United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
February 26, 2026
Lyle W. Cayce
Clerk

No. 25-40135

KEALANI DISTRIBUTION, L.L.C.; UNITED STATES VAPING ASSOCIATION, INCORPORATED; DIAMOND VAPOR, L.L.C.; JOHNNY COPPER, L.L.C.; SWT GLOBAL SUPPLY, INCORPORATED; CAROLINA VAPOR MILL, L.L.C.; CAROLINA VAPOR MILL WOODRUFF ROAD; CVM3, L.L.C.,

Plaintiffs—Appellants,

versus

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *in his official capacity as Commissioner of Food & Drug Administration*; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*,

Defendants—Appellees.

Appeal from the United States District Court
for the Eastern District of Texas
USDC No. 4:22-CV-856

Before JONES and ENGELHARDT, *Circuit Judges*, and SUMMERHAYS*, *District Judge*.

ROBERT R. SUMMERHAYS, *District Judge*:

*District Judge of the Western District of Louisiana, sitting by designation.

The Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act" or "TCA") restricts the sale of tobacco products that were not commercially marketed in the United States before February 15, 2007.[1] Absent certain limited exceptions, a manufacturer may not introduce such products into interstate commerce unless the U.S. Food and Drug Administration ("FDA") determines that the product is "appropriate for the protection of the public health."[2] In this case, we consider whether the FDA satisfied the Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 601, *et seq.*, when promulgating a final rule setting forth requirements for premarket tobacco product applications ("Final PMTA Rule" or "Final Rule"). Appellants—seven small-business manufacturers of e-liquids and a trade association that represents small-business vapor product manufacturers and retailers—filed suit for declaratory and injunctive relief, contending that the Final Rule was promulgated in violation of the Regulatory Flexibility Act. They argue that the FDA's certification that the rule would not have a significant economic impact on a substantial number of small entities is arbitrary and capricious. The district court granted summary judgment for the FDA, upholding the Final Rule. Because we find the FDA complied with the Regulatory Flexibility Act when promulgating the Final PMTA Rule, the decision of the district court is AFFIRMED.

I. Background

The 2009 Tobacco Control Act establishes a comprehensive scheme for the regulation of tobacco products, which Congress defined to include "any product made or derived from tobacco, or containing nicotine from any

---

[1] 21 U.S.C. §§ 387j(a)(1)(A), (a)(2).

[2] *Id.* § 387j(c)(2)(A).

source, that is intended for human consumption."[3] The Tobacco Control Act requires FDA authorization before any "new tobacco product" may be introduced into interstate commerce.[4] A "new tobacco product" is one that was not marketed in the United States before February 15, 2007, and the TCA subjects such products to a premarket authorization process.[5] There are several pathways to FDA approval. Relevant here, a manufacturer may submit a premarket tobacco product application ("PMTA") to the FDA to market its product.

Congress has mandated that FDA "shall deny" a PMTA if, after review of the information submitted in the application "and any other information before the [FDA] with respect to such tobacco product," the FDA finds "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."[6] To determine whether a product is "appropriate for the protection of the public health," the FDA must consider "the risks and benefits to the population as a whole" and "tak[e] 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."[7] Further, the FDA's decision must, "when appropriate, be determined on the basis of well-controlled investigations," including "clinical investigations."[8]

---

[3] *Id.* § 321(rr)(1).

[4] *Id.* § 387j(a)(1)–(2).

[5] *Id.* § 387j(a)(1)(A), (a)(2).

[6] *Id.* § 387j(c)(2).

[7] *Id.* § 387j(c)(4).

[8] *Id.* § 387j(c)(5)(A).

However, FDA may base its determination on "valid scientific evidence" other than well-controlled investigations if such evidence "is sufficient to evaluate the tobacco product."[9] Congress made these requirements immediately applicable to certain categories of tobacco products (*i.e.*, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco) and vested the Secretary of Health and Human Services with the authority to impose these requirements on "any other tobacco products that the Secretary by regulation deems to be subject to this subchapter."[10]

The Regulatory Flexibility Act imposes certain procedural requirements on federal agencies to ensure they consider the impact of their regulations on small entities.[11] The RFA is not a "substantive agency mandate."[12] Rather, it is a "procedural statute setting out precise, specific steps an agency must take."[13] One requirement of the RFA is that when agencies issue rules under the Administrative Procedure Act (the "APA"), they are to publish a "final regulatory flexibility analysis."[14] That analysis must include "a description of the steps the agency has taken to minimize the significant economic impact" on small businesses, "including a statement of

---

[9] *Id.* § 387j(c)(5)(B).

[10] *Id.* § 387a(b).

[11] 5 U.S.C. § 601, *et seq.*

[12] *Alenco Communications, Inc. v. F.C.C.*, 201 F.3d 608, 625 (5th Cir. 2000).

[13] *Aeronautical Repair Station Ass'n, Inc. v. F.A.A.*, 494 F.3d 161, 178 (D.C. Cir. 2007); *see also Nat'l Tel. Coop. Ass'n v. F.C.C.*, 563 F.3d 536, 540 (D.C. Cir. 2009) (Kavanaugh, J.) ("Though it directs agencies to state, summarize, and describe, the Act in and of itself imposes no substantive constraint on agency decisionmaking. In effect, therefore, the Act requires agencies to publish analyses that address certain legally delineated topics.").

[14] 5 U.S.C. § 604. Generally, the RFA also requires an agency to prepare an initial regulatory flexibility analysis before issuing a notice of proposed rulemaking. *Id.* § 603.

the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected."[15] However, an agency need not conduct a regulatory flexibility analysis if it "certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities," publishes the certification in the Federal Register, and includes "a statement providing the factual basis for such certification."[16]

In May 2016, the FDA issued a final rule ("Deeming Rule") deeming all products that meet the definition of "tobacco product"—including electronic nicotine delivery systems ("ENDS") and their component parts (which include the vapor products manufactured by Appellants)—to be subject to the Tobacco Control Act.[17] As a result, these products became subject to the Tobacco Control Act's premarket review provisions. In accordance with the RFA, the FDA published a final regulatory impact analysis, which found that the Deeming Rule would "have a significant economic impact on a substantial number of small entities."[18] The FDA

---

[15] *Id.* § 604(a)(6). A final regulatory flexibility analysis must additionally state the purpose of the rule; it must summarize the comments filed in response to the agency's initial regulatory flexibility analysis, the agency's assessment of those comments, and include a statement of any changes made to the proposed rule as a result of such comments; it must state the estimated number of small business that the rule will affect, if such an estimate is available; and it must provide a description of projected reporting, recordkeeping and other compliance requirements of the rule and the type of professional skills necessary for preparation of such reports and records. *Id.* § 604.

[16] *Id.* § 605(b).

[17] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973, 28,975 (May 10, 2016).

[18] That analysis was challenged by multiple manufacturers and industry associations in *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360 (D.D.C. 2017). The court

recognized that the PMTA requirements "could lead to significant product exit and reduced entry," but maintained that such requirements would "help[] ensure that new tobacco products are appropriate for the protection of the public health." While the FDA noted that "[e]stimating expected costs of submitting PMTAs is made complicated . . . by the flexibility firms have to decide on how best to provide the information expected in the PMTA," it nevertheless estimated that the costs of submitting a PMTA for e-liquids would be between $181,686 and $2,014,120.

On October 5, 2021, the FDA issued the Final PMTA Rule—the rule challenged in this proceeding.[19] While acknowledging that the Final Rule would "generate incremental costs related to the preparation of PMTAs for ENDS products," the FDA nevertheless certified that the Final Rule would "not have a significant economic impact on a substantial number of small entities."[20] The FDA based this certification on its finding that it expected the Final PMTA Rule to "generate net benefits or negligible net costs for most affected small entities," in part because the Final PMTA Rule was intended to improve the efficiency of submission and review of PMTAs, thereby reducing the number of premarket applications that are rejected.[21] The FDA additionally noted that it had "already included the costs to submit and review PMTAs for deemed tobacco products" in the final regulatory impact analysis for the May 2016 Deeming Rule.[22]

---

rejected the challenge, finding the FDA "complied with the procedural requirements of the Regulatory Flexibility Act." *Id.* at 408.

[19] Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55,300 (Oct. 5, 2021).

[20] *Id.* at 55,405.

[21] *Id.*

[22] *Id.*

Along with the Final Rule, the FDA published a final regulatory impact analysis addressing the effect of the "new requirements" of the Final Rule that were not included in the Deeming Rule's regulatory impact analysis. In that regulatory impact analysis, the FDA noted that in 2016, it had concluded that the Deeming Rule would "cause many existing firms to exit the market, creating significant market consolidation" due to "the compliance costs associated with the Deeming Rule," and that it expected the Deeming Rule "to have a significant impact on a substantial number of small entities." With regard to the Final PMTA Rule, the FDA found the forgoing impacts "are attributable to the Deeming Rule and not this final rule." It further found "that most applicants that submit ENDS PMTA bundles will *benefit* from the final rule," due to its clarification of PMTA requirements and streamlined procedures. The FDA concluded that "most small entities will either benefit from the final rule or will incur small annualized costs of approximately $2,000."

Appellants then filed suit for declaratory and injunctive relief, asserting that the Final PMTA Rule was promulgated in violation of the Regulatory Flexibility Act, because the FDA's certification that the rule would not have a significant impact on a substantial number of small entities is unsupported by the record and therefore arbitrary and capricious. The parties filed cross motions for summary judgment. The district court granted the FDA's motion, finding Appellants' challenge failed for two reasons: (1) the FDA satisfied the RFA by considering whether the Final PMTA Rule would have a significant impact on a substantial number of small entities and certifying, together with a factual basis, that it would not, and (2) Appellants failed to identify any procedural defect in the FDA's certification, instead raising only substantive disagreements with the FDA's factual basis, which are outside the scope of RFA review. Appellants now appeal that decision.

II. Standard of Review

We review the district court's grant of summary judgment de novo.[23] We review agency compliance with the Regulatory Flexibility Act "only to determine whether an agency has made a 'reasonable, good-faith effort' to carry out the mandate of the RFA."[24] The Administrative Procedure Act's arbitrary-and-capricious standard "requires that agency action be reasonable and reasonably explained."[25] Among other things, courts must assess whether an agency's decision was based on "consideration of the relevant factors."[26] "The Regulatory Flexibility Act makes the interests of small businesses a 'relevant factor' for certain rules. Therefore, the APA together with the Regulatory Flexibility Act require that a rule's impact on small businesses be reasonable and reasonably explained. A regulatory flexibility analysis is, for APA purposes, part of an agency's explanation for its rule."[27] Judicial review for compliance with the Regulatory Flexibility Act is deferential, and the court "simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision."[28]

---

[23] *Bruckner Truck Sales, Inc. v. Guzman*, 148 F.4th 341, 344 (5th Cir. 2025).

[24] *Alenco*, 201 F.3d at 625 (quoting *Associated Fisheries, Inc. v. Daley*, 127 F.3d 104, 114 (1st Cir. 1997)).

[25] *Federal Communications Commission v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

[26] *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted).

[27] *National Tel. Coop. Ass'n*, 563 F.3d at 540.

[28] *Prometheus Radio Project*, 592 U.S. at 423.

III. Discussion

Appellants contend the FDA's § 605(b) certification of the Final PMTA Rule is arbitrary and capricious for two reasons. First, Appellants contend that the FDA's finding that the Final PMTA Rule "will not have a significant economic impact on a substantial number of small entities" lacks adequate factual support, because it relies upon costs assessed in the 2016 Deeming Rule. They argue that these costs are not inclusive of the costs required to comply with the Final PMTA Rule. Second, Appellants contend that even assuming that the FDA's reliance on the costs assessed in the Deeming Rule was proper, the FDA violated the RFA by failing to consider less burdensome regulatory alternatives to the substantive PMTA content requirements in either the 2016 Deeming Rule or the 2021 Final PMTA Rule. Appellants confine their arguments on both issues to the statutory requirement that a PMTA must include "full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products."[29] Accordingly, we focus on that aspect of the Final PMTA Rule.

A. Whether the FDA lacks a factual basis for its 2021 certification.

Appellants assert the Tobacco Control Act provides a "wide berth" for the FDA to regulate what a PMTA must include with respect to health risk investigations. Appellants appear to argue that because the TCA permits the FDA to rely on "valid scientific evidence" other than "well-controlled investigations" when reviewing a PMTA, 21 U.S.C. § 387j(c)(5), the FDA should have considered less-costly alternatives to the statute's requirement

---

[29] 21 U.S.C. § 387j(b)(1)(A).

that an application to market a new tobacco product must include full reports of all health risk information known to the applicant, *id.* § 387j(b)(1)(A). Appellants further contend that when the FDA issued the Deeming Rule, "it did not purport to flesh out the PMTA requirements" because it anticipated doing so in the Final Rule. According to Appellants, the Deeming Rule "expressly premised the cost estimates on the 'format and content requirements of a PMTA *as described in the TCA*.'" Because the Final Rule expanded the "categories of topics covered and detail" required in a PMTA, the cost estimates set forth in the Deeming Rule constitute "an insufficient factual predicate" for the certification of the Final PMTA Rule, and therefore the certification lacks the requisite factual basis to satisfy the RFA.

In response, Appellees explain that the requirement that a PMTA contain full reports of all health risk investigations is mandated by the Tobacco Control Act, and the 2016 Deeming Rule is what makes that requirement applicable to Appellants' products. The 2021 Final PMTA Rule's stated purpose is "to improve the efficiency of the submission and review of PMTAs" by giving regulated entities additional detail about the information needed to satisfy the statutory standard and by establishing procedures to streamline review.[30] While acknowledging that the Final Rule would "generate incremental costs related to the preparation of PMTAs for ENDS products," ultimately the FDA expected the Final Rule to "generate net benefits or negligible net costs for most affected small entities."[31] In its regulatory flexibility analysis accompanying the Final PMTA Rule, the FDA

---

[30] 86 Fed. Reg. 55,300, 55,301.

[31] *Id.* at 55,405 (acknowledging the Final Rule will generate incremental costs related to the preparation of PMTAs—e.g., postmarket reporting requirements, costs incurred "to read and understand the rule," and costs incurred to maintain records; additionally finding the rule would create cost savings for applicants "by reducing the number of PMTAs submitted").

explained that the costs associated with the preparation of a PMTA that satisfies the Tobacco Control Act are attributable and accounted for in the Deeming Rule, rather than the Final PMTA Rule. It further found that its assessment of costs associated with health studies in the Deeming Rule's regulatory flexibility analysis, after adjustment for inflation and wage rates, continued to reflect the best available estimates for the cost of studies necessary for a PMTA and that the Final Rule would not impact those costs. On the basis of those findings, the FDA certified "the final rule will not have a significant economic impact on a substantial number of small entities."[32]

The Tobacco Control Act requires the FDA to deny an application to market a deemed tobacco product if "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."[33] In evaluating whether a deemed tobacco product is appropriate for the protection of the public health, the FDA must consider "whether such tobacco product presents less risk than other tobacco products,"[34] "the risks and benefits to the population as a whole,"[35] "the increased or decreased likelihood that existing users of tobacco products will stop using such products,"[36] and "the increased or decreased likelihood that those who do not use tobacco products will start using such products."[37] Ultimately, the burden is on the applicant to show its product is appropriate

---

[32] *Id.*

[33] 21 U.S.C. § 387j(c)(2)(A).

[34] *Id.* § 387j(b)(1)(A).

[35] *Id.* § 387j(c)(4).

[36] *Id.* § 387j(c)(4)(A).

[37] *Id.* § 387j(c)(4)(B).

for the protection of the public health.[38] In order to make this showing, the TCA mandates that an application to market a new tobacco product "shall contain . . . full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products."[39]

Appellants do not explain how the Final PMTA Rule significantly expands the "categories of topics covered and detail" required in a PMTA from that which was required in the Deeming Rule.[40] Nor do Appellants cite to any specific portion of the Final PMTA Rule in support of this argument.[41] Regardless, the requirement that an applicant include all known information concerning health risk investigations for its product in a PMTA is mandated by statute. It was Congress, not the FDA, that imposed this

---

[38] *See, e.g.*, *Bidi Vapor LLC v. U.S. Food and Drug Administration*, 134 F.4th 1282, 1292 (11th Cir. 2025).

[39] 21 U.S.C. § 387j(b)(1)(A).

[40] The Court notes Appellants "do not dispute the FDA's factual determinations" and they make "no argument here that FDA arrived at a mistaken estimate of the cost of a particular type of testing."

[41] Rule 28(a) of the Federal Rules of Appellate Procedure requires citations to the "parts of the record on which the appellant relies," FED. R. APP. P. 28(a)(8)(A), and our local rules require that "[e]very assertion in briefs regarding matter in the record must be supported by a reference to the page number of the original record . . . where the matter is found." 5TH CIR. R. 28.2.2. It is not the duty of the Court to compare the 156-page Deeming Rule against the 139-page Final PMTA Rule in an effort to find evidence to support Appellants' argument. *See, e.g.*, *Forsyth v. Barr*, 19 F.3d 1527, 1537 (5th Cir. 1994) (courts have no duty to "sift through the record in search of evidence" to support a parties' argument). Thus, this argument is forfeited due to inadequate briefing. *See, e.g.*, *Schnell v. State Farm Lloyds*, 98 F.4th 150, 161 (5th Cir. 2024) ("A party forfeits an argument through inadequate briefing . . . by failing to offer record citations" (quotation marks omitted)). Nevertheless, we address the merits.

requirement on new tobacco products. The FDA cannot by regulation dispense with a Congressional mandate.[42]

Finally, to the extent Appellants take issue with the FDA's attribution of PMTA-related costs to the Deeming Rule, that is a substantive factual conclusion underlying the FDA's certification. As such, it is outside of the scope of judicial review of alleged RFA violations.[43] Here, the FDA made a "reasonable, good-faith effort" to comply with the RFA's purely procedural requirements, and therefore Appellants have failed to show the FDA's certification of the Final PMTA Rule is arbitrary and capricious.

B. Whether the FDA Failed to Consider Less Burdensome Regulatory Alternatives to the PMTA Content Requirements.

Appellants further contend that the FDA's certification of the Final PMTA Rule is arbitrary and capricious because the FDA "never considered *any* alternative means of satisfying the TCA's substantive PMTA requirements" in the Deeming Rule or Final PMTA Rule, as required by the Regulatory Flexibility Act. According to Appellants, by allowing the FDA "to rely on its own studies, or other publicly available information" when determining whether a product is appropriate for the protection of public health, the Tobacco Control Act "offers up a clear alternative to the most expensive portion of PMTAs," *i.e.*, the requirement that applicants submit all information regarding health risk investigations. Because the FDA failed

---

[42] *Djie v. Garland*, 39 F.4th 280, 284 (5th Cir. 2022) ("To the extent a regulation attempts to carve out an exception from a clear statutory requirement, the regulation is invalid.").

[43] *See, e.g.*, *Council for Urological Interests v. Burwell*, 790 F.3d 212, 227 (D.C. Cir. 2015) ("So long as the procedural requirements of the certification are met, however, this court's review is highly deferential as to the substance of the analysis, particularly where an agency is predicting the likely economic effects of a rule." (quotation marks omitted)).

to consider these or similar alternatives, Appellants contend that the FDA failed to comply with the Regulatory Flexibility Act.

The FDA responds that because it certified that the Final PMTA Rule would not have a significant economic impact on a substantial number of small entities, it was not required to consider regulatory alternatives to the content of a PMTA under RFA § 604(a)(6). Nevertheless, it did provide a "regulatory impact analysis consistent with § 604(a) in responding to comments suggesting that the significant costs of preparing marketing applications should not be attributed to the deeming rule." As to Appellants' argument that the FDA should allow applicants to rely on the agency's "own studies, or other publicly available information" to satisfy the statutory standard for PMTAs, the FDA notes that "the PMTA rule in fact preserves applicants' flexibility in this respect."

To the extent Appellants contend the FDA should dispense with the statutory requirement that a PMTA must include all health risk investigations known to the applicant, again, the FDA cannot by regulation "carve out an exception from a clear statutory requirement."[44] With regard to Appellants' argument that the FDA failed to consider regulatory alternatives to the health risk investigation requirement in either the Deeming Rule or the Final PMTA Rule, their argument is unsupported by the record. In the Deeming Rule, the FDA specifically addressed comments pertaining to "the need for costly clinical studies to develop PMTAs that satisfy the requirements" of the TCA.[45] The FDA responded:

---

[44] *Djie*, 39 F.4th at 284. To the extent Appellants argue the FDA is required by statute to develop its own studies or publicly available information regarding ENDS, they have failed to support such an argument.

[45] 81 Fed. Reg. 28,973, 28,997.

> [I]n some cases, it may be possible for an applicant to obtain a PMTA marketing authorization order without conducting any new nonclinical or clinical studies where there is an established body of evidence regarding the public health impact of the product. However, in cases where there have been few or no scientific studies of a product's potential impact on the public health, new nonclinical and clinical studies may be required for market authorization.[46]

The FDA also responded to comments suggesting that the TCA "provides FDA with authority to develop a flexible framework for PMTAs that would not require well-controlled investigations," along with proposed "alternatives to the requirement of well-controlled investigations."[47] The FDA rejected each alternative, primarily because the proposals either would not show that marketing the product is appropriate for the protection of the public health, or the proposals did not comply with the requirements set forth in the TCA. The FDA explicitly acknowledged that the TCA allows it to consider other "valid scientific evidence" in lieu of "well-controlled investigations," if such evidence is sufficient to evaluate the product.[48] Accordingly, "if an application includes, for example, information (*e.g.*, published literature, marketing information) with appropriate bridging studies, FDA will review that information to determine whether it is valid scientific evidence sufficient to demonstrate that the product is appropriate for the protection of the public health."[49]

---

[46] *Id.*

[47] *Id.*

[48] *Id.* at 28,998.

[49] *Id.*; *see also id.* at 28,999–29,001 (further addressing comments suggesting alternatives to the PMTA requirements).

Likewise, the Final PMTA Rule notes that the implementing regulations do "not set requirements for specific studies that must be contained in every single PMTA."[50] Rather:

> As described throughout this document, a PMTA must contain at least some amount of substantive information regarding each of the topic areas in [the regulations] to be filed for substantive review. Additionally, a PMTA must contain full reports of all investigations that are published or known to, or which should reasonably be known to an applicant . . . . FDA generally expects that applicants will be able to meet the substantive information requirement . . . by submitting investigations that are published or known to, or which should reasonably be known to, an applicant . . .; however, in the event an application is lacking required substantive information, an applicant may need to conduct its own investigation to meet the filing requirements.[51]

In response to comments suggesting that the FDA was "providing too much flexibility for applicants and should instead require applicants conduct specific types of studies," the FDA responded:

> We decline to require that an applicant conduct a list of new studies as part of every application under this rule because there may be other ways in which an applicant can provide scientific information to inform FDA's review (*e.g.*, bridging, published literature). Additionally, while a PMTA must contain substantive information regarding certain categories of information . . . , an applicant has some flexibility in determining how to use existing information to support a PMTA for their product and what types of additional investigations it may need to conduct to provide FDA with

---

[50] 86 Fed. Reg. 55,300, 55,357.

[51] *Id.*

> information that demonstrates that permitting the marketing of its new tobacco product would be [appropriate for the protection of the public health].[52]

Considering these responses, we conclude that the FDA provided adequate discussion and reasoned rejection of "significant alternatives to the rule."[53]

* * *

In sum, the 2016 Deeming Rule's assessment of the cost for compliance provides an adequate factual basis for the FDA's certification that the 2021 Final PMTA Rule would not have a significant economic impact on a substantial number of small entities. Further, both rules include substantial discussion and reasoned rejection of significant alternatives to the requirements of those rules. Accordingly, we conclude that the FDA made a reasonable, good-faith effort to comply with the RFA's purely procedural requirements, and therefore the judgment of the district court is AFFIRMED.

---

[52] *Id.* at 55,357-55,358.

[53] 5 U.S.C. § 604(a)(5).