No. 21A176

In the Supreme Court of the United States

BREEZE SMOKE, LLC,

Applicant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

On Application for Stay

REPLY IN SUPPORT OF EMERGENCY APPLICATION FOR A STAY OF AGENCY ORDER PENDING THE DISPOSITION BY THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT OF A PETITION FOR REVIEW AND ANY FURTHER PROCEEDINGS IN THIS COURT

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INTRODUCTION

The Government does not dispute Breeze Smoke's showing as to several key stay factors. It does not deny that Breeze Smoke is suffering irreparable injury and will continue to do so absent this Court's relief. Likewise, the Government does not argue that a stay would be contrary to the public interest. The Government repeatedly touts the purported dangers from marketing of flavored e-cigarettes—in contrast to its previous position that forcing a sudden exodus of lower-risk e-cigarette products from the market would create a "genuine risk" of an adverse public health outcome. *Vapor Tech. Ass'n v. FDA*, 977 F.3d 496, 499 (6th Cir. 2020). Yet the Government does not (and could not) argue that denying a stay would meaningfully restrict e-cigarette access. Because of relief granted by other courts of appeals and actions taken by FDA itself, other flavored e-cigarette manufacturers can currently market their products and fill any gap left by Breeze Smoke's exodus. A stay would thus level the playing field by placing Breeze Smoke in the same position as other e-cigarette manufacturers while it pursues its challenge to a deeply flawed FDA order.

The Government devotes most of its Opposition to contesting Breeze Smoke's likelihood of success, either in prevailing on the merits in the Sixth Circuit or securing review from this Court on certiorari. But the Government has no effective response to the published opinion of the Fifth Circuit, which catalogued several errors in FDA's denial orders. *See Wages and White Lion Invs., v. FDA*, 16 F.4th 1130 (2021); Application App. 11a (Kethledge, J., dissenting). Instead, the Government follows the path of the Sixth Circuit below, trying to rehabilitate FDA's order with arguments

FDA never made, and even asserting that FDA's decision to ignore a critical aspect of Breeze Smoke's product applications (the marketing plans) was harmless error. Such arguments are baseless. So too is the Government's attempt to discount the prospect of this Court's review. The circuits are *already* split in published opinions that are completely irreconcilable. And further splintering is highly likely since challenges to functionally identical FDA orders are now pending in 10 circuits.

The Government also disputes whether a stay would provide Breeze Smoke with a meaningful remedy given that FDA started marketing its products without FDA authorization. The Fifth Circuit rejected that argument, and for good reason. FDA recognized it was unworkable to enforce the statute's premarketing approval regime before the agency had even set up that review process, and its enforcement policies distinguish between products with pending applications and those that are subject to denial orders. Granting a stay to Breeze Smoke would simply restore the *status quo ante,* placing the company in the same position as competitors whose denial orders have been stayed or withdrawn.

ARGUMENT

I. There is a reasonable probability that the Court will grant certiorari.

The Government's efforts (at 20-21) to downplay the need for this Court's intervention ignores the state of play in the lower courts and the nature of the all-but-inevitable circuit conflict. The circuits are *already* divided on important legal questions involving PMTA review, as the Fifth Circuit held that *identical* legal challenges to those pressed by Breeze Smoke here were likely to succeed. *See* Application at 18-21, 32-33. The Government does not dispute that Breeze Smoke

would have received a stay in the Fifth Circuit, since this case is "materially identical" to *White Lion*. Application App. A at 11a (Kethledge, J., dissenting). And although the Government tries (at 20) to minimize the split as "preliminary," it ignores that the Fifth Circuit issued a published (and thus binding) decision that provided detailed analysis of the merits, including a comprehensive rejection of the legal arguments pressed by the Government here. *White Lion*, 16 F. 4th at 1140-1142.

Moreover, contrary to the Government's suggestion (at 20), review in this Court will not amount to mere error correction. FDA decided product applications "*en masse* rather than individually," Application App. A at 11a (Kethledge, J., dissenting), but because FDA technically issued hundreds of separate orders, the ordinary statutory mechanisms available for consolidating review of an agency order in a single circuit are not available, *see* 28 U.S.C. § 2112(a). As a result, the validity of FDA's materially identical denial orders will likely arise in practically every circuit. It is likely, if not inevitable, that this will lead the circuits to reach conflicting results, resulting in the untenable situation in which an ENDS manufacturer's ability to market its product turns entirely on the happenstance of the circuit in which it is located. The Government's attempt (at 20) to dismiss the prediction that the circuits will conflict on the merits as "prognostication" ignores the highly unusual speed with which the appellate courts have disagreed with each other. And the need to avoid disparate treatment of identically situated companies across circuits provides ample basis for certiorari. *See, e.g.*, *PPL Corp. v. Comm'r*, 569 U.S. 329, 334 (2013) (granting review to resolve split in authority over the treatment of a specific foreign tax).

Nor does the Government's observation (at 21) that rulings vacating FDA's orders would result in agency remands have any bearing on cert-worthiness. Remand is the ordinary remedy in *every* APA case, *e.g.*, *Gonzales v. Thomas*, 547 U.S. 183, 186 (2006), and it certainly does not follow that the Court should cede the field in administrative law to the lower courts. To the contrary, the Court has often granted certiorari to review agency action even though its ultimate order is to remand to the agency for further explanation or consideration of its proposed action. *See, e.g.*, *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1916 (2020); *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2576 (2019).

Ultimately, the question is only whether there is a "*reasonable probability*" that four Justices will conclude the case presents questions that are "sufficiently meritorious to grant certiorari"—not whether full merits review is preordained. *Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010) (emphasis added). The application here amply satisfies the correct legal standard.

II. Breeze Smoke is likely to succeed on the merits.

A. The Government argues (at 25) that its new long-term study requirement does not run afoul of fair-notice and reliance principles because FDA never "categorically exempted manufacturers from the possible need to provide any particular type of evidence, or categorically assured them that certain other types of evidence would suffice." But the Government dilutes the applicable legal standard, which does not merely guard against perfect contradiction, but asks whether a shift in agency position has caused "unfair surprise," *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012), and whether the agency has "change[d] course,"

without considering reliance interests. *Regents of the Univ. of Cal.*, 140 S. Ct. at 1913. As the Fifth Circuit put it, "[t]he FDA did not have to completely flip flop for there to be a change in position. ... It is enough that the FDA's guidance indicated long-term studies were likely unnecessary, while the FDA's Order at the very least created a strong presumption that such evidence is required." *White Lion*, 16 F. 4th at 1141.

There is no serious question that FDA substantially modified its review requirements after the applicable filing deadline yet failed to address the reliance interests of industry. FDA *repeatedly* told applicants that it "d[id] not expect" that they "will need to conduct long-term studies" to secure approval. C.A. App. 60 (2019 Guidance).[1] Yet FDA ultimately issued *en masse* denial orders for every application that did not include a product-specific, long-term study of adult product usage and smoking cessation. Indeed, FDA undertook a self-described "fatal flaw" review, which screened applications to determine whether they contained long-term studies, such as a randomized controlled trial or longitudinal study. C.A. App. 310-11. If an application did not, it would "likely receive a marketing denial order." C.A. App. 311.

Presumably recognizing that the "fatal flaw" review process is indefensible, the Government tries to disavow it, insisting that although FDA "considered such an approach," it "rescinded" the memorandum adopting it during the review process. Opp. at 29 n.5. The record tells a different story. FDA's "Technical Review" document, which provides the reasoning underlying the agency's denial orders,

[1] *See also Premarket Tobacco Product Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50,566, 50,619 (Sept. 25, 2019); FDA Ctr. For Tobacco Products, *Premarket Tobacco Product Application Content Overview* (Oct. 23, 2018), https://bit.ly/30LkHJH.

borrows heavily from the supposedly rescinded "fatal flaw" memoranda, in many instances copying it *verbatim*.[2] The Government's attempt to rehabilitate FDA's review process also cannot explain the outcome: *en masse* denial orders that are virtually identical, all faulting applicants for failing to anticipate the new long-term study requirement. *See* Application at 15 n.4, 17 n.5. This Court's review of agency action is "deferential," but it is "'not required to exhibit a naiveté from which ordinary citizens are free.'" *Dep't of Com.*, 139 S. Ct. at 2575 (citation omitted).[3]

Moreover, although the Government insists (at 27) that FDA left open the formal possibility that it would consider "other evidence" than randomized controlled trials or longitudinal studies, it does not dispute that any such "other evidence" must be a product-specific study evaluating a flavored product's impact "on adult smokers' switching or cigarette reduction *over time*"—which is what FDA had told the industry was *not* required. Application App. C at 32a (emphasis added). FDA even acknowledged in its Technical Review that it had "stated that it did not expect that applicants would need to conduct long-term studies to support an application for ENDS." *Id.* at 30a n. xxiii. But the agency failed to consider reliance interests in making this shift, and the Government offers no defense for that omission.

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[2] *Compare* C.A. App. 331 (August 17, 2021 fatal flaw memorandum) ("Therefore, evaluating the behavioral outcomes needed to show any benefit of the product requires observing the actual behavior of users over time. With both RCT [randomized controlled trial] and cohort study designs, enrolled participants are followed over a period of time, with periodic and repeated measurement of relevant outcomes."), *with* Application App. C at 29a (Technical Review) (identical language).

[3] The Government tries to take credit for its forced reconsideration of application denials after recognizing, when challenged in court, that some applications may have included long-term studies after all. *See* Opp. at 15. The fact that FDA issued the same denial orders to these applicants and retreated to avoid an adverse decision only underscores the absence of meaningful individualized review.

FDA's treatment of Breeze Smoke's applications shows that, despite the Government's protestations, "the agency mechanically considered only whether its application included certain types of long-term studies." Opp. at 27. The Government insists (at 27-28) that FDA evaluated Breeze Smoke's customer survey, which Breeze Smoke put forward to show that its adult customers consider flavors important to their use. But the record shows that FDA reviewed the survey only to the point of confirming it did not satisfy the newly imposed long-term requirement. *See* Application App. B at 12a-13a (describing survey as "not sufficient … *because* it does not evaluate product switching or cigarette reduction resulting from use of these products *over time* …." (emphasis added)). FDA did *not* otherwise evaluate the customer survey or other evidence on its own merits. It was thus a blatant violation of the *Chenery* rule for the Sixth Circuit to offer its own post-hoc critiques of Breeze Smoke's evidence. *See* Application at 27; *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943). The Government does not defend the Sixth Circuit's reasoning under *Chenery*, even as it recapitulates Judge Moore's improper critiques. Opp. at 17.

In the end, the Government is left to fall back on repeated arguments that flavored e-cigarette products are harmful because it believes they are attractive to minors. Breeze Smoke does not dispute or seek to minimize the problem of youth access to e-cigarettes in their efforts to avoid traditional cigarettes, as the company works to ensure that its products are only accessed by adult customers—who themselves exhibit a strong preference for flavored e-cigarettes. *See* Application at 12-13. But FDA did not point to any evidence that the known risks of youth access

changed between July 2019 when it issued its final PMTA guidance and July 2021 when it secretly moved the goalposts for flavored e-cigarette applicants.

Moreover, to the extent FDA has now concluded, after its final PMTA guidance, that flavored e-cigarettes should be categorically banned or subject to more demanding evidentiary standards than tobacco-flavored products, the agency has the tools to impose such restrictions in a manner that provides fair notice and respects reliance—it can issue new tobacco product standards for all flavored e-cigarette products, after undergoing notice and comment. *See* 21 U.S.C. §§ 387g(c), (d)(1); *id.* § 387g(a)(1)(A) (prohibiting flavored cigarettes as a "tobacco product standard"). What the agency *cannot* do is take a shortcut by providing certain review standards in industry guidelines, but then imposing a different, behind-the-scenes standard that leads it to reject *all* of the millions of product applications that companies filed.

B. The Technical Review's treatment of marketing plans was riddled with contradictions that render the Denial Order arbitrary and capricious. In the Review, FDA recognized that "[a]s it relates to the risk of youth," the assessment of whether a product is appropriate for the protection of public health "includes evaluating the appropriateness of the proposed marketing plan." Application App. C at 28a. It also acknowledged that "[l]imiting youth access and exposure to marketing is a critical aspect of product regulation." *Id.* at 28a n.xix. Yet in the very same page and footnote, FDA declined to review Breeze Smoke's marketing plan "for the sake of efficiency." *Id.* According to FDA, none of the marketing plans it had reviewed "to date" would "decrease appeal to youth to a degree significant enough to address and

counter-balance the substantial concerns ... regarding youth use." *Id.* FDA did not explain in its Technical Review why the other marketing plans were deficient, or how those marketing plans compared to Breeze Smoke's.

The Government defends FDA's bypass of Breeze Smoke's marketing plan by arguing for the first time that its rationale is more fully explained in the 2019 Guidance. Opp. at 30. At the outset, FDA's backfilling violates the rule that an agency action may be defended on judicial review only on the grounds "upon which the administrative agency acted" that are "clearly disclosed." *Chenery*, 318 U.S. at 94. *Chenery* violation aside, pointing to the 2019 Guidance does little to show that FDA is likely to succeed in defending its failure to consider a "critical" component of Breeze Smoke's applications. The Guidance did not conclude that marketing plans would be ineffective in preventing youth use of e-cigarettes. Rather, FDA remarked that "age verification *alone* is not sufficient." C.A. App. 144 (emphasis added). Moreover, the marketing measures that FDA described in its 2019 Guidance were abstract proposals for "potential safeguards" provided by e-cigarette manufacturers, not specific marketing plans. C.A. App. 107. Nowhere did FDA suggest that marketing plans would not play a meaningful role in decreasing youth use, which should be considered as part of a *holistic* review of each application.

In the alternative, the Government suggests that, even if Breeze Smoke, the Fifth Circuit, and the Sixth Circuit are right in that FDA "should have more thoroughly considered" Breeze Smoke's marketing plan, Application App. A at 8a-9a, the agency's error was harmless because Breeze Smoke supposedly has not shown

that its marketing plan was better than other plans the agency had considered and found insufficient. Opp. at 32. That new argument mischaracterizes the standard for prejudicial error, which is not "a particularly onerous requirement." *Shinseki v. Sanders*, 556 U.S. 396, 410 (2009). Appeals to harmless error cannot be used to excuse blatant violations of *State Farm,* which requires the agency *itself* to always "consider an important aspect of the problem," and instructs reviewing courts not to "make up for" the agency's failure to do so. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

The Government's "no harm, no foul" argument is also unworkable. Recall that *every* applicant was required to submit a marketing plan, yet FDA appears to have refused to consider *any* such plans when issuing its *en masse* denials. Thus, according to FDA, each reviewing court should be asked to evaluate each applicant's marketing plan to determine whether the plan is meaningfully different from proposals FDA considered back in 2019, and to then assess whether consideration of the plan could have impacted the agency's risk-benefit analysis. In effect, the Government seeks to delegate to Article III courts a core aspect of FDA's PMTA review that the agency itself decided to skip "for the sake of efficiency." Application App. C at 28a.

III. The equitable factors strongly favor relief.

The equities in this case weigh strongly in favor of a stay. Absent action by this Court, FDA's order may drive Breeze Smoke out of business, even if Breeze Smoke ultimately prevails in petition for review. Meanwhile, Breeze Smoke's competitors in other circuits, such as the Fifth, not only can survive, but have an opportunity to expand by taking customers from Breeze Smoke and others who

cannot obtain a stay. As a result, leaving the Denial Order in place pending judicial review would not further any public health interests identified by FDA—it would simply allow geographic happenstance to determine the winners and losers.

The Government challenges little of this. It does not dispute that Breeze Smoke is suffering irreparable harm, which will continue and potentially accelerate if a stay is denied. Nor does the Government dispute that, given the Fifth Circuit's ruling, denying a stay would not meaningfully impact public access to flavored ENDS products. Instead, FDA argues that the Court should decline to grant company-saving relief to Breeze Smoke, primarily on the theory that a stay would not give Breeze Smoke authorization to lawfully market its products and thus would not redress its injuries. That argument fails for several reasons.

A. The basic premise on which FDA's argument—that *any* ENDS product that has not received approval from FDA is marketed unlawfully—proves far too much. After all, "manufacturers were widely marketing e-cigarettes throughout the United States" when FDA finalized the Deeming Rule in 2016. *White Lion*, 16 F.4th at 1134. Once the Deeming Rule took effect, *all* of those products became technically unlawful under the statute, yet FDA has allowed those products to remain on the market pending the review of PMTAs, in recognition of the disruption that would be caused by suddenly barring access to a product category that provides adult smokers with an alternative to traditional cigarettes. *See* Application at 8-11.

FDA's repeated attempt (*e.g.*, at 35) to cast aspersions on Breeze Smoke as having "profited from the unlawful marketing of [its] products" is thus misleading.

Breeze Smoke and other ENDS manufacturers openly marketed their products while FDA set the standards for PMTA review. This took place not merely because FDA's enforcement resources are limited, but because the agency previously considered continued e-cigarette access for adult smokers during the ramp up to PMTA review *desirable*. Thus, when anti-tobacco advocacy organizations sued FDA and asked a district court to substantially accelerate the agency's deadlines for PMTA filing and review, the agency vigorously *opposed* the request. FDA represented to the court that the truncated deadlines would pose a "genuine risk" to public health by forcing adult smokers to migrate back to traditional cigarettes—an outcome that FDA said "should be avoided if at all possible." *Vapor Tech. Ass'n*, 977 F.3d at 499 (quotation marks omitted). FDA's litigation representation makes no sense if, as it now argues, the legal status of e-cigarette products is determined by "the statute" alone, such that every unapproved product should immediately exit the market, regardless of whether an applicant has a timely filed PMTA still under review.

Given all of this, the relevant question is not, as FDA asserts (at 33), whether staying the Denial Order would result in the formal approval of Breeze Smoke's products or definitively "bar FDA from taking action" against Breeze Smoke. Instead, the question is whether staying the Denial Order would impact the status of Breeze Smoke's products under FDA's established enforcement policies. As to that question, there is no real dispute. FDA's Denial Order states that Breeze Smoke's products are deemed adulterated and misbranded "upon issuance" of the Order, and regulatory action may ensue "without further notice." App. B at 13a. FDA thus clearly views

the Denial Order itself as crucial. FDA's public statements confirm the point: FDA is treating products with denial orders as categorically different than products with pending applications, as the agency is explicitly directing its enforcement discretion toward "products for which no application is pending, including, for example, those with a Marketing Denial Order." Application at 35-36 & n.7.

In addition, the Government's own litigation conduct undermines its argument. *See* Application at 36. In multiple cases, FDA has rescinded challenged denial orders in order to allow for further review. *See id.* In doing so, the Government represented to applicants that it "has no intention of initiating an enforcement action" while an application is "back in the review process."[4] Despite relying on its withdrawal of the denial order in *Turning Point* elsewhere (at 15), the Government's Opposition completely ignores this statement. And it does not dispute that, if this Court granted a stay, Breeze Smoke would be in the same position as the companies like Turning Point. Those companies too "still lack the statutorily required authorization by FDA" that can only come from formal PMTA approval. Opp. at 4. Yet FDA is allowing those companies to stay on the market, in recognition of the fact that the agency's denial orders were legally unsupportable.

B. As a fallback, FDA claims (at 36-38) that a stay will not help Breeze Smoke because Breeze Smoke did not start marketing the relevant products until after the Deeming Rule. FDA did not make this argument before the court of appeals,

[4] *Turning Point Brands, Inc. v. FDA*, Sixth Cir. No. 21-3855, ECF No. 19 (Oct. 8, 2021) (internal quotations omitted); *Humble Juice Co. v. FDA*, Ninth Cir. No. 21-71326, ECF No. 11 (Nov. 3, 2021).

which deprived Breeze Smoke of the opportunity to develop the record showing that the ENDS products at issue were successors to products on the market before 2016. *See* App. to Reply; *see also* Opp. at 37 n.7 (acknowledging the relevance of the acquisition of a product line before the Deeming Rule). Regardless, FDA's argument conflicts with *White Lion*, as the applicant in that case also entered the market after the Deeming Rule was published (though four days before the Rule's effective date). 16 F.4th at 1134-35.

Nothing about Breeze Smoke's post-2016 market entry undermines the equitable case for a stay. While it is true that, by 2019, ENDS products were subject to premarket authorization under the Deeming Rule, it was equally clear that FDA was widely allowing ENDS manufacturers to market their products while their applications were pending. Even now, FDA's press releases emphasize that it is focusing its enforcement activities on manufacturers whose applications have been *denied*—not those who filed after 2016 but whose applications remain pending.[5] *See* Application at 11. Notably, the Government does not point to a single enforcement action FDA has brought based on products for which an application is pending, even if that product entered the market post-2016.

C. FDA's final argument—that the Court should not act until FDA sends Breeze Smoke a warning letter—makes little sense. FDA's denial letter informed Breeze Smoke that FDA might bring an enforcement action *without* a warning letter.

[5] The Government cites (at 37) its 2020 Guidance for the proposition that its compliance policy is limited to products that were on the market in 2016. But that documents states merely that it does not apply to post-2016 products. Nothing about that document undermines FDA's other statements that it is prioritizing enforcement against manufacturers whose applications were denied.

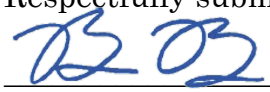
Application App. B at 13a. FDA acknowledges this (at 39) but assures the Court that it has no intention of doing the thing it told Breeze Smoke it might do. FDA should not be allowed to seek Breeze Smoke's submission through threats and then avoid judicial scrutiny by insisting it had no intention of carrying through on those threats.

In any event, leaving the Denial Order in place subject to the threat of enforcement with just 30 days' notice does not remotely address Breeze Smoke's irreparable harm. As Breeze Smoke has explained without contradiction, the Denial Order has had a devastating impact on its business, by disrupting relationships with distributors and retailers who reasonably believe that selling products subject to an unstayed denial order poses unacceptable risk. Application App. D at 49a-50a. If the Court declined to afford relief now, and thus allowed FDA to wield its enforcement authority against Breeze Smoke based on its Denial Order, subject to only 30 days warning, Breeze Smoke would have no realistic way to restore its commercial partnerships and keep its business running while it pursues judicial review.

CONCLUSION

The Circuit Justice should stay the Denial Order pending disposition of the petition for review in the Sixth Circuit and any further proceedings in this Court.

Respectfully submitted,



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