other regulated areas. U.S. Cert.-Stage Amicus Br. 19-20. Petitioner, however, insisted that the Court should take up this "one . . . case" to "provid[e] the lower courts with guidance" as to all the "distinct FDA regulatory schemes." Pet'r Cert.-Stage Supp. Br. 10. Indeed, petitioner perceived the rule advocated by the government to "ha[ve] nothing to do with whether the subject matter of the agency's regulation is 'food' or something else." *Id.*

Petitioner now focuses more of its arguments on aspects specific to food-label regulation. *See, e.g.*, Pet'r Br. 28-31. But petitioner has not abandoned its broader arguments, which risk conflating aspects of the FDCA that are quite different both substantively and procedurally. While there are numerous differences between food-label regulation and, *e.g.*, drug regulation, a few points are particularly salient here.

A. The FDA Does Not Review Juice Labels Individually, But Does Conduct Individual Review in Other Contexts

This case involves a categorical determination by the agency that juice mixtures may use a common name like the one respondent has given its "Pomegranate Blueberry Flavored" drink. The agency has chosen to do that by regulation because it "does not approve juice labels" individually. U.S. Cert.-Stage Amicus Br. 16. At a minimum, that regulation sets forth the agency's view that a juice mixture like respondent's is not "false" or "misleading," and therefore is not "misbranded," merely by virtue of its common name. 21 U.S.C. § 343(a)(1).

Petitioner contends (and the government agrees in part) that the *rest* of the label is fair game for a Lanham Act lawsuit. They state that because there is no regulation governing the aspects of the label that respondent finds objectionable, and because there is no individual review of respondent's label by FDA, the Lanham Act remedy is not ousted.[4] Pet'r Supp. Br. 4-5; U.S. Cert.-Stage Amicus Br. 9-11, 15-16.

Whatever the merits of that argument, it does not apply in other contexts where the FDA *does*, in fact, conduct individualized review in the context of an approval. As noted, the government specifically states that "affirmative FDA *approval* of specific labeling—*as in the prescription drug context, for example*, see 21 U.S.C. 355(d)—would preclude a claim under Section 43(a) of the Lanham Act, if that claim rested on grounds that would conflict with a determination underlying the agency's approval." U.S. Cert.-Stage Amicus Br. 16 (second emphasis added). In that context, the agency is obliged to review each and every element of the statutory test for approval of a drug, including whether any element of the labeling is misleading, before it allows the drug to go on the market.[5] A Lanham Act claim premised on the notion that the agency missed something in its review is no different than a claim that the agency affirmatively erred. Both types of claim assert that the drug is on the market in violation of the FDCA, and both are barred by the principle that private parties may not enforce the FDCA.

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[4] Respondent disputes that there is no regulation on point.

[5] The requirements for premarket approval of medical devices are similar. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008) (discussing 21 U.S.C. § 360e(d)(1)(A)).

Indeed, any rule that rewarded non-exhaustion would discourage objectors from bringing concerns to the FDA and encourage them to go to court instead. That would be exactly the wrong outcome, considering that the agency possesses both the scientific expertise to evaluate any such concern and the primary role in protecting the public health and safety from misbranded food, drugs, and devices.

B. The FDA Reviews Drug Advertising

The FDA is charged with ensuring that advertising for prescription drugs is not false or misleading. *See* 21 U.S.C. § 352(n). While in other areas regulated by the FDCA the Federal Trade Commission takes the lead in regulating advertising, the FDA "has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising." Memorandum of Understanding Between FTC and FDA, MOU 225-71-8003 (1971). The FDA has therefore promulgated regulations prohibiting specific deceptive practices in prescription drug advertising. 21 C.F.R. § 202.1(e)(5)-(7).

In carrying out its function, the FDA is sometimes, in exceptional cases (*see* 21 U.S.C. § 352(n)(3)(A)), called upon to review particular advertisements before they run. For example, the FDA has specified certain categories of advertising that it deems generally impermissible, but the FDA may approve particular prescription drug advertising within those categories based on a showing that an advertisement is "not false, lacking in fair balance, or otherwise misleading." 21 C.F.R. § 202.1(e)(6) (proviso). The FDA may also review advertisements submitted voluntarily.

At a minimum, the FDA's approval of an individual advertisement must be enough to give the regulated entity confidence that the advertisement is not false or misleading. For a private plaintiff to come along and second-guess the FDA's guidance would render that guidance altogether meaningless. That is not what the designers intended.

C. The Savings Clause on Which Petitioner And the Government Rely Is Limited To Food Labeling

While no state-law claim is at issue here, both petitioner and the government seek to draw inferential support from a clause saving state-law claims from preemption—but *only* in the food context. U.S. Cert.-Stage Amicus Br. 10, 11; Pet. 17-18. The preemption provisions of the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343-1(a) & note, apply only to food labeling. Its exception from preemption for state-law food-labeling requirements that are "identical to" federal law has no bearing on any other portion of the FDCA. [6]

In the generic-drug context in particular, the preemption rule is considerably different. *See, e.g.*, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). At a minimum, there is no statutory blessing for addi-

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[6] Indeed, it is doubtful that the savings clause even supports the inference in the food context. The fact that Congress has saved some "identical" state-law claims from preemption, or has failed to preempt other state-law claims (Pet'r Br. 28-32), does not mean that Congress itself has *created*, in the Lanham Act, a separate but "identical" federal cause of action that plaintiffs may pursue despite the bar on private enforcement of the FDCA.

tional, separately enforceable requirements to be placed on generic drug manufacturers. And where a state-law claim directly implicates the FDA's role, there is a strong case for *conflict* preemption, even if there is an exception to *express* preemption. *See Buckman*, 531 U.S. at 352-53 (discussing Section 337(a) and explaining why state causes of action dependent on the FDCA are conflict-preempted even if they are within a statutory savings clause).

In particular, the savings clause for food labeling requirements "identical to" the federal requirements cannot provide any support for a Lanham Act claim based on *disagreement* with how the FDA has applied the federal requirements. When the FDA applies a statutory term like "bioequivalent," it is interpreting federal law, and its interpretation is entitled to deference. A jury's decision to disagree with such a determination is hardly the application of an "identical" standard.

At least outside the food-related context at issue here, there can be no inference that Congress specifically intended private enforcement through the Lanham Act. That aspect of petitioner's reasoning therefore is limited to the context of this case, not to the entire FDCA.

CONCLUSION

The judgment of the court of appeals should be affirmed. In the alternative, the terms of any reversal and remand should be limited to the context in which the FDA has not reviewed a food label and has not specifically dealt with the allegedly misleading content or design in a regulation.

Respectfully submitted.

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