No. 13–1379

IN THE

Supreme Court of the United States

ATHENA COSMETICS, INC.,

Petitioner,

v.

ALLERGAN, INC.,

Respondent.

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

SUPPLEMENTAL BRIEF FOR PETITIONER

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RULE 29.6 STATEMENT

Undersigned counsel state that no amendment is needed to the Rule 29.6 Statement in Athena Cosmetics, Inc.'s Petition for a Writ of Certiorari.

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SUPPLEMENTAL BRIEF FOR PETITIONER

It is one thing for the Government to sanction private claims—fraud, negligence, failure to warn—that are "based on 'traditional state tort law' that 'predate[s]' the FDCA but happens to 'parallel it.'" *Caplinger* v. *Medtronic, Inc.*, ___ F.3d ___, 2015 U.S. App. LEXIS 6630, *10-11 (10th Cir. Apr. 21, 2015) (quoting *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)). Such claims were "a prominent part of the legal landscape" at the FDCA's enactment. *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 341-42 (2008) (Ginsburg, J., dissenting). They do not intrude on the "relationship between [FDA] and…entit[ies] it regulates." *Buckman*, 531 U.S. at 347. And they "serve[] a compensatory function distinct from federal regulation." *Wyeth* v. *Levine*, 555 U.S. 555, 563 (2009).

It is quite another thing for the Government to invite private claims like this one, which led to a product's ouster from the marketplace based *solely* on lack of FDA preclearance—even though FDA was not a party and had never intimated that approval was necessary.[1] Such claims are the antithesis of "'traditional state tort law' that 'predate[s]' the FDCA.'" Before that statute's enactment in 1938,

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[1] The Government does not endorse Allergan's fanciful suggestion that Athena might have obtained "drug" approval from *state* regulators. Indeed, it agrees that "lack of FDA approval" is an "element of [Allergan's] claim." Gov't Br. 16.

there was no notion of premarket approval (federal *or* state). Pet. 6. The FDCA pioneered that requirement—and, in the same breath, provided that its "enforcement…shall be by and in the name of the United States." 21 U.S.C. § 337(a). Even if the enacting Congress meant to "preserve" "widely available state rights of action [that] provided [monetary] relief for injured consumers," *Levine*, 555 U.S. at 567, 574, it could not have imagined "parallel" private suits to police the premarket approval requirement. Indeed, neither Allergan nor the Government disputes that, until this case, *no court anywhere had ever permitted such a claim*.

A few short years ago, the Government agreed with Athena, arguing that "FDA, as the administrator of its own approval process, needs absolute discretion to determine what must be submitted to it…." Tr. of Oral Arg., *Warner-Lambert Co.* v. *Kent*, No. 06-1498 (Feb. 25, 2008), 19-21. Now, however, the Government argues that judges and juries in private lawsuits may "determine what must be submitted" to FDA—and ban products if those submissions have not been made. This contradicts § 337(a) and *Buckman*, and would lead to absurd consequences. It cannot be correct.

The Government is also incorrect that this case is not cert-worthy. The distinctions it draws in the caselaw are illusory. Moreover, it does not dispute that lower courts are crying out for clarification. Just weeks ago, a leading appellate jurist implored this Court to "revisit[] and reconcil[e]" its decisions in this

area. *Caplinger*, 2015 U.S. App. LEXIS 6630, *12-13 (Gorsuch, J.).

The time for that reconciliation is now. The decision below went further than any has gone in arrogating regulatory authority to private plaintiffs. Moreover, as the Government tacitly acknowledges, this Petition has none of the "vehicle problems" that plague many similar petitions (*e.g.*, interlocutory posture or alternative *express*-preemption holdings). The Petition should be granted.

I. THE GOVERNMENT IS WRONG ON THE MERITS.

In the Government's view, *no* claim is impliedly preempted by the FDCA as long as the state-law rule of decision is "substantively identical to the [FDCA's] requirements." Gov't Br. 3, 8. Because California and federal law have similar definitions of "drug," the Government reasons, there is no preemption—Q.E.D.

That reasoning is thrice flawed. First, it turns on an unstated (and erroneous) assumption that judges and juries will *apply* that open-ended definition in the same manner FDA would. Second, it is irreconcilable with § 337(a) and *Buckman*, which establish that even "parallel" claims are preempted if they implicate "dealings with the FDA." Finally, it invites a torrent of novel and disruptive litigation.

A. "Parallel" Rules Do Not Guarantee "Parallel" Outcomes.

"[N]ominally equivalent" standards, when applied by different tribunals, may not be "*genuinely* equivalent." *Bates* v. *Dow Agrosciences L.L.C.*, 544 U.S. 431, 454 (2005). In *Buckman*, that was one of the Government's arguments *for* preemption:

> Even if juries in different States applied the same substantive standards as FDA, it would not eliminate th[e] conflict…."[A] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law."

Br. of United States (Merits), *Buckman*, 2000 U.S. S. Ct. Briefs LEXIS 504, *50-51 (Sept. 13, 2000) (quoting *Garner* v. *Teamsters*, 346 U.S. 485, 490-91 (1953)).

This is a case in point. Although California shares the FDCA's definition of "drug," that definition hinges on an article's "intended use." "'[I]ntended use' is broadly defined," 63 Fed. Reg. 40025, 40038 (July 27, 1998), and ascertaining it "entail[s] the exercise of judgment grounded in policy concerns," Pet. 9. Conflict is guaranteed if tribunals nationwide are permitted to interpret and apply such a loose standard. *See Armstrong* v. *Exceptional Child Ctr.*, 135 S. Ct. 1378, 1385 (2015). Indeed, the Government does not dispute that, here, the courts below applied the "in-

tended use" test in a manner different from FDA's usual practice. Pet. 8-10, 16-17.

The Government papers over this conflict by assuming the conclusion of the parties' dispute: that RevitaLash is a "drug" under the "intended use" test, as FDA would apply it. Indeed, the Government reframes the Question Presented as whether the FDCA "impliedly preempts a private suit…to enjoin…distribution of *a new drug* that has not been approved," and answers that reframed question: "California may authorize courts to restrain the…sale…of unapproved *new drugs*." Gov't Br. i, 11 (emphasis added). This just presumes that FDA would consider RevitaLash a "drug"—a proposition that has never been established (and the Government does not even advance). The true Question is different: whether the need for "drug" approval can be determined in a *private state-law suit*, to which FDA is not a party.

B. Section 337(a) Precludes Even "Parallel" Claims If They Involve The FDA-Approval Process.

There is a deeper problem: § 337(a) impliedly preempts even *truly* "parallel" state-law claims where they intrude on the "inherently federal" FDA-approval process. *Buckman*, 531 U.S. at 347, 352-53; Pet. 29-30; *see also* Br. of United States (Certiorari), *Buckman*, 1999 U.S. S. Ct. Briefs LEXIS 1003 ("U.S. *Buckman* Cert. Br."), *28 (June 7, 1999) ("[T]he duties of persons in connection with their submission of applications to a federal agency for…regulatory ap-

proval involve 'uniquely federal interests' that 'warran[t] the displacement of state law.'").

The Government distinguishes *Buckman* to within an inch of its life, but none of those distinctions bears scrutiny.

- *"Dealings" with FDA versus "failure to deal."*

Per the Government, "[this] suit does not turn on [Athena's] actual 'dealings with the FDA,' as in *Buckman*," because Athena "never submitted a marketing application to FDA." Gov't Br. 16. Instead, the Government suggests, this case is about *failure to deal* with FDA.

But Athena *had* "actual 'dealings'" with FDA. While it never submitted a New Drug Application, it "provided FDA with detailed information" in response to Agency inquiries. Pet. 10-11. And nothing in *Buckman* limits its reach to claims alleging *affirmative* impropriety in "dealings" with FDA, as opposed to improper omissions or "failure to deal." Indeed, as *Buckman* observed, federal law "inherently" controls not only how a party's relationship with FDA "is governed," but also how it "originates." 531 U.S. at 347.

Moreover, the Government's distinction cannot be squared with *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011). There, PLIVA asserted that it could not change its label without FDA's permission. The plaintiffs faulted PLIVA for "not even *try[ing]* to" obtain permission. *Id.* at 2578-79. The Government's view here would make that inaction subject to state-

law attack, since it was a "failure to deal," not an affirmative misstatement to FDA. But this Court—citing *Buckman*—held that PLIVA's "failure to ask the FDA" for permission was "not a matter of state-law concern." *Id.* at 2578, 2581.

- *Claims outside States' "historic purview" versus claims within it.*

The Government argues that this case is different from *Buckman* because it lies "within the State[s'] historic purview to regulate health and safety." Br. 17. That distinction is untenable. *Buckman* addressed the claims of thousands of plaintiffs injured by a medical device. Even those claims did not "implicat[e]…state regulation of matters of health and safety," 531 U.S. at 347-48, however, because they "d[id] not depend on any showing that the device was [unsafe]," U.S. *Buckman* Cert. Br., *26-27. Here, too, liability did not depend upon the safety of RevitaLash. Indeed, Allergan made no showing that *a single consumer* was harmed.

The Government similarly argues that this case implicates the States' "historic purview…to protect against unfair competition." Gov't Br. 17. But "'[u]nfair competition,' as known to the common law," was "a limited concept" concerning "the palming off of one's goods as those of a rival trader." *A.L.A. Schechter Poultry Corp.* v. *United States*, 295 U.S. 495, 531-32 (1935). In other words, it involved *deception*. Here, Allergan stipulates that its claim "is not based on misrepresentation or deception." Pet. 15-16. Long after the FDCA's enactment, California amend-

ed its statutes to define *any* unlawful act (state or federal) as "unfair competition."[2] That did not retroactively enlarge California's "historic purview" to encompass dealings with federal agencies.

- *Claims that "supplant" FDA decisions versus claims that do not.*

The Government argues that the *Buckman* plaintiffs' claims amounted to a collateral attack on FDA's decision to approve the challenged device, while this suit does not "supplant any regulatory determination by FDA." That is so, it explains, because FDA's "inaction" does not "equate to an affirmative…decision that RevitaLash is not a…drug." Gov't Br. 10-11.

In context, however, FDA's refusal to proceed against Athena cannot be construed as mere inaction. Whether RevitaLash was a "drug" was brought to FDA's attention repeatedly. Although it took action against eyelash conditioners marketed with express "growth" claims, it did not so much as send Athena a warning letter. Pet. 10-12. Indeed, when Allergan complained about RevitaLash, FDA *disagreed* with its position. Pet. 11.

But whether FDA reached a determination about RevitaLash is ultimately immaterial. *Buckman*'s rationale had nothing to do with "supplanting" final FDA decisions. Preemption flowed from the "inherently federal" nature of "the relationship between a

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[2] *See Cel-Tech Commc'ns, Inc.* v. *L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 194-95 (1999) (Kennard, J., dissenting).

federal agency and the entity it regulates." *Id.* at 347-48. Indeed, the Government argued that the plaintiffs' "fraud-on-the-FDA" claim would be preempted *even if* FDA made a finding of fraud and withdrew the device's approval. *See* 531 U.S. at 354 n.2 (Stevens, J., concurring).

As the Government has noted elsewhere, "a rule that ma[kes] preemption turn on the presence or absence of a decision by FDA" invites "interference with the federal scheme." Br. of United States, *Kent*, 2007 U.S. S. Ct. Briefs LEXIS 1867 ("U.S. *Kent* Br."), *40-42 (Nov. 28, 2007). Such a rule would make FDA "the gatekeeper for private tort liability." *Ibid.* "Parties would…seek extensive information from FDA" about internal deliberations, and petition it "to make findings" to support or preclude private claims. *Ibid.* This would "exert an extraneous pull" on FDA and "divert its resources away from its core public health mission." *Ibid.* (quoting *Buckman*, 531 U.S. at 353).

- *Device cases versus "drug" cases.*

Finally, the Government cites language in the Drug Amendments of 1962 that "[n]othing *in th[ose] amendments*…shall be construed" to preempt state law, absent "a direct and positive conflict." Gov't Br. 2-3, 13-14. The implication is that preemption is less appropriate here than in device cases like *Buckman*.

But the Government previously argued that "[t]he preemption question under *Buckman*…should not turn on…the particular product under the FDCA." U.S. *Kent* Br., *17 n.3. As it noted, "'the relationship

between a federal agency and the entity it regulates is inherently federal in character,'" and "there is no meaningful distinction between drugs and devices in this respect." *Id.*, *27.

In any event, the "saving clause" the Government invokes is irrelevant. It concerns the preemptive effect of the Drug Amendments of 1962 *themselves*. It does not salvage claims that are preempted even "in the absence of [those] amendments," Gov't Br. 2, 13—such as those preempted under § 337(a).[3]

C. The Government's Position Has Unacceptable Consequences.

Tens of thousands of cosmetics are sold in the United States. On the Government's reasoning, any number of them—however safe, effective, and widely-used—could be banned by private lawsuits, on the ground that they have an incidental effect on bodily "structure," and are therefore "drugs." Until now, it has fallen to FDA to take such action when, in its judgment, the public interest demands it. *See, e.g.*, FDA Response to Am. Dental Ass'n Citizen Petition (Apr. 22, 2014), http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0566-0005 (denying associ-

[3] The Government stirs confusion by asserting that "premarket approval" in its "modern" form "dates from" the 1962 Amendments. Gov't Br. 2. Those Amendments made the process more rigorous, *see Levine*, 555 U.S. at 567, but they did not *create* it. Premarket approval, like § 337(a), was part of the original 1938 Act. *See* Pub. L. No. 75-717, ch. 675, §§ 307, 505, 52 Stat. 1040, 1046, 1052-53.

ation's request to classify whitening toothpastes as "drugs"). If the Government's position here succeeds, those decisions will be made by self-interested competitors and trial lawyers.

For example, although FDA recently declined to find that whitening toothpastes are "drugs," it made no determination to the contrary. *Ibid.* So dentists could sue toothpaste manufacturers, arguing—like Allergan did—that those products are "drugs"; that their sale reduces dentists' revenue; and that this "unfair competition" should be enjoined. *Cf. North Carolina State Bd. of Dental Examiners* v. *FTC*, 135 S. Ct. 1101, 1104 (2015) (discussing dentists' self-interested action against competing "nondentist teeth whitening service providers and product manufacturers"). For good measure, class-action attorneys could seek restitution on behalf of purchasers of these "unapproved drugs."

These lawsuits would engulf the cosmetics industry, and others would hardly be immune. *See* Warning Letter to General Mills (May 5, 2009), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm162943.htm (suggesting that Cheerios was an "unapproved new drug" because it was promoted as "lower[ing] cholesterol"). Besides clogging the courts, these suits would create a crazy-quilt, where products are salable in some jurisdictions but banned in others, depending on where plaintiffs choose to sue and how each court applies the nebulous "intended use" test.

The Government maintains that this poses no "greater threat to national uniformity" than occasional money judgments in "traditional" personal-injury suits. Gov't Br. 14-15. But this is so patently wrong that it should call the Government's entire argument into question.

II. THE GOVERNMENT IS WRONG ON CERT-WORTHINESS.

The Government argues that there is no "clear split of authority" regarding "lack-of-FDA-approval" claims. Gov't Br. 18. Here, too, it is mistaken—but even so, review would be warranted to provide guidance for which lower courts are clamoring.

A. The Circuits Are Divided.

As Athena has shown, the Second, Sixth, and Ninth Circuits—unlike the Federal Circuit—will not entertain "lack-of-FDA-approval" claims. Pet. 20-22.

The Government tries to distinguish *Loreto* v. *P&G*, 515 F. App'x 576 (6th Cir. 2013), and *PDK Labs, Inc.* v. *Friedlander*, 103 F.3d 1105 (2d Cir. 1997), as "essentially efforts to enforce the FDCA itself, rather than parallel state law." Not so. There, the plaintiffs sued under *state consumer-protection statutes*. Pet. 20-21. Those statutes purportedly required the defendants to obtain FDA approval. This does not mean the plaintiffs were "enforcing the FDCA itself": as the Government recently noted, "a state-law claim predicated on a violation of a federal statute or regulation remains a state-law claim." Br. of United States, *Bank of Am., N.A.* v. *Rose*, 2014

U.S. S. Ct. Briefs LEXIS 2004, *23 (May 27, 2014). The claims in *Loreto* and *PDK Labs*, therefore, were "parallel" state-law claims—just like Allergan's. Either all should be preempted, or none.

The Government also tries to distinguish *Perez* v. *Nidek Co.*, 711 F. 3d 1109 (9th Cir. 2013), and *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919 (9th Cir. 2010), on the ground that, there, FDA "ultimately approved" the challenged devices. Gov't Br. 19-20. But that had nothing to do with the Ninth Circuit's reasoning. The question in both cases was whether the defendants acted improperly by marketing a device "before it was approved." *Perez*, 711 F.3d at 1112. The court held such claims impliedly preempted because the existence of the FDA-approval regime is "a critical element"—*not* because a damages award for pre-approval conduct would substantively conflict with FDA's approval decision. *Id.* at 1119; *PhotoMedex*, 601 F.3d at 927-28.

B. Lower Courts Urgently Need Guidance.

Weeks ago, the Tenth Circuit noted that this Court's FDCA-preemption decisions have spawned "considerable 'uncertainty' among the lower courts." *Caplinger*, 2015 U.S. App. LEXIS 6630, *6. In particular, "[l]ower courts have struggled" to reconcile "the notion that § 337(a) shows Congress intended [FDA] to enjoy exclusive enforcement authority" with "the notion that [the FDCA] permits private tort suits that do no more than parallel the [statute]." *Id.*, *11. Judge Gorsuch lamented that "apply[ing]" this Court's "competing instructions" is like "navigating

between Scylla and Charybdis," and urged the Court to "revisit[] and reconcil[e]" them. *Id.*, *12-13.

Many other courts have voiced similar sentiments. *See, e.g.*, *Schouest* v. *Medtronic, Inc.*, 13 F. Supp. 3d 692, 700 (S.D. Tex. 2014) ("Courts have struggled with applying the Supreme Court's [FDCA] preemption rulings"); *Waltenburg* v. *St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 825 (W.D. Ky. 2014) ("[C]ourts have struggled to discern the precise scope of [FDCA] preemption."); *Carrelo* v. *Advanced Neuromodulation Sys., Inc.*, 777 F. Supp. 2d 303, 310 (D.P.R. 2011) (noting "the present struggle…to determine whether state-law claims are preempted by the [FDCA]").

Even if there were no truly irreconcilable circuit split, the lower courts' professed confusion and the mounting cry for clarification are reason enough to grant review now.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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