No. _____

In the Supreme Court of the United States

BREEZE SMOKE, LLC,

Applicant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

On Application for Stay

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

Brian T. Burgess
Counsel of Record
Andrew Kim
Mark S. Raffman
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
202.346.4000
bburgess@goodwinlaw.com

Counsel for Breeze Smoke, LLC

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To the Honorable Brett M. Kavanaugh, Associate Justice of the United States Supreme Court and Circuit Justice for the Sixth Circuit:

In accordance with Supreme Court Rule 22 and 23 and the All Writs Act, 28 U.S.C. § 1651, applicant Breeze Smoke, LLC ("Breeze Smoke") respectfully requests an immediate stay of respondent United States Food and Drug Administration's ("FDA") September 16, 2021 order denying Breeze Smoke's Premarket Tobacco Product Applications, pending the disposition of Breeze Smoke's petition for review filed on October 4, 2021, in the United States Court of Appeals for the Sixth Circuit, and any further proceedings in this Court.

INTRODUCTION

The Circuit Justice's intervention is urgently needed to redress the regional circuit courts' inconsistent treatment of substantively identical orders by the Food and Drug Administration (FDA), which denied marketing applications for *millions* of e-cigarette products using standard form letters that all employ the same deeply flawed reasoning. If not stayed, FDA's action will cause continued irreparable injury to petitioner Breeze Smoke, LLC—a fact that FDA did not dispute below. The only reason FDA's action was not stayed is because Breeze Smoke filed its petition for review in the Sixth Circuit rather than in the Fifth or Seventh Circuit, which have stayed indistinguishable FDA orders. *See, e.g.*, App. A at 11a (Kethledge, J., dissenting from denial of stay application) ("I would grant the motion for a stay for substantially the reasons stated by the Fifth Circuit.").

In 2016, FDA decided to regulate Electronic Nicotine Delivery Systems products (known as ENDS or e-cigarettes) as "tobacco products," which subjected this product category to a premarket approval requirement under the Family Smoking Prevention and Tobacco Control Act (TCA). FDA recognized that forcing these products off the market while they completed the review process would have been disruptive and detrimental to public health, since e-cigarettes offer adult smokers a safer alternative to traditional cigarettes. *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 29,011 (May 10, 2016) ("Deeming Rule"); *see also* App. A at 5a ("ENDS products may provide a beneficial alternative to combustible cigarettes because they deliver nicotine without also bombarding the user's lungs with the toxins found in cigarettes."). FDA thus suspended enforcement of the TCA's premarketing requirement, providing a deadline for e-cigarette manufacturers to submit product applications (ultimately set to September 2020), and making clear that the agency "expect[ed] … manufacturers [to] continue to market their products without FDA authorization" during the compliance period. Deeming Rule, 81 Fed. Reg. at 29,010.

In the meantime, FDA developed guidance for the premarket applications. As relevant here, FDA told the industry that the agency "d[id] not expect that applicants will need to conduct long-term studies" of their products to secure approval; instead

they could rely on background scientific literature. C.A. App. 59-60. FDA also told applicants that their marketing plans—which were to include plans for restricting product access by minors—would be a "critical" input to the agency's approval decisions. Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,566, 50,581 (Sept. 25, 2019).

But faced with an unexpected surge of applications before the September 2020 deadline, FDA decided to "move[] its regulatory goalposts" and "change[] the regulatory requirements." *Wages and White Lion Invs., v. F.D.A.*, __ F.4th __, 2021 WL 4955257, at *1 (5th Cir. Oct. 26, 2021) ("*White Lion*"). In particular, FDA "changed its mind" about whether applicants had to provide product-specific, long-term studies, *id.*—their absence was now considered a "fatal flaw" that justified denial of *every* application to market a flavored e-cigarette product, C.A. App. 310-311. In addition, FDA decided "for the sake of efficiency" not to review each applicant's marketing plan. *See* App. C at 28a n.xix; *White Lion*, 2021 WL 4955257, at *3-*4. As a result, FDA was able to decide millions of product applications "*en masse* rather than individually," App. A at 11a (Kethledge, J., dissenting), issuing cookie-cutter denial orders to applicants across the country, including to Breeze Smoke, *see* App. B ("Denial Order").

The TCA directs applicants seeking to challenge an FDA denial order to petition for review in the court of appeals, 21 U.S.C. § 387*l*, and dozens of applicants have already done so, with petitions pending in at least 10 of the 12 regional circuits. *See* App. E (providing a list of known petitions for review). Moreover, because FDA

issued materially identical orders to each applicant, the circuits are reviewing the same challenges to FDA's reasoning (or lack thereof). Already, the Fifth Circuit has issued a published decision finding a challenge to an FDA denial order likely to succeed, because FDA's denial orders departed from the standards of reasoned decisionmaking in several respects, including by ignoring reliance interests and refusing even to review an applicant's marketing plans. See *White Lion*, 2021 WL 4955257, at *3-*5. The Fifth Circuit thus stayed FDA's denial order pending the petition for review. *Id.* The Seventh Circuit, in an unpublished order, also stayed a substantively identical FDA denial order. *See Gripum LLC v. F.D.A.*, Seventh Cir. No. 21-2840, ECF No. 18 (Nov. 4, 2021).

In this case, however, the Sixth Circuit refused to stay the denial of Breeze Smoke's applications. *See* App. A. In a 2-1 published decision authored by Judge Moore, the court "disagree[ed] … with our colleagues on the Fifth Circuit" about whether FDA's denial orders were likely to survive review. *Id.* at 6a-10a. Judge Kethledge dissented, and stated that he would have followed the Fifth Circuit's decision in *White Lion*. *Id.* at 11a. As he explained, "[t]he FDA essentially decided these applications *en masse* rather than individually; that case is thus materially identical to this one." *Id.*

As a result, Breeze Smoke's competitors can stay on the market selling their e-cigarette products without threat of FDA enforcement, while Breeze Smoke can do nothing but watch. This obvious unfairness should not be allowed to stand. FDA's Denial Order should be stayed pending resolution of Breeze Smoke's petition for

review in the court of appeals and any subsequent proceedings before this Court. *See West Virginia v. EPA*, 136 S. Ct. 1000 (2016) (per curiam).

First, Breeze Smoke is highly likely to succeed on the merits, either in the Sixth Circuit or on a petition for certiorari to this Court. There is *already* a circuit split, which may quickly expand since parallel challenges to materially indistinguishable FDA orders are proceeding in courts of appeal across the country. Identically situated competitors should not be treated differently based on their circuit of residence. Moreover, the Sixth Circuit's decision was plainly wrong. As the Fifth Circuit explained in *White Lion*, FDA imposed a "surprise switcheroo" on the industry, telling ENDS manufacturers that product-specific, long-term studies were not necessary, and then denying those applications *en masse* for failing to include those very studies. 2021 WL 4955257, at *5. And, making matters worse, FDA refused to evaluate individual applicants' marketing studies it had previously identified as "critical" because FDA believed that *other* marketing studies had not been sufficient. *Id.* at *3. The Sixth Circuit tried to rationalize the gaps in FDA's reasoning, but could do so only by offering its own *post hoc* justifications for the Denial Order—thus violating "the foundational principle of administrative law that a court may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015).

Second, allowing FDA's Denial Order to remain in place pending review will inflict obvious, irreparable harm on Breeze Smoke. FDA's Denial Order bars Breeze Smoke from marketing products that account for nearly *sixty percent* of its revenue—

losses Breeze Smoke could not later recover. *See* Declaration of Steven Haddad ¶ 6 (App. D). Even if Breeze Smoke ultimately prevails, it will have lost market share to competitors that it may never recover.

Third, the balance of hardships and public interest also favor a stay. While denying a stay would inflict significant harm on Breeze Smoke, there is no corresponding public benefit in granting one. FDA has recognized that e-cigarettes—including flavored e-cigarettes—can benefit the public by providing an attractive and healthier alternative to traditional cigarettes. And, in any event, denying a stay is unlikely to impact overall sales of e-cigarettes since sales that would have gone to Breeze Smoke can simply go to its competitors instead. Moreover, there is an overring "public interest … in having governmental agencies abide by the federal laws that govern their existence and operations." *White Lion*, 2021 WL 4955257 at *9; *accord Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2490 (2021) (per curiam). The public interest thus favors a stay given FDA's flagrant violation of basic rules governing agency decisionmaking.

OPINIONS BELOW

The Sixth Circuit's order denying Breeze Smoke's motion for a stay pending review is reported at *Breeze Smoke, LLC v. FDA*, ___ F. 4th ___, 2021 WL 5276303 (6th Cir. Nov. 12, 2021).

JURISDICTION

The Circuit Justice has jurisdiction over this application pursuant to 28 U.S.C. § 1254(1) and has authority to grant Breeze Smoke relief under the Family Smoking

Prevention and Tobacco Control Act, 21 U.S.C. § 387*l*(b), and the All Writs Act, 28 U.S.C. § 1651(a).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS

Pertinent statutory provisions are reprinted in the Statutory Addendum, *see* App. F.

STATEMENT

I. FDA subjects e-cigarettes to premarketing approval and later issues guidance on the process.

A. FDA "deems" that e-cigarettes should be regulated as tobacco products.

FDA historically lacked jurisdiction to regulate tobacco products. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000). That changed in 2009, when Congress enacted the TCA. The TCA requires "new tobacco products," defined as "any tobacco product … that was not commercially marketed in the United States as of February 15, 2007," to receive FDA approval before the product may be introduced into interstate commerce. 21 U.S.C. § 387j(a). Manufacturers of "new tobacco products" that are not substantially equivalent to a pre-2007 product must undergo premarket review by filing a Premarket Tobacco Product Application (PMTA). *Id.* § 387j(a)-(b).

In evaluating a PMTA, the TCA instructs FDA to consider whether "permitting" the manufacturer's product "to be marketed would be appropriate for the protection of the public health." *Id.* § 387j(c)(2)(A). That question "shall be determined"

> with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—
>
> (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
>
> (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

Id. § 387j(c)(4).

The TCA itself identifies only certain tobacco products as being subject to its marketing restrictions—specifically, "cigarettes," "cigarette tobacco," "roll-your-own tobacco," and "smokeless tobacco." 21 U.S.C. § 387a(b). But the statute also authorizes FDA to issue regulations "deem[ing]" "other tobacco products" as "subject to" the TCA's premarketing approval regime. *Id.*

In April 2014, FDA issued a notice of proposed rulemaking for what became the "Deeming Rule," which it finalized in 2016. 79 Fed. Reg. 23,142 (Apr. 25, 2014). The Proposed Rule solicited comments on "how e-cigarettes should be regulated," taking account of the fact that e-cigarettes "may be less hazardous than combustible products," *id.* at 23,143, have "the potential to help with [smoking] cessation," and "may substantially reduce exposure to tobacco-specific toxicants." *Id.* at 23,152. In its final form, the Deeming Rule defined all e-cigarettes as "tobacco products" subject to the TCA's premarket approval process. 81 Fed. Reg. at 28,974. This created a "serious and obvious problem" because, by that point, "manufacturers were widely marketing e-cigarettes throughout the United States." *White Lion*, 2021 WL 4955257, at *1.

In the face of widespread industry concern, FDA assured e-cigarette manufacturers that the agency did not intend to force their products off the market. FDA acknowledged that e-cigarettes afforded a valuable public health benefit because "the availability of alternatives to traditional tobacco flavors in some products (e.g., ENDS) may potentially help some adult users who are attempting to transition away from combusted products." Deeming Rule, 81 Fed. Reg. at 28,977. FDA thus announced that it would exercise its enforcement discretion to let ENDS manufacturers continue to sell their products while FDA developed guidance and later reviewed the PMTAs. *Id.* at 28,977-78.

B. In guidance to e-cigarette manufacturers, FDA provides assurance that long-term, product-specific studies are not required for approval and promises to review marketing plans.

In October 2018, FDA held a meeting to "improve public understanding … on the policies and processes for the submission and review of [PMTAs]." Tobacco Product Application Review – A Public Meeting (October 22, 2018), https://bit.ly/30SciU7. At that meeting, FDA advised manufacturers that "*[n]o specific studies are required for a PMTA*; it may be possible to support a marketing order for an ENDS product without conducting new nonclinical or clinical studies given other data sources can support the PMTA." FDA Ctr. For Tobacco Products, *Premarket Tobacco Product Application Content Overview* (Oct. 23, 2018), https://bit.ly/30LkHJH (emphasis added).

Then, in July 2019, FDA issued a guidance document for e-cigarette manufacturers (the "2019 Guidance"). The 2019 Guidance assured applicants that, "[g]iven the relatively new entrance of ENDS on the U.S. market, FDA understands

that limited data may exist from scientific studies and analyses." C.A. App. 59. FDA stated: "[I]n general, FDA *does not expect* that applicants will need to conduct long-term studies"—which the Guidance defined as a study of six months or longer in duration—"to support an application." *Id.* at 60 (emphasis added). The agency suggested that applicants could satisfy the public-health standard by pairing scientific literature with "bridging" studies showing that the studies covered in the literature apply to the applicant's product. *Id.*

FDA then issued a notice of proposed rulemaking for a rule that would promulgate the principles set forth in the 2019 Guidance. 84 Fed. Reg. at 50,619. The proposed rule emphasized the significance FDA would place on the applicant's marketing plans. FDA stated that it "*will* review the marketing plan," which "provide[s] input that is critical to FDA's determination of the likelihood of changes in tobacco product use behavior, especially when considered in conjunction with other information contained in the application." *Id.* at 50,581 (emphasis added).

II. FDA categorically denies approval to flavored e-cigarettes, including Breeze Smoke's.

The compliance period was adjusted several times, and became the subject of litigation, but FDA ultimately required that PMTAs for existing products be filed by September 9, 2020. *See Vapor Tech. Ass'n v. FDA*, 977 F.3d 496, 500 (6th Cir. 2020) (summarizing the evolution of the compliance period and related litigation). FDA had predicted that it would receive a "flood[]" of upwards of 7,000 applications before the deadline. Decl. of Mitchell Zeller ¶ 19, *Am. Acad. of Pediatrics v. FDA*, No. 18-cv-883 (D. Md. June 12, 2019) (ECF No. 120-1) ("Zeller Decl."). Instead, FDA was

wracked by a tsunami—it received more than 6.5 *million* applications before the September 2020 deadline, the "majority" of which were for e-cigarettes.[1] Nearly a year later, as the deadline for FDA review of the PMTAs was set to expire, FDA rejected applications for more than a million ENDS products. By September 23, 2021, FDA had issued more than 300 marketing denial orders "accounting for more than 1,167,000 flavored ENDS products."[2] To the best of Breeze Smoke's knowledge, FDA has not approved *any* applications for a flavored e-cigarette.

As explained below, FDA's blanket denial for these products did not rest on meaningful case-by-case consideration of the studies or marketing plans submitted. Instead, FDA instituted what it described as a "fatal flaw" review process in which denied the applications *en masse* based on their failure to include the very studies that FDA had said *were not necessary*. And, making matters worse, FDA refused to consider individual applicants' marketing plans—which it had previously identified as "critical" to determining population-wide health effects—based on the bizarre theory that *other* marketing materials it had considered had not been sufficient.

A. Breeze Smoke spends millions of dollars assembling and submitting its PMTAs in reliance on FDA's guidance.

Breeze Smoke manufactures disposable, flavored, pod-based e-cigarettes. C.A. App.323 n.2; App. D ¶¶ 3-4 . Breeze Smoke undertook the PMTA process after careful review of FDA's public guidance, including the 2019 Guidance. The company spent

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[1] Janet Woodcock & Mitch Zeller, *FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted* (Sept. 9, 2021), https://bit.ly/3DHvsuy.

[2] *FDA in Brief: FDA Warns Firms for Continuing to Market E-cigarette Products After Agency Denied Authorizations* (Oct. 7, 2021) ("FDA in Brief"), https://bit.ly/3xgUDl9.

$11.25 million to assemble PMTAs that spanned tens of thousands of pages, and retained an Official Correspondent and Representative to manage the process. *Id.* ¶¶ 11-12.

Breeze Smoke timely submitted its PMTAs on September 3, 2020. *Id.* ¶ 11. Consistent with the 2019 Guidance, Breeze Smoke provided an extensive literature review (101 pages covering hundreds of scientific studies in peer-reviewed articles), which surveyed existing scientific research showing there is "great harm reduction to adult smokers who switch to ENDS use," and that "ENDS use is a benefit to the population as a whole." C.A. App. 174. Moreover, the literature indicated that "[f]lavored e-liquids," like Breeze Smoke's products, "are beneficial to those smokers wishing to reduce or cease their use of combustible cigarettes," and were more helpful than tobacco-flavored ENDS and "traditional nicotine replacement therapy" in helping smokers quit combustible cigarettes. *Id.* at 173. Breeze Smoke also offered "bridging" material showing that the composition of its ENDS made them materially similar to the products examined in the literature. *Id.* at 284.

The PMTAs included information confirming that Breeze Smoke's products help its customers switch away from traditional cigarettes. Breeze Smoke provided survey data that its customer base is composed of adults, the overwhelming majority of whom are ex-smokers. The average age of the respondents was 34.1 years; 81% admitted to smoking traditional cigarettes in the past, but 78% stated they did not currently smoke cigarettes, and only 22% were currently using both Breeze Smoke ENDS and combustible cigarettes. C.A. App. 162. A full 94% of respondents

answered "yes" "[w]hen asked if vaping products were helpful in keeping them from smoking cigarettes," and "89% would recommend vaping as an alternative to a friend of family member who smokes." *Id.* at 163. In addition, 92% of respondents reported that the availability of flavors was important to their choice to use ENDS as an alternative to cigarettes. *Id.* at 164.

Finally, Breeze Smoke provided materials showing that its products are *not* marketed to children, and that the company has developed a program to prevent youth access. The PMTAs furnished FDA with analysis distinguishing Breeze Smoke's adult-focused marketing from the tactics of distributors who had received warning letters from FDA. C.A. App. 157-160. Breeze Smoke's marketing plan included prominent visual warnings to accompany its products, and the distribution of guidance to retail stores and distributors (*e.g.*, reminders to check all IDs; guidance not to offer the products in automatic vending machines unless the facility is adults-only) to ensure that only adults purchase Breeze Smoke products. *Id.* at 166-167.

B. FDA adopts a new "fatal flaw" review process that results in mass denial orders across the industry.

The administrative record FDA filed in this case shows that, in July and August 2021, FDA circulated a series of internal memoranda that laid out a "streamlined" review process for cutting through the millions of ENDS applications. C.A. App. 310-311, 322-338. A July 9, 2021 FDA memorandum shows that FDA, in an effort to "effectively manage" the "large number of applications" it had received, secretly reversed its 2019 Guidance. Specifically, FDA took the view that product-specific studies, such as randomized controlled trials or longitudinal studies, were

"necessary" for approval, and that "[t]he absence of these types of studies is considered a fatal flaw," *Id.* at 310-311. FDA then established a literal box-checking exercise: reviewers would "determin[e the] presence or absence of such studies," and applications without them were marked to "likely receive a marketing denial order." *Id.* at 311.

On August 17, 2021, FDA distributed another non-public memorandum, which purported to explain the agency's new (and unannounced) long-term study requirement. Relying on background literature, FDA concluded that all flavored e-cigarettes pose the same "substantial risk to youth." C.A. App. 330. In view of this understanding, FDA concluded that applications for flavored e-cigarettes would have to put forward "strong evidence" of offsetting "potential benefits to [adult] smokers"—evidence that "could be generated using either a[randomized controlled trial] design or longitudinal cohort study design." *Id.* at 331. The memorandum also stated that, based on FDA's initial review experience, "advertising and promotion restrictions" had not "decrease[d] appeal to youth to a degree significant enough to address and counter-balance the substantial concerns … regarding youth use." App.330 n.xxii. So, "for the sake of efficiency," FDA instructed reviewers not to consider marketing and access-restriction plans in deciding whether the benefits to adult smokers from product access outweighed the risk to minors. C.A. App. 330.[3]

[3] An August 25, 2021 memorandum purported to rescind the August 17, 2021 memorandum. C.A. App. 343. But FDA did not explain that ostensible rescission, or set forth any other process that would replace it.

C. FDA denies Breeze Smoke's application based on its "fatal flaw" review process.

On September 16, 2021, FDA denied nine of Breeze Smoke's PMTAs in a short, three-page form letter. App. B. FDA denied Breeze Smoke's applications on the ground that they did not include "sufficient evidence demonstrating that [its] flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth" because they did not have "a randomized controlled trial and/or longitudinal cohort study." *Id.* at 1. The Denial Order, which is virtually identical to other such orders received by other e-cigarette manufacturers,[4] mentioned that Breeze Smoke's applications included "survey data," but FDA did not analyze those surveys other than to note that they were not equivalent to long-term clinical trials or longitudinal studies. *Id.* at 1-2. FDA stated that, given the absence of such studies, it "did not proceed to assess other aspects of the applications." *Id.* at 2.

FDA's file for Breeze Smoke's applications includes two completed forms: (1) a "Review for Flavored ENDS PMTAs," C.A. App. 344-353, and (2) a "Technical Project Lead (TPL) Review of PMTAs" ("Technical Review"), App. C. Both documents confirm that FDA did not evaluate the data and marketing plan submitted by Breeze Smoke, but rather relied on the agency's "fatal flaw" review.

[4] *See, e.g.*, Mot. for Stay at A034-A035, *Bidi Vapor LLC v. FDA*, No. 21-13340 (11th Cir. Oct. 25, 2021); Mot. for Stay at A1-A2, *Gripum, LLC v. FDA*, No. 21-2840 (7th Cir. Oct. 17, 2021) (ECF No. 5); Mot. for Stay at A1-A2, *Wages & White Lion Invs. v. FDA*, No. 21-60766 (5th Cir. Oct. 6, 2021); Mot. for Stay at A1-A2, *Turning Point Brands, Inc. v. FDA*, No. 21-3855 (6th Cir. Sept. 30, 2021) (ECF No. 17).

The "Review for Flavored ENDS PMTAs" visually depicts FDA's box-checking exercise. The form asks whether an application included "a randomized controlled trial, longitudinal cohort study, and/or other" similar "evidence." C.A. App. 345. The reviewers checked off boxes confirming that no such long-term studies were found:

Presence of Evidence for Flavored ENDS Products

Criterion A	Present		Absent
Randomized Controlled Trial (RCT) on new product use and smoking behavior	☐		☒
Instructions: To select "Present", all of the following boxes must be checked "Yes":	**Yes**	**No**	**N/A[2]**
Was the RCT conducted using new products?	☐	☐	☒
Does the RCT include a tobacco-flavored arm and a flavored product arm[3]?	☐	☐	☒
Do the outcomes include users' ENDS and smoking behavior to assess switching and/or cigarette reduction (e.g., measures of cigarettes per day, smoking cessation, ENDS use)?	☐	☐	☒
Comment(s): N/A			

Criterion B	Present		Absent
Longitudinal Cohort Study (LCS) on new product use and smoking behavior	☐		☒
Instructions: To select "Present", all of the following boxes must be checked "Yes":	**Yes**	**No**	**N/A[2]**
Was the LCS conducted and does it include users of new products who are followed over time?	☐	☐	☒
Was use of tobacco-flavored products and other flavored products assessed[3]?	☐	☐	☒
Do outcomes include users' ENDS and smoking behavior to assess switching and/or cigarette reduction (e.g., measures of cigarettes per day, smoking cessation, ENDS use)?	☐	☐	☒
Comment(s): N/A			

[2] Not applicable, because no such study was present.
[3] Check "yes" if at least one non-tobacco flavored product is compared to a tobacco-flavored product.

The Technical Review, which is labeled a "template," parrots the contents of the August 17 memorandum,[5] including its refusal to consider Breeze Smoke's "advertising and promotion restrictions" to guard against youth access. App. C at 28a n.xix. The Technical Review acknowledged that "[l]imiting youth access and exposure to marketing is a critical aspect of product regulation," and it conceded that it was "theoretically possible that significant mitigation efforts could adequately reduce youth access and appeal." *Id.* But because FDA had not been impressed by marketing restrictions in *other* applications, it decided, "for the sake of efficiency," not to review any of the "marketing plans submitted with [Breeze Smoke's] applications." *Id.*

Instead, the Technical Review confirmed that Breeze Smoke's applications were denied because they "did not contain evidence from a randomized controlled trial and/or longitudinal cohort study examining the benefit to adult users of their flavored ENDS over an appropriate comparator tobacco-flavored ENDS in terms of switch from or reducing cigarettes." App. C at 31a. Although the Technical Review gestured to the possibility that "other types of evidence … could be adequate if sufficiently reliable and robust," it did not identify what evidence could qualify. *Id.* at 29a. Moreover, the Technical Review stated that evidence would only be adequate if it studied "enrolled participants … over a period of time." *Id.* Acknowledging that

[5] The Technical Review is materially indistinguishable from the sample Technical Review FDA has published on its website and the Technical Reviews attached to other denial letters from the same time period. *See, e.g.*, FDA, *Sample Technical Project Lead Review of ENDS-Product PMTA* (Sept. 17, 2021), https://bit.ly/3oPoTA4; Mot. for Stay at A35-A49, *Wages and White Lion Invs. v. FDA*, No. 21-60766 (5th Cir. Oct. 6, 2021); Mot. for Stay at A15-A29, *Turning Point Brands, Inc. v. FDA*, No. 21-3855 (6th Cir. Sept. 30, 2021) (ECF No. 17).

FDA had "previously stated" that it "did not expect that applicants would need to conduct long-term studies," the Technical Review suggested that studies of at least six months were likely needed since "the behavior change of interest … occurs over a period of time." *Id.* at 13a. In addition, the Technical Review stated that a study could only pass muster if it was "product-specific." Thus, contrary to the pre-deadline guidance, applicants would *not* be allowed to "bridg[e]" from studies involving other companies products. *Id.* at 13a n.xxv.

III. The Circuits are divided on whether to stay functionally identical FDA denial orders.

The TCA authorizes judicial review of an FDA denial order through a petition for review in the court of appeals, with venue proper either in the D.C. Circuit or in the circuit in which the applicant has its principal place of business. 21 U.S.C. § 387*l*(a)(1)(B). Unsurprisingly, FDA's *en masse* denials of e-cigarette marketing applications has led to a massive wave of such petitions, with challenges now pending in at least 10 out of 12 regional circuits. *See* App. E. In several cases, the applicant sought a stay of FDA's denial order, relying on the reviewing court's authority to grant "interim relief." 21 U.S.C. § 387*l*(b); *see also* 5 U.S.C. § 705 (granting courts authority to stay an agency action pending judicial review). The Fifth and Seventh Circuits have both granted stays pending review. The Sixth Circuit here did not, over Judge Kethledge's dissent.

A. The Fifth and Seventh Circuits stay FDA denial orders.

In *White Lion*, the Fifth Circuit confronted a motion to stay an FDA denial order "materially identical" to the one at issue here. *See* App. A at 11a (Kethledge,

J., dissenting). In a published opinion, the Fifth Circuit concluded that the applicant (a company called Triton) had "shown a strong likelihood of success" that the denial order was invalid because "FDA failed to reasonably consider the relevant issues and reasonably explain the Order." *White Lion*, 2021 WL 4955257 at *3 (quotation marks and alterations omitted). The Fifth Circuit identified several issues that FDA failed to consider or address, two of which are directly relevant here.

First, the court concluded that FDA had "failed to reasonably consider Triton's legitimate reliance interests" by denying its application based on its failure to include the kind of long-term study that FDA had announced was not necessary. *Id.* at *4. As the court explained, Triton and other e-cigarette companies had prepared their PMTAs based "on the FDA's repeated insistence that it did 'not expect that applicants will have to conduct long-term studies to support an application.'" *Id.* But "[t]hen the FDA pulled a surprise switcheroo on regulated entities," denying PMTAs by "requir[ing] the very studies it originally expected it didn't need." *Id.* at *5 (quotation marks and alterations omitted). Making matters worse, "FDA never mentioned, let alone reasonably considered, whether e-cigarette manufacturers, like Triton, could've reasonably relied on the FDA's prior meetings and guidance." *Id.* The agency thus impermissibly failed to consider the "serious reliance interests" that "must be taken into account" when "an agency changes course." *Id.*

Second, FDA erred by failing to "reasonably consider Triton's proposed marketing plan." *Id.* at *3. As it did for Breeze Smoke, FDA wrote that, for the "sake of efficiency," the "evaluation of the marketing plan in applications will not occur at

this stage of review, and we have not evaluated any marketing plans submitted with [Triton's] applications." *Id.* The Fifth Circuit rejected that explanation, reasoning that "efficiency" does not justify ignoring critical information. *Id.* Likewise, the Fifth Circuit explained it was "unreasonable for the FDA to stop looking at proposed plans because past ones have been unpersuasive." *Id.* at *4.

Finally, the Fifth Circuit concluded the other stay factors favored Triton; indeed, FDA had not "contest[ed] irreparable harm" and also "fail[ed] to argue" the public interest factor. *Id.* at *8-*9. The Fifth Circuit rejected the one argument that FDA had raised, which challenged the court's ability to issue interim relief since Triton would still lack FDA approval. *Id.* at *9. The Fifth Circuit explained that the court has power to issue a stay that would merely "preserve the *status quo ante*, before the FDA issued the Order" finding Triton's products misbranded and adulterated. *Id.*

Following the Fifth Circuit's decision, the Seventh Circuit also stayed an FDA denial order. *See Gripum LLC v. F.D.A.*, No. 21-2840, ECF No. 18 (Nov. 4, 2021).

B. The Sixth Circuit refuses to stay FDA's identical denial of Breeze Smoke's application.

Breaking from the decisions by the Fifth and Seventh Circuits, the Sixth Circuit refused to stay the Breeze Smoke denial order.[6] The panel majority did not dispute Judge Kethledge's observation in dissent that the case was "materially identical" to the *White Lion* case in the Fifth Circuit. App. A at 11a. To the contrary, the majority announced that it "disagree[d] … with our colleagues on the Fifth

[6] A Ninth Circuit panel also declined to stay a marketing denial order, in an unpublished decision. *See My Vape Order, Inc. v. FDA*, No. 21-71302, ECF No. 18 (Oct. 28, 2021).

Circuit" that FDA had violated principles of fair notice and reasonably consideration of reliance. *Id.* at 7a-8a. In support, the majority relied on its own assessment of Breeze Smoke's application, offering methodological critiques of Breeze Smoke's customer survey that FDA had not raised itself. *Id.* As to "FDA's formulaic consideration of Breeze Smoke's youth marketing plan," the majority acknowledged that "FDA likely should have more thoroughly considered [it]." *Id.* at 8a-9a. But the Sixth Circuit excused FDA's "oversight" on the theory that its departure from reasoned decisionmaking had "not permeated the entire adjudication process." *Id.* at 9 (citation, alterations, and internal quotation marks omitted).

Having concluded that Breeze Smoke had not shown "a strong likelihood of success on the merits," the Sixth Circuit declined to "consider the other stay factors" or FDA's argument challenging the court's authority to issue interim relief. *Id.* at 10a. The Sixth Circuit agreed, however, that Breeze Smoke's application was procedurally proper because it would have been "'impracticable'" for the company to seek relief from FDA first, since "the order takes effect immediately and the FDA can take months to consider an agency-level request for a stay." *Id.* at 2a (quoting Fed. R. App. P. 18(a)(2)(A)(i)-(ii)); *accord White Lion*, 2021 WL 4955257 at *2 n.1.

REASONS FOR GRANTING THE STAY

There is "no question" that the Circuit Justice has authority to issue a stay when the court of appeals has declined to do so, and this case meets all of the standards for granting such relief. *Heckler v. Lopez*, 463 U.S. 1328, 1330 (1983) (Rehnquist, J., in Chambers); *see also West Virginia*, 577 U.S. at 1126 (staying EPA

rule after D.C. Circuit had denied a stay); *cf. Ala. Ass'n of Realtors*, 141 S. Ct. at 2488 (per curiam) (vacating a stay pending appeal after lower courts had declined to do so); *Tandon v. Newsom*, 141 S. Ct. 1294, 1298 (2021) (per curiam) (holding that applicants were entitled to an injunction pending appeal, which the circuit had erroneously denied).

The traditional stay factors all support granting relief to Breeze Smoke. *See Nken v. Holder*, 556 U.S. 418, 426-427 (2009). Breeze Smoke has a strong likelihood of success—either in winning before the Sixth Circuit or in seeking certiorari and prevailing before this Court. *See Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010) (granting stay when there is "a reasonable probability that four Justices will consider the issue sufficiently meritorious to grant certiorari" and "a fair prosect that a majority of the Court" will reverse). Breeze Smoke would suffer massive and irreparable harm absent a stay, including the unrecoverable loss of nearly *sixty percent* of its revenue (App. D ¶ 6), which will inevitably lead to irreversible structural changes to its business. Moreover, a stay would further the public interest by ensuring that FDA acts consistent with the law and avoiding disruption for Breeze Smoke customers who use Breeze Smoke products as safter alternatives to traditional cigarettes. Notably, aside from contesting likelihood of success, FDA has not disputed that the other stay factors are satisfied. FDA's alternative argument that reviewing courts are powerless to direct meaningful interim relief under the TCA is wrong, as the Fifth Circuit recognized. *See White Lion*, 2021 WL 4955257 at *9.

I. Breeze Smoke is likely to prevail on the merits of its arguments, which are identical to arguments the Fifth Circuit endorsed.

Breeze Smoke is highly likely to establish that FDA's denial was arbitrary and capricious for either of two independent reasons: (1) FDA told Breeze Smoke it did not need product-specific, long-term studies (*i.e.*, controlled trials or longitudinal cohort studies), but then denied Breeze Smoke's application for failing to submit those very studies; and (2) FDA identified individual marketing plans as "critical" to its review, but then refused to consider Breeze Smoke's marketing efforts to mitigate the risk of access by minors. Moreover, given the circuit split that already exists, and the dozens of pending review petitions challenging indistinguishable FDA orders in nearly every circuit, Breeze Smoke is likely to obtain this Court's review if it does not prevail before the Sixth Circuit.

A. FDA ignored Breeze Smoke's reliance interests and deprived it of fair notice by changing the rules for PMTAs after the submission deadline.

"[A]gencies should provide regulated parties 'fair warning of the conduct [a regulation] prohibits or requires.'" *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155-56 (2012) (citation omitted). Agency decisions that fail to honor this "[r]ule of law principle[]" are arbitrary and capricious. *Circus Circus Casinos, Inc. v. NLRB*, 961 F.3d 469, 476 (D.C. Cir. 2020). Furthermore, agencies may not "change[] course" without considering "serious reliance interests" in the previous policies. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020). FDA violated those key benchmarks for reasoned decisionmaking by "chang[ing] its mind" about approval requirements after the filing deadline, without notice to the

industry or any apparent consideration of the reliance interests of applicants like Breeze Smoke. *White Lion*, 2021 WL 4955257, at *1, *5 (quotation marks omitted).

1. FDA repeatedly assured e-cigarette manufacturers that they were not required to submit their own long-term product studies to secure approval, as FDA recognized the practical difficulties with asking each manufacturer to conduct such studies in the limited time available. In its 2019 Final Guidance, the agency unambiguously told applications that "FDA does not expect that applicants will need to conduct long-term studies to support an application." C.A. App. 60. Applicants like Breeze Smoke relied on FDA's guidance, as Breeze Smoke spent millions of dollars to submit PMTAs before the September 2020 deadline. *See* App. D ¶¶ 11-12. But when faced with a mountain of applications, FDA "moved its regulatory goalposts" and "changed the regulatory requirements," *White Lion*, 2021 WL 4955257, at *1, by determining that the absence of product-specific, long-term studies was a "fatal flaw" that justified denying more than a million applications en masse using standard-form letters. *See* pp. 15-18, *supra.*

Manufacturers like Breeze Smoke were deprived of fair notice by FDA's post-filing deadline reversal, which the Fifth Circuit aptly described as a "surprise switcheroo on regulated entities." *White Lion*, 2021 WL 4955257, at *5 (citation omitted). It was arbitrary and capricious for FDA to depart from its guidance *after* the due date for PMTA applications, which left applicants like Breeze Smoke with no "opportunity to conform their behavior to legal rules" set by FDA. *Circus Circus Casinos*, 961 F.3d at 476. If FDA had announced in advance of the filing deadline

that applications for flavored e-cigarettes should include long-term studies documenting the usage patterns of adult consumers, then Breeze Smoke could have invested in those studies and submitted them with its applications. Yet because Breeze Smoke did not anticipate that FDA would change its mind, the company was hit with a business-destroying Denial Order that found Breeze Smoke's products "misbranded" and "adulterated." App. B at 13a. FDA's bait-and-switch cannot be reconciled with "[t]he rule of law." *PHH Corp. v. CFPB*, 839 F.3d 1, 48 (D.C. Cir. 2016) (Kavanaugh, J.), *reinstated in relevant part*, 881 F.3d 75, 83 (D.C. Cir. 2018).

FDA compounded its error by failing to consider the degree to which its last-minute change negatively impacted manufacturers like Breeze Smoke that had relied on agency guidance. "When an agency changes course, … it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account. … It would be arbitrary and capricious to ignore such matters." *Regents of the Univ. of Cal.*, 140 S. Ct. at 1913 (citation and internal quotation marks omitted). Here, FDA acknowledged that it had "previously stated that it did not expect applicants would need to conduct long-term studies to support an application for an ENDS." App. C at 30a n.xxiii. Yet FDA did the opposite, faulting Breeze Smoke for not having studies assessing "adult smokers' tobacco use behavior over time." *Id.*; *see also White Lion*, 2021 WL 4955257, at *6 ("[T]he administrative record makes clear that the FDA now requires direct evidence through studies performed 'over time' for flavored e-cigarettes."). But inexplicably, "[d]espite the radical difference, the FDA never mentioned, let alone reasonably considered, whether e-

cigarette manufacturers, like [Breeze Smoke] could've reasonably relied on the FDA's prior … guidance." *Id.* at *5. This glaring omission renders the Denial Order unlawful. *See, e.g.*, *Regents of the Univ. of Cal.*, 140 S. Ct. at 1913; *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-516 (2009).

2. In denying Breeze Smoke's stay application, the Sixth Circuit majority "disagree[d]" with their "colleagues on the Fifth Circuit" that FDA had "introduce[d] a new standard of review" after the filing deadline. App. A at 8a-9a. According to the majority, FDA had previously only stated that it "*might* accept evidence other than long-term studies," and did not promise that applications without studies would always be approved. *Id.* But as the Fifth Circuit explained when rejecting that same argument, "FDA did not have to completely flip flop for there to be a change in position." *White Lion*, 2021 WL 4955257, at *6. "It is enough that 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." *Id.* The Administrative Record has revealed that, if anything, the Fifth Circuit *understated* the case. FDA did not merely create "a strong presumption" that long-term, product specific studies are required; its internal memoranda reveal that the agency deemed the absence of such studies a "fatal flaw," as it categorically denied millions of marketing applications for flavored e-cigarettes without meaningful individualized review *solely* because the applications did not include that studies that FDA's pre-filing Guidance stressed were not mandatory. *See* pp. 15-18, *supra*.

The Sixth Circuit majority thus missed the point in asserting that Breeze Smoke supposedly did not show that its products have sufficient health benefits to adult smokers to offset the possible risks to minors. App. A at 6a. FDA's decision cannot be salvaged by an argument that it *could* have lawfully denied Breeze Smoke's applications in a more reasoned manner. The error committed by the Sixth Circuit is well illustrated by the majority's contention that Breeze Smoke's user survey "presents methodological issues" with supposedly "biased respondents." *Id.* at 7. Of course, FDA itself did *not* identify any such methodological problems with Breeze Smoke's survey, since the agency studiously avoided any such individualized analysis. *See* App. B at 12a-13a (referencing the survey, but faulting it without analysis solely on the ground that it did not qualify as the type of long-term study that FDA is now requiring). The Sixth Circuit's reasoning thus contradicts "the foundational principle of administrative law," *Michigan*, 576 U.S. at 758, that courts may not supply a reasoned basis for the agency's action that the agency itself has not given, *see SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947); *accord White Lion*, 2021 WL 4955257, at *6 ("The FDA cannot cure … deficiencies by offering *post hoc* rationalizations before our court.").

Ultimately, the Sixth Circuit's position on fair notice and reliance runs up against common sense—it is not plausible that an *entire industry* misread FDA's guidance, as one would have to credit its *en masse* denial orders all premised on the same "fatal flaw." Perhaps recognizing the tenuous nature of its reasoning, the Sixth Circuit endorsed the Federal Government's alternative argument discounting

reliance by manufacturers on the 2019 Guidance because it was "nonbinding" and too new to "qualify as 'longstanding.'" App. A at 4a, 8a. But courts have rightly rejected similar attempts by agencies to disregard reliance interests as "deeply unsettling." *PHH Corp.*, 839 F.3d at 48 (Kavanaugh, J.) (holding that agency violated fair notice by contradicting an interpretation announced in an informal letter). Indeed, this Court has held that informal agency guidance and policies may give rise to reliance interests, notwithstanding standard caveats that agency policies are subject to change. *See Regents of the Univ. of Cal.*, 140 S. Ct. at 1901, 1913 (memorandum by the Department of Homeland Security created reliance interests, even though it "stated that the program 'conferred no substantive rights' and provided benefits only in two-year increments").

As for the vintage of FDA's guidance, the agency's rapid whipsaw simply compounds the problem. FDA "created a serious and obvious problem" when it deemed that e-cigarettes should regulated as tobacco products before the agency had even developed a process for their review. *White Lion*, 2021 WL 4955257, at *1. It should be no surprise that when FDA belatedly issued guidance in 2019, Breeze Smoke and other industry participants took it seriously. The guidance was sufficiently longstanding to engender significant reliance interests by shaping the studies that *every* e-cigarette manufacturer included in its application. That is all that matters.

In any event, arguments about the formality or firmness in FDA's guidance cannot possibly save FDA's Order. Consideration of "the strength of any reliance

interests" "must be undertaken by the agency in the first instance, subject to normal APA review." *Regents of the Univ. of Cal.*, 140 S. Ct. at 1913-14. "There was no such consideration," *id.* at 1914, here, which makes FDA's Order arbitrary and capricious.

B. FDA acted arbitrarily and capriciously by refusing to consider its marketing plan "for the sake of efficiency."

In the Deeming Rule and the 2019 Guidance, FDA promised to engage in holistic, "case-by-case" review of the contents of each PMTA to determine whether, on balance, an e-cigarette is appropriate for the protection of the public health. Deeming Rule, 81 Fed. Reg. at 28,990; C.A. App. 59. But FDA did not follow through on its commitment, as its "fatal flaw" review dispensed with meaningful individualized analysis. As a result, FDA declined to consider evidence that Breeze Smoke had submitted in reliance on FDA's 2019 Guidance.

In particular, FDA refused to review Breeze Smoke's marketing plan, which delineated the significant measures that Breeze Smoke takes to deter minors from accessing its products. C.A. App. 166-167. To the extent that marketing plan would successfully avoid use by minors—and Breeze Smoke strongly believes it would—it would undermine FDA's rationale for prohibiting Breeze Smoke from marketing its products. Nevertheless, FDA reported that, "for the sake of efficiency," it had "not evaluated any marketing plans submitted with [Breeze Smoke's] applications." App. C at 28a n.xix.

Agencies act arbitrarily and capriciously when they "entirely fail[] to consider an important aspect of the problem" before them. *Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Here, there is no

question that Breeze Smoke's marketing plan was relevant to whether approval would be appropriate for protection of the public health, because FDA *has repeatedly said it is*. FDA previously explained that an applicant's individualized marketing plan would help the agency decide if a new product meets the approval standard, because those plans "provide input that is *critical* to FDA's determination of the likelihood of changes in tobacco product use behavior, especially when considered in conjunction with other information contained in the application." 84 Fed. Reg. at 50,581 (emphasis added). Even in the Technical Review, FDA reaffirmed that an applicant's marketing plan "is a critical aspect of product regulation" and conceded that it was "theoretically possible" that an effective plan could determine whether a new tobacco product should be approved. App. C at 28a n.xix.

Yet FDA declined to evaluate Breeze Smoke's marketing plan because other applicants' plans were found wanting, and because it would be more "efficien[t]" for the agency to assume that Breeze Smoke's plans would fall short, too. *Id.* Those reasons for refusing to consider "an important aspect" of the review task before FDA are facially inadequate. *State Farm*, 463 U.S. at 43. FDA's desire to take a shortcut is perhaps understandable, given the overwhelming volume of PMTAs it received, but its refusal to consider relevant—indeed, "critical"—information to promote efficiency conflicts with the basic APA requirement of "[r]easoned decisionmaking." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2576 (2019). As the Fifth Circuit observed, "'efficiency' is no substitute for 'reasoned decisionmaking,'" and it is "unreasonable for the FDA to stop looking at proposed plans because past ones have been

unpersuasive." *White Lion*, 2021 WL 4955257, at *3-4; *see also Judulang v. Holder*, 565 U.S. 42, 64 (2011) ("[C]heapness alone cannot save an arbitrary agency policy.").

Even taken on its own terms, FDA's reasoning is conclusory in the extreme. FDA did not explain *why* it thought other marketing plans were inadequate or even disclose how many marketing plans it had considered before reaching its negative evaluation. FDA also did not compare Breeze Smoke's marketing plan to those the agency had previously deemed inadequate—FDA simply reverted to boilerplate. The APA demands more. An agency must offer "genuine justifications for important decisions, reasons that can be scrutinized by courts and the interested public." *Dep't of Com.*, 139 S. Ct. at 2575-2576.

Remarkably, notwithstanding its decision to withhold relief, the Sixth Circuit majority described FDA's approach as "formulaic," and acknowledged that "FDA likely should have more thoroughly considered Breeze Smoke's marketing plan." App. A at 8a. Of course, that is putting it mildly: as Judge Moore later conceded, "the FDA *ignored* the marketing plan *entirely* because prior marketing plans had not satisfied the agency." *Id.* at 9a (emphasis added). But rather than defend FDA's actual reasoning, the Sixth Circuit majority denied the stay on the theory that FDA's deliberate oversight could be excused because its bottom-line conclusion supposedly was sound. *Id.*

Once again, the majority's work-around violates *Chenery*. Nothing in FDA's denial suggests that individualized consideration of Breeze Smoke's marketing plan would have been meaningless. *See* App. A at 9a (acknowledged that "[i]t is not clear

how the FDA could have known" whether the marketing plan is impactful without considering it). And a reviewing court "should not attempt itself to make up for … deficiencies" in an agency's reasoning, *State Farm*, 463 U.S. at 43. The point of arbitrary and capricious review is to ensure that *the agency itself* "has reasonably considered the relevant issues and reasonably explained the decision." *Regents of the Univ. of Cal.*, 140 S. Ct. at 1933 (Kavanaugh, J.) (concurring in the judgment in part and dissenting in part). "It is not the role of the courts to speculate" about whether the agency would have reached the same result if it had evaluated all relevant information. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016).

C. If Breeze Smoke does not prevail before the Sixth Circuit, it is likely to obtain this Court's review.

This Court's consideration of whether to grant a stay may also encompass whether the Court is likely to "grant review" if and when a petition for a writ of certiorari is filed. *See Hollingsworth*, 558 U.S. at 19; *Does 1-3 v. Mills*, __ S. Ct. __, 2021 WL 5027177, at *1 (2021) (Barrett, J., concurring in denial of application for injunctive relief). Here, there is every reason to think that, if Breeze Smoke does not prevail on the merits before the Sixth Circuit, this Court's discretionary review would be warranted. Both the Fifth and Seventh Circuits have granted stays of materially identical FDA denial orders, with the Fifth Circuit issuing a published decision documenting the flaws in FDA's reasoning in detail. There is thus already a circuit conflict. And that conflict is already causing deep unfairness. Triton—the company whose products are at issue in the Fifth Circuit's *White Lion* case—is a competitor of Breeze Smoke, and can now poach Breeze Smoke's customers solely because Triton

is based in the Fifth Circuit while Breeze Smoke is based in the Sixth Circuit. *See* App. D ¶¶ 24, 27.

Given that two circuits have already agreed that Breeze Smoke's position is likely to succeed, and that petitions for review of other indistinguishable FDA denial orders are pending in numerous other circuits, it is exceptionally unlikely that every court of appeals will bless FDA's *en masse* PMTA denials. Thus, even if the Sixth Circuit ultimately rejects Breeze Smoke's position on the merits, such a ruling would almost certainly entrench a circuit conflict on an important question that warrants this Court's consideration. And, for the reasons explained above, Breeze Smoke is likely to prevail before this Court.

II. Given the significant and irreparable harm that FDA's order is inflicting on Breeze Smoke, the equities strongly support a stay.

In deciding whether to grant a stay, this Court "'balance[s] the equities, . . . explor[ing] the relative harms to applicant and respondent, as well as the interests of the public at large.'" *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (quoting *Barnes v. E-Systems, Inc. Grp. Hosp. Med. & Surgical Ins. Plan*, 501 U.S. 1301, 1305 (1991) (Scalia, J., in chambers)). A stay is appropriate where "[r]efusing" relief "may visit an irreversible harm on [the] applicant[], but granting it will apparently do no permanent injury to respondent[]." *Philip Morris USA Inc. v. Scott*, 561 U.S. 1301, 1305 (2010) (Scalia, J., chambers). One such "irreversible harm" is a monetary loss that "cannot be recouped." *Id.*; *see also Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 (finding irreparable harm when there was "no guarantee of eventual recovery"). Here, the equities strongly support a stay.

A. Breeze Smoke is suffering massive and irreparable harm as a result of the Denial Order. The products subject to the Denial Order previously made up a critical portion of Breeze Smoke's revenue—57% in 2020. App. D ¶ 6. Not only has the Denial Order drained Breeze Smoke's coffers, it has also dimmed the company's future prospects. Breeze Smoke is losing business opportunities with distributors, retailers, and customers; several distributors (including Breeze Smoke's largest) have canceled existing orders; and no distributor has placed a new purchase order since the Denial Order. *Id.* ¶¶ 26-28. The company is losing market share to companies with e-cigarette products that have been allowed to remain on the market because the applications for those products are still under review, or in the case of Triton, because the Fifth Circuit stayed the marketing denial order governing Triton's products. *Id.* ¶¶ 27, 30. And because Breeze Smoke took steps to stop manufacturing the subject products once the Denial Order issued, it has suffered loss of goodwill with its manufacturing partners. *Id.* ¶ 29. Courts across the country consistently recognize analogous harms as irreparable. *See, e.g.*, *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012); *Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264, 279 (6th Cir. 2015).

Given the federal government's sovereign immunity, Breeze Smoke has no hope of recovering its monetary losses from FDA. *E. Bay Sanctuary Covenant v. Biden*, 993 F.3d 640, 677–78 (9th Cir. 2021). Worse still, the temporary loss of distributor- and retailer-customers will eventually become permanent. These customers are turning to Breeze Smoke's competitors, App. D ¶¶ 27-28, 30, which

have been able to stay on the market solely because they have not yet been subjected to FDA's arbitrary and capricious decisionmaking or because a court other than the Sixth Circuit stayed the relevant denial order. It will be difficult to turn the customers back to Breeze Smoke's products even if Breeze Smoke were to prevail in its petition for review. *Id.* ¶ 28.

B. FDA did not dispute below that forcing Breeze Smoke's products off the market is causing Breeze Smoke significant and irreparable harm. (Nor has FDA disputed irreparable injury in cases involving other similarly situated applicants. *See White Lion*, 2021 WL 4955257, at *8.) Instead, FDA suggested that a stay would have no meaning because the Court could not order FDA to approve Breeze Smoke's products. To the extent FDA renews that argument, it is plainly wrong.

The Denial Order states that "[*u*]*pon issuance* of this order," Breeze Smoke's products are "misbranded" and "adulterated." App. B at 13a (emphasis added). It further directs that "[f]ailure to comply" may result in an immediate enforcement action "without further notice." *Id.* FDA press releases affirm that the agency is "prioritizing enforcement against tobacco product manufacturers who received a negative action on their application, such as a Marketing Denial Order." FDA In Brief, *supra*. By contrast, e-cigarette manufacturers with PMTAs still under review have been allowed to remain on the market, as FDA directs its enforcement discretion

toward "products for which no application is pending, including, for example, those with a Marketing Denial Order."[7]

FDA's litigation actions also confirm that approval status matters. For example, after a company called Turning Point filed a stay motion in the Sixth Circuit, FDA voluntarily rescinded its denial order. In doing so, it recognized that, because Turning Point's application was "back in the review process," "FDA has no intention of initiating an enforcement action against any of [Turning Point's] products" still under review.[8] FDA took the same tack with another applicant in the Ninth Circuit, choosing to stand down, rescind a denial order, return the application "back into the review process," and declare that it had no intention to bring an enforcement action while the application was pending.[9]

By asking for a stay, Breeze Smoke likewise merely seeks to restore "the *status quo ante*, before FDA issued the [Denial] Order," *White Lion*, 2021 WL 4955257, at *9, which would place Breeze Smoke in the same position as other manufacturers with pending applications, including those whose denial orders have been stayed or rescinded. The Circuit Justice has ample authority to grant such a remedy. *See* p. 21-22, *supra*.

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[7] Janet Woodcock & Mitch Zeller, *FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted* (Sept. 9, 2021), https://bit.ly/30SWzVd.

[8] *See Turning Point Brands, Inc. v. FDA*, No. 21-3855, ECF No. 19 (Oct. 8, 2021) (internal quotations omitted).

[9] *See Humble Juice Co. v. FDA*, No. 21-71326, ECF No. 11 (Nov. 3, 2021).

C. As the Fifth Circuit recognized when confronting identical facts, the balance of harms and public interest also favor a stay. *White Lion*, 2021 WL 4955257, at *8-9. As discussed, the harm to Breeze Smoke absent a stay is catastrophic—depending on how long it takes the Sixth Circuit to issue an opinion, it could drive the company out of business. And there is no comparable harm to FDA or to the public. FDA originally intended to give e-cigarette manufacturers until August *2022* to file product applications, until a district court forced the agency to dramatically accelerate its timeframe. *See Vapor Tech. Ass'n*, 977 F.3d at 498-499 (summarizing history). FDA adopted such a timeline in recognition of the fact that e-cigarettes may offer important public health benefits, and driving them off the market would risk "potentially less harmful ENDS products back to combustible tobacco products within the population of addicted adult smokers who have completely switched to ENDS." Zeller ¶ 12.

Moreover, as the Fifth Circuit recognized, the "public interest is in having governmental agencies abide by the federal laws that govern their existence and operations." *White Lion*, 2021 WL 4955257, at *9. Where, as here, the agency has so obviously flouted the demands of reasoned decisionmaking, there is a strong public interest in holding the agency into account and not allowing its unlawful action to take effect.

Finally, since several marketing denial orders have already been rescinded or stayed, denying relief to Breeze Smoke would likely not impact the availability of e-cigarettes—it would simply allow geographic happenstance to determine winners and

losers in this industry. ENDS manufacturers whose applications are pending or whose denial orders have been stayed can fill the gap left by the forced exit of Breeze Smoke from the market. It does not serve the public interest to let a circuit split determine which e-cigarette manufacturers can survive as parallel challenges to substantively identical FDA orders move forward.

CONCLUSION

For all of these reasons, Breeze Smoke respectfully requests a stay of the Denial Order pending disposition of the petition for review in the Sixth Circuit and any further proceedings in this Court.

Respectfully submitted,

Brian T. Burgess
Counsel of Record
Andrew Kim
Mark S. Raffman
GOODWIN PROCTER LLP
1900 N Street, N.W.
Washington, D.C. 20036
202.346.4000
bburgess@goodwinlaw.com

Counsel for Applicant
Breeze Smoke, LLC

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