United States Court of Appeals for the Fifth Circuit

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Fifth Circuit
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Lyle W. Cayce
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No. 24-60032

SHENZHEN IVPS TECHNOLOGY COMPANY, LIMITED; ECIGRUSA, L.L.C., *doing business as* WORLDWIDE VAPE DISTRIBUTION,

Petitioners,

versus

FOOD & DRUG ADMINISTRATION,

Respondent.

Petition for Review from the Food & Drug Administration
Agency No. PM0001254.PD6

Before WIENER, STEWART, and SOUTHWICK, *Circuit Judges*.

LESLIE H. SOUTHWICK, *Circuit Judge*:

Petitioner Shenzhen IVPS Technology Company, Ltd. submitted applications for its electronic nicotine delivery systems, which the Food and Drug Administration denied. It and a retailer seek to have the denial order set aside as being arbitrary and capricious and then to have FDA ordered to reconsider. We DENY the petition.

FACTUAL AND PROCEDURAL BACKGROUND

I. Administrative Background

Under the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"), the Food and Drug Administration regulates "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and . . . any other tobacco products that the Secretary by regulation deems to be subject to" the TCA. 21 U.S.C. § 387a(b). In 2016, FDA issued a final rule extending its regulatory authority to all electronic nicotine delivery systems ("ENDS"). Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act ("Deeming Rule"), 81 Fed. Reg. 28,974, 29,028 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143) ("In this final rule, FDA clarifies that although there are many types of ENDS (including e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes), all are subject to FDA's chapter IX authorities with this final deeming rule."). ENDS devices use electricity to heat an e-liquid, which can contain nicotine, flavorings, and other ingredients. The e-liquids are converted into an aerosol and inhaled in a process called vaping. There are two types of ENDS devices: open-system ENDS and closed-system ENDS. Closed-system ENDS devices utilize pre-filled, replaceable cartridges or pods to provide the e-liquid. Open-system ENDS devices allow for the user to fill the device themselves with e-liquid. The e-liquid for these devices comes in two forms: freebase nicotine and nicotine salt formulations. This petition only concerns open-system ENDS devices; e-liquid is sold separately from the devices.

Tobacco products that were not on the market as of February 15, 2007, must obtain marketing authorization from FDA. § 387j(a)(1)(A)–(a)(2)(A). FDA provides three pathways to obtain marketing authorization: (1) a premarket tobacco product application ("PMTA"); (2) a substantial

equivalence report (only available if the applicant can show the tobacco product "is substantially equivalent" to one on the market as of February 15, 2007); and (3) a substantial equivalence exemption report. §§ 387j(a)(2)(A)–(B), 387e(j).

There are statutory requirements for PMTA applications. Relevant here are these provisions:

> (2) The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that —
>
> > (A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health.

§ 387j(c)(2)(A). In determining whether the product is appropriate for the protection of the public health, FDA must consider "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." § 387j(c)(4). FDA must account for:

> (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.

§ 387j(c)(4)(A)–(B). Extensive reports and data must be in the application. § 387j(b)(1).

In addition to the statutory guidance, FDA issued a draft guidance document in 2016, which provided ENDS-specific application recommendations. The agency finalized the guidance recommendations in June 2019. U.S. Food & Drug Admin., Premarket Tobacco Product Applications for Electronic Nicotine Delivery

SYSTEMS (REVISED): GUIDANCE FOR INDUSTRY ("PMTA GUIDANCE") (Mar. 2023).[1] The guidance document contained nonbinding recommendations detailing the studies and data that should be included in applications and had a section specifically addressing open-system ENDS devices. *Id.* at 19–45. FDA proposed a rule for PMTAs in September 2019. *See* Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,566 (proposed Sept. 25, 2019) (codified at 21 C.F.R. pts. 1100, 1107, 1114). The rule became final in October 2021. *See* Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55,300, 55,399 (Oct. 5, 2021) (codified at 21 C.F.R. pts. 1100, 1107, 1114).

Many ENDS products were already on the market when FDA issued the final rule putting ENDS under its authority. Those products entered the market after February 15, 2007, but did not have premarket authorization. They therefore were "adulterated" under the Act. § 387b(6)(A). FDA announced it would permit products introduced on the market between February 15, 2007, and August 8, 2016, to remain on the market if the manufacturer filed a PMTA by August 8, 2018. Deeming Rule, 81 Fed. Reg. at 29,011. For manufacturers who submitted a PMTA by the deadline, FDA stated it would not bring enforcement action for the products until August 8, 2019, unless FDA denied the manufacturer's application before that date. *Id.* FDA later attempted to delay the application deadline further, but a federal district court ordered the PMTAs be submitted within 10 months of its order. *American Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019). The deadline was later extended until September 9, 2020, due to

[1] Though the guidance document was revised in March 2023, the parties agree that the relevant portions remained unchanged from the June 2019 version. The guidance can be found at https://perma.cc/B29W-TFCD.

COVID-19. *American Academy of Pediatrics v. FDA*, No. 18–CV–883 (D. Md. Apr. 22, 2020), ECF No. 182.

II. Procedural History

In July and September 2020, Shenzhen IVPS Technology Co., Ltd. ("IVPS") applied for premarket authorization for six open-system ENDS devices and components, including replacement pods, or cartridges, and atomizers. IVPS's devices are designed to "allow each user to customize his or her own vaping 'experience.'" Users can do so by "vary[ing] the voltage output from the battery," which "affect[s] the volume and content of the nicotine-containing aerosol generated and intended to be inhaled." Users can also customize their experience by purchasing their preferred e-liquid to use with the device.

In the applications, IVPS included "extensive product characterization information," "results from *in vitro* toxicology studies," "extensive 'extractables' and 'leachables' studies to determine whether the device components in contact with the e-liquid or aerosol could cause contamination," "extensive scientific literature reviews and results from multiple clinical studies involving human subjects," and "extensive human health risks assessments that favorably compared the subject products' health risks to those of combustible cigarettes." Ultimately, "IVPS's applications concluded that, when compared to the exposure to harmful and potentially harmful constituents found in combustible cigarettes, IVPS's open-system ENDS products presented substantially lower levels of cancer and non-cancer risks." IVPS also determined that because "IVPS's target market is combustible cigarette smokers, the products were 'appropriate for the protection of public health.'"

After reviewing the applications, FDA sent IVPS a deficiency letter on March 29, 2023, which stated FDA "preliminarily determined that these

applications do not in their present form support a positive scientific determination" and "identifie[d] information that FDA needs to complete its scientific review." FDA identified specific deficiencies, but noted "[i]t should not be understood to communicate a list of all substantive concerns that may be observed during the review of [the] applications and other information." The letter requested the necessary information within 90 days and alerted IVPS that FDA did not intend to extend the deadline or issue any additional deficiency letters.

Three deficiencies are relevant here. [text redacted]. The third deficiency cited the abuse liability potential of the products. IVPS timely responded to the deficiency letter. It [text redacted] and suggested a label for the products to address the abuse liability concerns. FDA reviewed IVPS's response and denied the application because IVPS failed to meet its "burden of 'showing' that permitting the marketing of the new products would be [appropriate for the protection of public health] as required by Section 910(c)(2)(A)." As a result, IVPS cannot legally "introduce or deliver for introduction these products into interstate commerce in the United States."

The denial letter cited three deficiencies, which echoed the three relevant deficiencies from the March 2023 letter. [text redacted]. The third deficiency concerns the abuse liability potential for the products. While FDA acknowledged the labeling suggested by IVPS, FDA stated it was unable to evaluate whether consumers would understand the label without consumer comprehension and compliance studies. Following the denial, IVPS filed this petition for review claiming the denial violates the TCA and each of the three bases for the denial is arbitrary and capricious.

JURISDICTION

Under 21 U.S.C. § 387*l*(a)(1)(B) "any person adversely affected by" the denial of an application filed pursuant to 21 U.S.C. § 387j(c) may petition

for review in the D.C. Circuit or "the circuit in which such person resides or has their principal place of business." The Supreme Court recently affirmed that "any person adversely affected by" includes those who would otherwise sell the products. *FDA v. R.J. Reynolds Vapor Co.*, 145 S. Ct. 1984, 1993 (2025).

Although IVPS is headquartered in Shenzhen, China, with no offices, facilities, or employees located within the Fifth Circuit, the company has joined forces in this petition with Worldwide Vape Distribution, which is a distributor with its principal place of business in Texas. Because one of the Petitioners has its principal place of business within the Fifth Circuit, venue is proper under Section 387*l*(a)(1)(B). *See R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 188 (5th Cir. 2023), *aff'd*, 145 S. Ct. 1984 (2025).

DISCUSSION

IVPS contends "FDA's denial order is arbitrary, capricious, and violates the Tobacco Control Act's requirement that FDA engage in a holistic risk-benefit analysis before issuing a marketing denial order." IVPS contends FDA neglected to weigh the potential public health benefits of its products against the potential risks. Additionally, IVPS argues the stated reasons for denial are each arbitrary and capricious because FDA did not consider important aspects of the problem, treated IVPS less favorably than similarly situated applicants, and imposed tobacco product standards without duly promulgating those standards.

Under the Administrative Procedure Act, "[t]he reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

"The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio*

Project, 592 U.S. 414, 423 (2021). This "standard ensures that an administrative agency 'examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *FDA v. Wages & White Lion Invs., L.L.C.*, 145 S. Ct. 898, 917 (2025) (alterations adopted) (quoting *Motor Vehicle Mfrs. Ass'n of U. S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Under this narrow scope of review, "courts must exercise appropriate deference to agency decisionmaking and not substitute their own judgment for that of the agency." *Id.*

FDA denied IVPS's application for three reasons. Because each reason is independently sufficient for a marketing denial order on new products, we will only grant IVPS's petition if all three reasons are arbitrary and capricious. *See BNSF Ry. Co. v. Fed. R.R. Admin.,* 105 F.4th 691, 695 (5th Cir. 2024). Therefore, we will discuss only the third reason for the denial, insufficient information on abuse liability. "Abuse liability refers to the ability of the product to promote continued use and the development of addiction and dependence."

I. Weighing the Risk and Benefits

IVPS argues FDA failed to weigh the risks and benefits of its products as required by the TCA. IVPS cites a D.C. Circuit case to support its argument. *See Fontem US, LLC v. FDA*, 82 F.4th 1207 (D.C. Cir 2023). In *Fontem*, the D.C. Circuit considered a similar ENDS device marketing authorization denial. It vacated FDA's marketing denial of the petitioner's unflavored products because "FDA acted unlawfully by failing to engage in the holistic public health analysis required by the statute." *Id.* at 1211. There, FDA issued one deficiency letter, Fontem responded, and then the agency denied the applications "entirely on the finding that Fontem had not sufficiently demonstrated that permitting its products to be marketed would

be 'appropriate for the protection of the public health.'" *Id.* at 1213 (quoting 21 U.S.C. §387j(c)(2)). Although FDA identified specific deficiencies, it did not "explain how the specific deficiencies relate to its overall conclusion that Fontem failed to demonstrate its unflavored products were appropriate for the protection of public health." *Id.* at 1217. The court noted that in the absence of promulgated regulations with specific requirements and standards, FDA was required "to analyze the tradeoffs necessary to make a public health finding." *Id.* Because FDA "chose[] to proceed application by application under the public health ground, it [had to] undertake the holistic inquiry required by the statute." *Id.* at 1218. IVPS contends *Fontem* should guide our analysis because here, as in *Fontem*, FDA denied the application without conducting "the holistic inquiry required by the statute." *Id.*

FDA distinguishes *Fontem*. Here, FDA explained how the deficiencies were related to the protection of the public health. After analyzing the data provided by IVPS and identifying the data it lacked, FDA stated "there is a reasonable basis to conclude that the risks associated with the new products may outweigh purported benefits," especially in terms of the abuse liability potential. Thus, FDA argues, "this is not a case where FDA denied applications based on technical deficiencies that might not have mattered to the ultimate decision." According to FDA, it "amply explained the importance of determining a product's abuse liability and the relevance of that information to the statutory public-health inquiry."

In *Fontem*, the D.C. Circuit stated FDA "*must* deny an application to market a new tobacco product if it makes" a finding that "'there is a lack of a showing' that marketing the product is 'appropriate for the protection of the public health.'" *Id.* at 1212 (emphasis added) (quoting 21 U.S.C. § 387j(c)(2)). The court acknowledged that "[w]hile public health standing alone may be a capacious concept, the Act specifies the basis for such a

finding." *Id.* at 1215. As we have already mentioned, the TCA requires FDA to account for both the "likelihood that existing users of tobacco products will stop using such products" and the "likelihood that those who do not use tobacco products will start using such products." § 387j(c)(4).

FDA denied IVPS's PMTA because it "lack[ed] sufficient information regarding abuse liability of the new products (*i.e.*, the addictiveness, abuse, and misuse potential of the new products and the exposure to nicotine during product use)." IVPS provided data from a clinical study showing that abuse liability outcomes between the products were comparable to combustible cigarettes under prescribed conditions, but the application did not include comparisons for actual-use conditions. Evidence showed much higher nicotine concentrations when the products were used with certain e-liquids under actual-use conditions. Without comparison data for actual-use conditions, FDA could not tell whether the abuse liability for the products would be greater than combustible cigarettes. Instead of providing the comparison data, IVPS elected to add a warning to the products to discourage use of the products with the e-liquids that seemingly increased the abuse liability potential. That said, IVPS did not provide any comprehension studies to show consumers would understand and comply with the warning. Without the abuse liability data or comprehension studies indicating the data was unnecessary, FDA stated it was unable to find the products appropriate for the public health.

In the denial letter, FDA explained why the data was necessary for its evaluation:

> [U]se of the new products with [certain] e-liquids . . . may contribute to a higher abuse liability and subsequent increased nicotine dependence compared to combusted cigarettes under actual use conditions. A new product with higher abuse liability compared to combusted cigarettes could promote

> craving of the new product and compulsive and continued use of the new product despite harm or risk of harm. A new product with higher abuse liability could also increase the potential for addiction to the new product, relative to combusted cigarettes, in individuals who use tobacco and nonusers, including youth. Thus, to understand the abuse liability of the new products, FDA must consider whether consumers will understand and comply with the instructions . . . . This includes both current users of tobacco products and nonusers, including youth, who may initiate use of your new products. Because abuse liability relates to the relative risks of tobacco products, we need to understand the abuse liability of these new products to determine whether their public health benefits outweigh their risks and, therefore, whether they are [appropriate for the protection of public health].

FDA's denial of IVPS's PMTA did not violate the TCA's mandate to weigh the risks and benefits of the products to determine whether the products are appropriate for the protection of the public health.

II. Single Deficiency Letter

IVPS also argues that when considering the risks and benefits of the product, it was arbitrary and capricious to base the denial in part on the lack of label comprehension data for the product's proposed label. IVPS asserts that it offered the label in response to FDA's abuse liability data concerns. Therefore, if FDA had concerns about the label, FDA should have provided IVPS with the opportunity to undertake an iterative review process.

IVPS argues that FDA historically engaged in such an iterative review process involving multiple rounds of letters and responses, so FDA's change in position to issuing only a single deficiency letter with a 90-day response deadline was arbitrary and capricious. There are two components to this argument: (1) whether the agency impermissibly changed its position;

and (2) whether the agency failed to treat like cases alike. We consider each argument in turn.

A. Change-in-Position Doctrine

FDA initially justifies its decision to issue only a single deficiency letter by emphasizing that the TCA does not require FDA to issue any deficiency letters at all. IVPS counters that "[e]ven absent a statutory command, FDA's longstanding practice was thus sufficient to create a reliance interest on the part of IVPS when it submitted its application that FDA would not depart from its past practice."

Nevertheless, a long-standing practice does not mandate a permanent practice. It is well established that an agency may change its course so long as it "suppl[ies] a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored." *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970). The Supreme Court recently provided clarification on this change-in-position doctrine. *See Wages & White Lion*, 145 S. Ct. at 918–19. A change-in-position analysis must ask two questions: (1) did the agency change its policy; and, if so, (2) "[d]id the agency 'display awareness that it *is* changing position' and offer 'good reasons for the new policy'?" *Id.* at 918 (quoting *FCC v. Fox Television Stations*, *Inc.*, 556 U.S. 502, 515 (2009)). We consider the questions in that order.

First, did the agency change its policy? "[T]his occurs when an agency acts 'inconsistently' with an 'earlier position,' performs 'a reversal of its former views as to the proper course,' or 'disavows' prior 'inconsistent' agency action as 'no longer good law.'" *Id.* (alterations adopted and citations omitted) (first quoting *Encino Motorcars LLC v. Navarro*, 579 U.S. 211, 224 (2016); then quoting *State Farm*, 463 U.S. at 41; and then quoting *Fox Television Stations*, 556 U.S. at 517). Here, FDA

announced it would only issue a single deficiency letter, which was inconsistent with its prior practice. U.S. Food and Drug Admin., Deemed Product Review: A Conversation with the Center for Tobacco Products Office of Science 24 ("Deemed Product Review") (June 11, 2021), https://perma.cc/6PD3-FLXG. Therefore, FDA changed its policy.

Second, did the agency acknowledge the change in position and offer good reasons for the change? The agency need not "show 'that the reasons for the new policy are *better* than the reasons for the old one'" or "provide a more detailed justification than what would suffice for a new policy created on a blank slate." *Wages & White Lion*, 145 S. Ct. at 918 (quoting *Fox Television Stations,* 556 U.S. at 515). "But the agency must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.'" *Id.* (quoting *Encino Motorcars*, 579 U.S. at 221–22). Here, FDA expressly stated it would generally limit the application review to one deficiency letter and explained the reason was to streamline the processing of the many applications it received around the September 2020 ENDS PMTA deadline. Deemed Product Review at 24. Although FDA announced the change nearly a year after IVPS submitted its applications, the announcement came nearly two years before IVPS received its deficiency letter. IVPS could not have been surprised when FDA adhered to the new single-deficiency-letter policy.

Further, IVPS was aware of the recommendation that applicants "include studies demonstrating that users and nonusers understand the product's labeling and instructions for use," which was part of FDA's 2019 guidance for PMTAs. PMTA Guidance at 43. The proposed rule likewise suggested data on "the ability of individuals to understand the labeling and instructions for use and use the product in accordance with those instructions." Premarket Tobacco Product Applications and Recordkeeping

Requirements, 84 Fed. Reg. at 50,606. IVPS acknowledged the proposed requirement of label comprehension studies, even quoting portions of the guidance and proposed rule in its application. IVPS conducted the studies for other portions of its original application. IVPS's failure to include the studies in its response to the deficiency letter does not require FDA to give IVPS additional opportunities.

IVPS asserts it was impossible for IVPS to conduct the necessary studies within the 90-day deadline to respond to the deficiency letter. IVPS contends it likely needed nine months to conduct the study and provide the results to FDA. Nevertheless, IVPS never requested an extension to respond to the deficiency letter. True, the deficiency letter stated "[i]n general, to maximize review efficiency of applications, we do not intend to provide an extension of time for response to deficiency letters." That does not necessarily mean FDA would not grant an extension if it were necessary. In the same meeting where FDA announced the single deficiency letter policy, it advised applicants who could not respond within 90 days to "still respond with what they have and then also give us a detailed plan with a timeline for all remaining data." DEEMED PRODUCT REVIEW at 32. IVPS even directs us to an application it claims received an extension. IVPS cannot now claim to be unaware and prejudiced that FDA adhered to its two-year-old policy if IVPS never alerted FDA it would need more time to provide an adequate response under that policy.

Ultimately, IVPS argues FDA's announcement was insufficient to "justify the differential treatment accorded IVPS." IVPS submitted its applications nearly a year before the announcement in 2021. IVPS also laments that FDA "rejected requests for pre-submission meetings" which left "IVPS to speculate as to certain aspects of the abuse liability studies it planned to perform and as to exactly what amount of evidence FDA would require." Although FDA did not hold pre-submission meetings, it provided

guidance. FDA did not change that guidance and then deny IVPS's application based on the changed guidance. Instead, FDA denied IVPS's application for a failure to provide the data that IVPS was aware FDA considered important in determining whether the products were appropriate for the public health.

We hold FDA's change in position from multiple deficiency letters to one deficiency letter was not arbitrary and capricious because it was acknowledged and adequately explained.

B. Treating Like Cases Alike

IVPS also argues that FDA issuing only one deficiency letter is arbitrary and capricious because it failed to treat like cases alike. "It is a bedrock principle of administrative law that an agency must treat like cases alike." *University of Texas M.D. Anderson Cancer Ctr. v. HHS*, 985 F.3d 472, 479 (5th Cir. 2021) (quotation omitted). "An agency must provide an adequate explanation to justify treating similarly situated parties differently." *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776 (D.C. Cir. 2005). If the agency fails to do so, "its action is arbitrary and capricious and cannot be upheld." *Id.* at 777.

According to IVPS, FDA's practice up to the point of IVPS's application was to engage in an iterative review process, and similarly situated applicants received more than one deficiency letter. FDA argues the applicants IVPS cites were not similarly situated. One application for a smokeless tobacco product was filed several years earlier and another was processed under a completely different authorization path, the substantial-equivalence path. In response, IVPS argues there is no meaningful distinction between PMTA and substantial-equivalence pathways that justifies the different treatment. According to IVPS, PMTAs are even more deserving of multiple deficiency letters because substantial-equivalence

pathway applications are considerably simpler. We conclude FDA has adequately explained the different treatment between PMTA and substantial-equivalence pathways applications. Although both pathways are used to approve new tobacco products, the requirements for each are different and it is reasonable for FDA to treat the applications differently.

Additionally, IVPS cites prior PMTA applications, including one for a smokeless tobacco product in 2015. FDA asserts that PMTAs for e-cigarettes are fundamentally different because e-cigarette products were already being marketed due to the sequencing of the TCA and the rule that deemed e-cigarettes subject to the TCA. FDA argues the presence of these products on the market before FDA's approval created exigencies that were not present in the applications where the applicant received multiple deficiency letters. IVPS counters that the three-and-a-half-year review period shows there was no true sense of urgency in FDA's actions and undercuts FDA's assertion that exigencies required the move from multiple deficiency letters to a single deficiency letter. According to IVPS, FDA cannot seriously contend it believed it was bound by the Maryland district court's timeline, because FDA did not issue the deficiency letter until well after the court's mandated deadline. Further, IVPS argues its dependence on established revenue from ENDS products sales weighed in favor of FDA issuing more than one deficiency letter and providing IVPS with more time to conduct the necessary research.

FDA's delay in evaluating IVPS's application is more indicative of the volume of applications than a lack of urgency. As FDA argues, it is unique that products regulated by FDA would be on the market without authorization. IVPS's ENDS products were already on the market, so FDA had an incentive to streamline the application process. Moreover, it is FDA's statutory duty to ensure only tobacco products that are appropriate for the protection of the public health are on the market. *See* § 387j(c)(2)(A).

FDA has adequately explained the difference in treatment between applications filed before and after the Deeming Rule.

In its reply brief, IVPS directs our attention to one applicant who applied after IVPS's first application was submitted and received a two-month extension for a response to the deficiency letter and the opportunity to provide additional information through a teleconference. "Adequate briefing requires a party to raise an issue in its opening brief." *Guillot ex rel. T.A.G. v. Russell*, 59 F.4th 743, 751 (5th Cir. 2023). By citing this application in its reply brief, IVPS did not give FDA the opportunity to differentiate it. Thus, we will not consider it.

CONCLUSION

We hold FDA's denial based on the abuse liability deficiency was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See* 5 U.S.C. § 706(2)(A). Because this deficiency is sufficient to sustain the denial of the application, we need not consider the other two independent reasons given for the denial.

The petition for review is DENIED.