IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

HELIX INNOVATIONS LLC; NJOY, LLC; TEXAS FOOD & FUEL ASSOCIATION; GWT DISTRIBUTING LLC d/b/a BRADY'S PACKAGE STORE; and HOMETOWN LIQUOR, LLC,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION;

KYLE DIAMANTAS, in his official capacity as the Acting Commissioner of Food and Drugs; and

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

Civil Action No. _____

COMPLAINT

I. Introduction

1. This is a case about the failure of the U.S. Food and Drug Administration ("FDA") to comply with its obligations under the Family Smoking Prevention & Tobacco Control Act ("TCA") and the Administrative Procedure Act ("APA"). The TCA expressly requires the FDA to authorize the marketing of new tobacco products (including alternatives to cigarettes) as "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). To facilitate such authorizations, the statute requires the FDA to grant or deny new product applications as promptly as possible, and "in no event later than 180 days after the receipt of an application." *Id.* § 387j(c)(1)(A). The FDA has never complied with this deadline. It violated it even for products the TCA covered when it was passed in 2009. Then in 2016, the FDA exacerbated the problem by "deeming" countless new products subject to premarket review, forcing manufacturers to file millions of new applications. In 2017, the FDA attempted to ease the backlog through discretionary relief, which a federal court invalidated in 2019. At that time, the FDA should have made changes to align its review process with the TCA and APA's requirements.

2. Instead, in October 2021, the FDA did the opposite. Operating under the Biden Administration's Acting Director Janet Woodcock, the FDA finalized a rule—over an avalanche of objections and evidence—for Premarket Tobacco Product Applications ("PMTAs") that violated the TCA and the APA ("2021 PMTA Rule"). The result was a flood of illicit products into the U.S. market, at the expense of law-abiding manufacturers, U.S. retailers and consumers, and American public health.[1] The 2021 PMTA Rule is the agency action challenged in this suit.

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

3. The 2021 PMTA Rule has directly injured Plaintiffs Helix Innovations LLC and NJOY, LLC and their retail partners, including Plaintiffs GWT Distributing LLC d/b/a Brady's Package Store and Hometown Liquor, LLC. Helix and NJOY manufacture smoke-free products that the FDA itself has found to be less harmful than combustible cigarettes and that retailers wish to sell in accordance with FDA orders authorizing the marketing of those products. But the regulatory roadblocks in the 2021 PMTA Rule have prevented Plaintiffs and other U.S. tobacco companies and retailers who comply with the Rule from obtaining the timely FDA review the TCA requires. As a result, American adult consumers have been deprived of access to new products by a rule that violates the TCA and APA by codifying practices that had already proved unworkable, and by adding onerous new requirements that significantly expanded the amount of information applicants were required to submit and, in turn, FDA staff had to review. The obvious result—as commenters warned based on a decade-long record the FDA arbitrarily disregarded—was an insurmountable logjam of PMTAs that the FDA admitted it could not review in accordance with the TCA's timing and substantive provisions.

4. After the 2021 PMTA Rule was finalized, lawful new product applications were strangled by red tape while foreign (and particularly Chinese) manufacturers sold U.S. consumers vast quantities of unauthorized smoke-free products that were never submitted to the FDA for premarket review and in many instances expressly targeted American youth. The FDA recently acknowledged the blind spot that allowed this to happen: Because only domestic owners and operators of manufacturing establishments must register and list their tobacco products, the agency lacks information about foreign owners and operators of manufacturing establishments supplying the illicit market. The agency recently proposed a new rule to address this gap. *See Establishment*

Registration and Product Listing for Tobacco Products, 91 Fed. Reg. 39,168, 39,168–69 (June 29, 2026) (proposed rule).

5. In addition, the FDA recently attempted to mitigate the dire consequences of the 2021 PMTA Rule on new product reviews through two discretionary initiatives. First, in late 2025 the FDA announced a pilot program to fast-track review of certain nicotine pouch products. Second, in May 2026, the FDA issued new guidance on enforcement priorities for unauthorized products as part of its attempt to "facilitate an orderly shift toward a regulated market in which compliant products, supported by appropriate evidence and subject to meaningful oversight, can replace unauthorized offerings."[2] But the shift toward a regulated market of lawful products cannot succeed while the 2021 PMTA Rule remains in place—as demonstrated by the fact that the agency still faces a backlog of millions of applications and the "pilot program" has produced (nearly a year after its launch) authorizations for only a fraction of Helix's pouch products that had long-pending applications—and even those authorizations were *still* issued long past the TCA's 180-day deadline.

6. The administrative record for the 2021 PMTA Rule establishes every element of Plaintiffs' claims under the TCA and the APA. Altria—the parent company of Helix and NJOY—warned the FDA of the 2021 PMTA Rule's shortcomings during the notice-and-comment period. For example, Altria observed that the Rule, if finalized, would cause an "indefinite delay" in the

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[2] *Enforcement Priorities for Certain New Tobacco Products Marketing Without Premarket Authorization*, 91 Fed. Reg. 25,892, 25,893 (May 12, 2026), https://www.federalregister.gov/documents/2026/05/12/2026-09368/enforcement-priorities-for-certain-new-tobacco-products-marketed-without-premarket-authorization#action; *see also* FDA, *Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization - Guidance for Industry* (May 8, 2026), https://www.fda.gov/media/192403/download (collectively, "May 2026 Guidance").

processing of PMTAs. Altria Comment at 11, 12 (Dec. 16, 2019), https://www.regulations.gov/comment/FDA-2019-N-2854-1057. Recognizing the public-health need to provide "scientifically-demonstrated, potentially reduced-risk products to adult smokers as rapidly as possible," Altria proposed that the FDA "develop PMTA format alternatives [that] would reduce the burden associated with the submission and review of an application" and support a collaborative effort between government and industry to "meet[] statutory and regulatory requirements." *Id.* at 4 (quotation marks omitted).

7. But the FDA failed to fix these flaws. As promulgated, the 2021 PMTA Rule violates both the TCA and APA in ways the FDA's recent guidance and pilot program cannot cure because they cannot ensure the timely marketing decisions the TCA commands. Nor can the guidance and pilot program remedy the delay the 2021 Rule has already unlawfully imposed on Helix and NJOY's applications—some of which have been pending for more than 2,270 days (six years) and are still awaiting the orders the TCA requires the FDA to issue within 180 days. As alleged in greater detail below, the 2021 PMTA Rule is unlawful and should be vacated for two main reasons.

8. *First*, the 2021 PMTA Rule exceeds the FDA's statutory authority. The TCA requires the agency to decide PMTAs no later than "180 days after the *receipt* of an application." 21 U.S.C. § 387j(c)(1)(A) (emphasis added). But the 2021 PMTA Rule replaced this express statutory mandate with an open-ended process that starts the 180-day period only when the FDA decides that it has received the "last piece of information necessary to complete the submission"—a moment the agency alone controls, and one that almost always arrives, if ever, only after the FDA separately "accepts" and then "files" an application. 21 C.F.R. § 1114.27(a)–(c); 86 Fed. Reg. at

55,382. Each of those preliminary phases routinely takes months because the FDA returns applications to the filer for follow-up information—including product samples that the Rule forbids applicants from submitting with the application in the first place—and because it requires convoluted administrative forms that lack the required fields for companies to fill out, that frequently change, that do not align with the requirements of the 2021 PMTA Rule itself, and that cause the FDA to reject applications for purely administrative reasons. This effort to game the start date of the TCA's review period violates the plain meaning of the statutory term "receipt," and it subverts the statutory review process from its inception. For this reason alone, the 2021 PMTA Rule is contrary to law under the TCA and APA: It expressly contemplates the agency will *not* decide PMTAs within 180 days of "receipt" as Section 387j(c)(1) requires.

9. *Second*, the 2021 PMTA Rule is arbitrary and capricious in violation of the APA. The most glaring problem with the Rule is that it exacerbated known violations of the TCA's review deadlines by creating a more complicated, more time-consuming PMTA review process against an already insurmountable backlog of applications. In October 2021, the FDA arbitrarily and capriciously disregarded this concern and rejected several proposals from commenters that would have aligned the review process with the TCA's statutory deadlines. Instead, the FDA unreasonably obstructed the review process with even more requirements that make it impossible for the agency to review the vast majority of applications in compliance with the TCA. The Rule is arbitrary and capricious for the further reasons that the FDA's stated justification for deferring the start of the review clock was internally inconsistent, that the agency never explained how it could meet the 180-day deadline given the backlog it had created, that it refused to consider obvious alternatives such as a streamlined pathway for smoke-free products, and that it attributed the Rule's costs to a different rule adopted five years earlier.

10. None of this is an objection to a pre-market review system characterized by high standards and rigorous science. Plaintiffs want those things. Nor is the aim of this lawsuit parochial. Plaintiffs seek relief that will improve the functioning of the entire industry and ensure that the FDA complies with the TCA, which will benefit consumers and the general public more than anyone. The aim of this lawsuit is to end the dysfunction caused by a regulator that cannot do the job the TCA requires, in the time the statute requires the agency to do it. That dysfunction hurts ordinary people most, punishes legitimate market participants, and helps only illicit-market actors that *nobody* believes have Americans' best interests at heart.

11. For these and other reasons detailed below, this Court should vacate the 2021 PMTA Rule. It also should remand for the FDA to adopt a new process for reviewing PMTAs that is consistent with the statutory requirement to decide PMTAs within 180 days. Finally, the Court should enter a declaratory judgment and injunction preventing the FDA from enforcing the TCA, including its premarket-review requirements, against Helix and NJOY's products that are covered by PMTAs that have been pending for more than 180 days.

II. Parties

12. Plaintiff Helix Innovations LLC is a Delaware limited liability company headquartered in Richmond, Virginia.

13. Plaintiff NJOY, LLC is a Delaware limited liability company headquartered in Richmond, Virginia.

14. Plaintiffs Helix and NJOY and their affiliates manufacture and sell a large portfolio of tobacco products for adult customers (over age 21). These products include smoke-free e-vapor products that the FDA calls electronic nicotine delivery systems ("ENDS") and smoke-free pouch products.

15. As the FDA has recognized for years, these smoke-free e-vapor and pouch products protect the public health because they deliver nicotine without combustion (*i.e.*, without smoke or ash) and help smokers transition away from riskier combustible tobacco products such as traditional cigarettes. These smoke-free products thus reduce harm by providing an alternative to smokers who are otherwise unwilling or unable to quit. They also reduce health risks for adult consumers who wish to use nicotine products and would otherwise start smoking or purchase non-FDA-authorized devices from unregulated suppliers, often foreign manufacturers operating illicitly in the United States.

16. Helix and NJOY have consistently complied with the TCA by seeking FDA review and authorization of their products pursuant to statutory and regulatory requirements.

17. Plaintiff Texas Food & Fuel Association, Inc. ("TFFA") is a Texas non-profit trade association headquartered in Austin, Texas. TFFA represents the retail and wholesale sectors of the oil and gas industry in Texas, including in litigation against federal and state agencies, to advance the interests of the convenience retail industry. TFFA's members include owners and operators of convenience stores, filling stations, grocery stores, and truck stops that sell pouch, e-vapor, and other tobacco products. Its members would like to sell more such products, including Helix and NJOY products, that have been authorized by the FDA pursuant to the process Congress established in the TCA. But they have suffered regulatory uncertainty about all of the nicotine products they sell, as well as how to allocate shelf space.

18. Plaintiff GWT Distributing LLC d/b/a Brady's Package Store is a Texas limited liability company headquartered in Lubbock, Texas. GWT Distributing LLC sells pouch and other tobacco products, including Helix and NJOY products, in Texas. GWT Distributing LLC would like to sell more such products, including Helix and NJOY products, that have been authorized by

the FDA pursuant to the process Congress established in the TCA. But GWT Distributing LLC has suffered regulatory uncertainty about all of the nicotine products it sells, as well as how to allocate shelf space. In the meantime, GWT Distributing LLC's competitors currently sell illicit products manufactured by other companies who do not even attempt to comply with the TCA, and GWT Distributing LLC is losing business to those competitors.

19. Plaintiff Hometown Liquor, LLC is a Texas limited liability company headquartered in Brownwood, Texas. Hometown Liquor, LLC sells pouch, e-vapor, and other tobacco products, including Helix and NJOY products, in Texas. Hometown Liquor, LLC would like to sell more such products, including Helix and NJOY products, that have been authorized by the FDA pursuant to the process Congress established in the TCA. But Hometown Liquor, LLC has suffered regulatory uncertainty about all of the nicotine products it sells, as well as how to allocate shelf space. In the meantime, Hometown Liquor, LLC's competitors currently sell illicit products manufactured by other companies who do not even attempt to comply with the TCA, and Hometown Liquor, LLC is losing business to those competitors.

20. Defendant FDA is an agency within the U.S. Department of Health and Human Services ("HHS").

21. Defendant Kyle Diamantas is the Acting Commissioner of Food and Drugs. He has been delegated authority to administer the TCA by the Secretary of HHS. *See* 2016 FDA Staff Manual Guide § 1410.10(1)(A)(1) (Feb. 22, 2023), https://bit.ly/2KGT7Ts. Acting Commissioner Diamantas is named in his official capacity only.

22. Defendant HHS is an executive department of the United States.

III. Jurisdiction and Venue

23. This action arises under the APA, 5 U.S.C. §§ 500 *et seq.*, the TCA, 21 U.S.C. §§ 387 *et seq.*, and FDA rules and regulations.

24. This Court therefore has jurisdiction under 28 U.S.C. § 1331.

25. Plaintiffs have standing to bring this suit. Plaintiffs are injured by the 2021 PMTA Rule because it increases compliance costs; causes and exacerbates unlawful delays in premarket review for Helix's and NJOY's products; creates regulatory uncertainty about all nicotine products Plaintiffs and members of TFFA manufacture or sell, and results in lost sales; prevents retailers, including Plaintiffs and members of TFFA, from selling new products authorized for marketing pursuant to the process contemplated by the TCA; and disadvantages Plaintiffs by providing a competitive advantage to manufacturers and retailers who sell illicit products.

26. Venue is proper in this district under 28 U.S.C. § 1391(e) because GWT Distributing LLC d/b/a Brady's Package Store and Hometown Liquor, LLC reside in this district. Moreover, Defendants' actions have effect, and all Plaintiffs have suffered and will suffer harm, in this District.

IV. Background

A. The TCA

27. In 2009, the TCA amended the Food, Drug, and Cosmetic Act ("FD&C Act") to grant the FDA authority to regulate tobacco products that fall within the statute's ambit. 21 U.S.C. § 387a(a).

28. One of the TCA's stated purposes was to "continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers." Pub. L. No. 111-31, § 3(7) (June 22, 2009).

29. Initially, the Act applied only to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b).[3] Congress decided not to regulate all tobacco products at that time, including existing products such as cigars and pipe tobacco or other kinds of tobacco products not specifically enumerated in the statute.

30. Instead, Congress delegated further regulatory authority to the Secretary of HHS, granting the Secretary complete authority to "deem[]" "any other tobacco products" to be subject to the Act's requirements by regulation. 21 U.S.C. § 387a(b). The Secretary redelegated that authority to the FDA. *See* 2016 FDA Staff Manual Guide §§ 1410.10(1)(A)(1), 1410.21(1)(G)(1) (Aug. 26, 2016), https://bit.ly/2KGT7Ts.

31. The TCA generally provides that after 2007, any "new tobacco product" requires premarket review by the FDA. 21 U.S.C. § 387j(a)(1), (2). Congress defined a "new" tobacco product to include "any modification" to a tobacco product, including its components or parts. *Id.* § 387j(a)(1). To market a new tobacco product, a company must first obtain an order from the FDA authorizing the product to be introduced into interstate commerce.

32. Most relevant here, companies that wish to market a new tobacco product must submit a "premarket tobacco product application," or "PMTA." A PMTA must establish that marketing the product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). Congress recognized, however, that this regime puts businesses that make products—and adult consumers who purchase them—at the agency's mercy. So, the TCA put guardrails around the process to ensure that applications would not get stuck in regulatory red tape. Most importantly, the Act required the FDA to issue an order allowing a product to be introduced

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[3] The FDA has concluded that "[n]icotine pouch products ... do not meet the definition of smokeless tobacco." FDA, *Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization – Guidance for Industry* at 2 n.3.

into interstate commerce (or forbidding the product from being introduced) "[a]s promptly as possible, but ***in no event later than 180 days after the receipt of an application***." 21 U.S.C. § 387j(c)(1) (emphasis added).

B. The Premarket-Review Process for New Tobacco Products

33. A central piece of the TCA's regulatory framework is the premarket-review process for a "new tobacco product."

34. The FDA has expansively interpreted the term "new tobacco product." According to current FDA guidance, any post–February 2007 change to a tobacco product is a "modification" that renders it a new tobacco product—even a change "so minor that it is not even capable of being quantified in the finished product." *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)*, FDA, at 16 (March 2023), https://bit.ly/2IxH3RE; *see PMTA Rule*, 86 Fed. Reg. 55,300, 55,392 (Oct. 5, 2021) ("[A]ny modification to [a] tobacco product results in a new tobacco product.").

35. As a result, the FDA considers many tobacco products that have been on the market for years to be "new tobacco products." For example, if a manufacturer switches the "antimicrobial agent" found in the "paper used for [a] filter's plug wrap," that change would make the product "new" and require authorization. *Demonstrating the Substantial Equivalence*, *supra*, at 17.

36. A new tobacco product that is marketed without FDA authorization is considered "adulterated" or "misbranded." 21 U.S.C. §§ 387b(6), 387c(a)(6). Marketing adulterated or misbranded products may lead to FDA enforcement actions, including seizure of offending products, *id.* § 334, injunctions against manufacturers, distributors, and retailers, *id.* § 332, and criminal prosecution, *id.* §§ 331(a)–(c), 333(a), 335.

37. The Act's premarket-review provisions contemplate three main pathways for a manufacturer to follow to gain authorization to introduce a new tobacco product to the market.

38. *First*, the Act sets forth a process for manufacturers to obtain authorization for new tobacco products that are *not* substantially equivalent to any existing product. Under this pathway, manufacturers submit a PMTA. The PMTA must establish that marketing the product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). This is sometimes referred to as the "PMTA pathway." For PMTAs, the Act expressly requires the FDA to issue an order allowing a product to be introduced into interstate commerce (or forbidding a product from being introduced) "[a]s promptly as possible, but *in no event later than 180 days*" after the manufacturer files an application. 21 U.S.C. § 387j(c)(1) (emphasis added).

39. *Second*, the Act provides for a process under which a manufacturer may submit a substantial-equivalence "report" under Section 387e(j) demonstrating that a product *is* "substantially equivalent" to a predicate tobacco product—meaning a product that was on the market as of February 15, 2007. *See* 21 U.S.C. § 387e(j). After a manufacturer files a substantial-equivalence report ("SE Report"), the FDA must issue an order concluding that the product is (or is not) substantially equivalent to a predicate product. *Id.* § 387j(a)(2)(A)(i), (B)(ii). This is sometimes referred to as the "SE pathway."

40. *Third*, the Act provides for an even more streamlined process in situations where a product includes only a "minor modification" of a "tobacco additive" relative to a tobacco product currently on the market and an SE Report is "not necessary" to determine that marketing the tobacco product "would be appropriate for protection of the public health." 21 U.S.C. § 387e(j)(3). This is sometimes referred to as the "SE exemption pathway."

41. These statutory pathways, taken together, confirm that PMTAs are the most complex and time-consuming requests for premarket review—and Congress nevertheless expressly ordered the FDA to grant or deny those applications within 180 days.

C. The 2016 Deeming Rule

42. The TCA does not itself expressly address the e-vapor or pouch products at issue in this complaint. The Act states that it "shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b). The Act also authorizes the Secretary "by regulation" to "deem any other tobacco products" "to be subject to this chapter," *id*., meaning the Secretary may impose the TCA's premarket-review and other requirements on tobacco products beyond the four products enumerated by Congress.

43. But the Act expressly allows the FDA to make individual exceptions to tobacco standards for regulated products and to subject different products to different levels of premarket review. 21 U.S.C. § 387j(a)(2)(A), (b)(1)(D). The Act also expressly authorizes the agency to "revis[e] ... tobacco product standards" to account for a wide variety of factors including the "creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand." *Id.* § 387g(b)(2).

44. In 2016, the FDA promulgated the Deeming Rule, which subjected virtually *all* tobacco products to the TCA's premarket-review provisions. *See Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act*, 81 Fed. Reg. 28,974, 29,106 (May 10, 2016). The Deeming Rule thus swept in the universe of e-vapor products, which the FDA refers to as "electronic nicotine delivery systems" or "ENDS," as well as nicotine pouch products. *Id.* at 28,975–76.

45. Because of the Deeming Rule, there were now millions of newly regulated tobacco products, including vast numbers of e-vapor and pouch products, which meant that without enforcement discretion from the FDA the products could be forced off the market by the agency until manufacturers could submit PMTAs or SE Reports.

46. To make matters worse, seven years after the Act's passage, the Obama Administration had still not articulated what information—other than the statutory baseline—manufacturers would be required to include in PMTAs for other newly deemed products, including e-vapor and pouch products. The Deeming Rule itself cited only short "draft guidance" documents relating to e-vapor products that said the FDA would consider "issu[ing] additional guidance" later. 81 Fed. Reg. at 29,001; *see also id.* at 29,004, 29,012–13.

47. The FDA apparently had expectations for what additional information it wanted to see in these applications but failed to notify applicants when it promulgated the Deeming Rule. To avoid dealing with problems stemming from this informational mismatch and to account for the fact that the Deeming Rule required "premarket review" for products that were already on the market, the FDA established a "compliance policy." Specifically, the FDA established timetables for manufacturers of newly deemed tobacco products to submit PMTAs and SE Reports. 81 Fed. Reg. at 28,978.

48. For PMTAs, the FDA told manufacturers that they would have until August 8, 2018—24 months from the Deeming Rule's effective date—to file applications, as well as another 12 months upon the timely filing of an application before the FDA would initiate any enforcement actions "for th[ose] products remaining on the market without FDA authorization." 81 Fed. Reg. at 28,978. The FDA indicated that the compliance policy would give the agency time to establish its regulatory framework for PMTAs and SE Reports, provide manufacturers with "sufficient

time . . . to prepare high quality applications" that complied with the agency's developing requirements, and then allow for the FDA to review millions of applications for newly deemed products in just 12 months. *Id.* at 29,012.

49. As commenters pointed out at the time, the FDA's timelines were not realistic given that the agency had not even finished its guidance about what it wanted to see in PMTAs for e-vapor products or other newly deemed products. 81 Fed. Reg. at 29,012. Moreover, the FDA had prior experience with cigarettes and smokeless tobacco that showed it was plainly incapable of getting through PMTAs and SE Reports for all tobacco products as quickly as the Deeming Rule assumed. In 2011, the FDA received about 3,600 SE reports that the agency was unable to review within 180 days (or anywhere close to that statutory deadline). *See FDA Update on Provisional Substantial Equivalence (SE) Review Process*, FDA (Apr. 5, 2018), https://tinyurl.com/4zy338fc.

50. As predicted, after the Deeming Rule the FDA—even with the benefit of the expanded deadlines in the compliance policy—was unable to notify stakeholders of its review requirements or conduct application reviews in accordance with the TCA and APA.

D. The FDA's August 2017 Guidance Deferring PMTA Review and Enforcement

51. In 2017, the FDA twice extended the deadlines in the Deeming Rule to give itself more time to try to get through the massive backlog that rule created. Ultimately, the FDA's August 2017 guidance announced that the agency was extending the deadline for PMTAs for "non-combustible" tobacco products to August 8, 2022, and allowing manufacturers who timely filed applications to keep their products on the market indefinitely pending the FDA's decisions on those applications. *See Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability*, FDA, at 3–4 (Aug. 2017), https://bit.ly/3eKjk1k.

52. The FDA's resort to serial deadline extensions confirmed its inability to meet the statutory obligations it chose to assume in the Deeming Rule.

53. In May 2019, the U.S. District Court for the District of Maryland vacated the August 2017 guidance extending the compliance period for newly deemed products. *See Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 491 n.10, 494–98 (D. Md. 2019). The court entered an order providing that manufacturers of new tobacco products on the market as of the Deeming Rule's effective date (August 8, 2016) would have to file their reports or applications by September 9, 2020, and extended the enforcement safe harbor to September 9, 2021. Order, *Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-00883 (D. Md. Apr. 22, 2020), ECF No. 182; *see also Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019).

E. The FDA's 2021 PMTA Rule

54. In September 2019—after more than a decade of extreme delays in premarket review and the District of Maryland's decision invalidating the FDA's enforcement moratorium—the FDA proposed a rule to "set forth requirements related to the content and format of PMTAs" and "the procedure by which FDA would review PMTAs." *Premarket Tobacco Product Applications*, 84 Fed. Reg. 50,566, 50,567 (Sept. 25, 2019) ("Proposed Rule"). The FDA should have used this rulemaking as an opportunity to address PMTA applications in accordance with the TCA. But instead, the FDA adopted a final rule that disregarded comments, evidence, and obvious alternatives that would have facilitated that result. As a result, the final 2021 PMTA Rule made the PMTA process even more time-consuming and unwieldy than it was before.

55. The TCA enumerates six categories of required content for a PMTA, *see* 21 U.S.C. § 387j(b)(1):

a. A "full report[ ]" of all reasonably knowable information "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";

b. A "full statement" of the "components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product";

c. A "full description" of the methods, facilities, and controls used to manufacture, process, package, and install such tobacco product;

d. An "identifying reference" to any applicable FDA-promulgated tobacco product standard and "adequate information" to show that the product "fully meets" or warrants "any deviation from" that tobacco product standard;

e. "Such samples" of the tobacco product "as the Secretary may reasonably require"; and

f. Specimens of the product's labeling.

56. The TCA also provides that PMTAs must contain "such other information relevant to the subject matter of the application as the Secretary may require." 21 U.S.C. § 387j(b)(1)(G).

57. The Proposed Rule did not set forth a viable way for the FDA to timely apply the statutory-authorization criteria to the vast number of new product applications the Deeming Rule required. Instead of trying to dig out of the application backlog the FDA had created for itself, the Proposed Rule required vast amounts of additional information from applicants—well beyond the TCA's requirements, as well as the requirements for other product applications reviewed by the FDA. As one commenter summarized, the Proposed PMTA Rule contained nearly "*100 informational requirements*, significantly more than those mandated for [a prescription] drug or medical device," raising the "bar impossibly high for any ENDS product manufacturer." E-Alternative

Solutions Comment at 14 (Dec. 16, 2019), https://www.regulations.gov/comment/FDA-2019-N-2854-1098. These criteria imposed "a much more burdensome, onerous, and expensive process for each individual product." RAI Servs. Co. Comment at 10 (Dec. 16, 2019), https://www.regulations.gov/comment/FDA-2019-N-2854-1082.

58. For example, the Proposed Rule required PMTAs to include granular descriptions of "product formulation" that had little to do with any conceivable public health concern. 84 Fed. Reg. at 50,584. Manufacturers would have to explain, among many other things: whether the tobacco product included software or technology; how a container closure system (if any) is designed to protect against damage during transportation; and the product's dimensions and construction "using a diagram or schematic." *Id.* at 50,584–86.

59. The Proposed Rule also required extensive supporting materials, such as "[t]est data including test protocols," 84 Fed. Reg. at 50,644, extensive behavioral data "regarding how the product . . . will affect the tobacco use behavior of both users and nonusers of tobacco products," *id*. at 50,619, and "all studies concerning the pharmacological profile" of the product, *id*. at 50,602.

60. The FDA also proposed requiring the submission of unnecessarily detailed design-parameter information—stretching across nearly *ten* pages of the Federal Register and 30 tables. *See* 84 Fed. Reg. at 50,586–95; Tables 1–20a. For e-vapor devices, commenters explained that much of the design information requested had no "direct correlation to aerosol emission" inhaled by the user and, as such, no bearing on FDA's assessment of the devices' impact on public health. RAI Servs. Co. Comment at 18.

61. The FDA also proposed procedures for its own review of PMTAs that would *ensure* delays beyond those contemplated by the statutory text. The TCA sets forth a simple directive: The FDA must issue "an order" determining whether a tobacco product may be marketed as

"promptly as possible, but in no event later than 180 days after the *receipt* of [the] application." 21 U.S.C. § 387j(c)(1)(A) (emphasis added). Despite that statutory requirement, the FDA built in a variety of mechanisms that would allow it to avoid starting the clock in the first place or to pause the clock indefinitely.

62. Specifically, the FDA proposed that it would not start the clock until the "last piece of information necessary to complete the submission" was tendered, including product samples. 84 Fed. Reg. at 50,615. The FDA then proposed mandating that applicants submit product samples only *after* the FDA had "accepted" the application, rather than as part of an initial submission—effectively allowing the FDA to unilaterally determine when Congress's 180-day review period started. *Id.* at 50,580.

63. The FDA further proposed separating its review procedure into an "acceptance" phase, a "filing phase," and a substantive-review phase. 84 Fed. Reg. at 50,614. After an applicant submitted a PMTA, the FDA first would conduct an "initial review" to determine whether to "accept" the application. *Id.* The FDA would often refuse to accept the application on non-substantive grounds such as failure to "comply with the applicable format requirements." *Id.*

64. This "acceptance" phase alone often takes longer than the agency's 180-day statutory deadline. For example, under the 2021 Final Rule, Helix's PMTAs for certain of its *on!* flavor pouch products were submitted on September 25, 2024, but not "accepted" until August 12, 2025—321 days later. This delay is typical because the 2021 Rule requires applicants to submit a convoluted and burdensome set of administrative forms that frequently change and do not align even with the requirements of the 2021 PMTA Rule itself. For example, these forms sometimes lack the requisite fields for all products—causing the FDA to refuse to accept applications for

purely administrative reasons. Helix's PMTAs for its original *on!* PLUS pouch products, for instance, were submitted on June 24, 2024, but were refused acceptance 179 days later—on December 20, 2024—solely because the submission included a prior version of one of the FDA's administrative forms. Helix resubmitted the applications on December 23, 2024—three days after the FDA's 179-day-long "acceptance" review. This delay violates the TCA.[4]

65. The delays the 2021 Rule endorsed in violation of the TCA do not end when an application is accepted. Even for accepted PMTAs, the FDA would "conduct a filing review to determine whether the application contains sufficient information to permit a full substantive review of the application." 86 Fed. Reg. at 55,379. Based on this review, the FDA would refuse to file a PMTA if, for example, the FDA believed the PMTA lacked "adequate technical information" (such as "correct design parameters") or did not contain "substantive information regarding" broad categories of information the applicant could not have reasonably anticipated (such as citations to certain literature or investigations). *Id.* at 55,379–80. This "filing" review typically takes even longer than "acceptance" review.

66. Even after an application had been accepted and filed, the FDA would sometimes require *further* information from the applicant—including product samples that applicants offered with their initial submissions but which the FDA proposed *prohibiting* them from tendering. 84 Fed. Reg. at 50,580. The FDA would consider itself on the TCA's 180-day clock for application review only after applicants submitted product samples or any other "last piece of information necessary to complete the submission." *Id.* at 50,616.

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[4] The delay also is inconsistent with the FDA's own regulations on acceptance reviews, which are designed to make acceptance straightforward and impose only limited requirements for refusing to accept a PMTA—for example, that it is not in English, does not pertain to a tobacco product, or does not identify the type of submission. *See Refuse To Accept Procedures for Premarket Tobacco Product Submissions*, 81 Fed. Reg. 95,863 (Dec. 29, 2016).

67. As Altria—the parent company of Helix and NJOY—pointed out at the time, this procedural gimmick allowed the FDA to "indefinitely delay filing an application for review by creating an additional step between acceptance and filing." Altria Comment at 12 (Dec. 16, 2019), https://www.regulations.gov/comment/FDA-2019-N-2854-1057. Altria urged the FDA to "allow applicants to submit product samples as part of an initial PMTA" to ensure that "applications are complete as promptly as possible." *Id.*

68. Commenters raised concerns that the Proposed Rule's requirements would, if adopted, slow down the PMTA process, causing significant harm to industry and to public health. The "viability of the PMTA pathway depends on a timely review process." Altria Comment at 11; *see also* Philip Morris Comment at 18 (Dec. 16, 2019), https://www.regulations.gov/comment/FDA-2019-N-2854-1056 (explaining that the "predictability and transparency of the PMTA pathway depends on a timely review process"). Because e-vapor and pouch products help smokers transition away from combustible tobacco, delays in reviewing PMTAs for those products specifically would affirmatively *harm* public health. Accordingly, Altria explained, "all parties should work diligently towards meeting statutory and regulatory requirements with the goal of providing scientifically-demonstrated, potentially reduced-risk products to adult smokers as rapidly as possible." Altria Comment at 4.

69. But the FDA's proposed PMTA requirements—along with its significant backlog of pending PMTAs resulting from the Deeming Rule—made it impossible for the FDA to issue orders on the vast majority of PMTAs within 180 days. *See, e.g.*, Altria Comment at 12; RAI Servs. Co. Comment at 10; E-Alternative Solutions Comment at 14. In short, commenters warned, "[c]omplex and burdensome PMTA processes will impact the innovation in tobacco products and

as a consequence may delay development and introduction of new tobacco products with reduced harm potential to the U.S. market." Philip Morris Comment at 18.

70. Manufacturers of e-vapor products also told the FDA that, even if all the foregoing requirements were needed for PMTAs for combustible products (such as cigarettes), the FDA should create a streamlined pathway for e-vapor products. *See, e.g.*, Altria Comment at 4 ("FDA should continue to develop PMTA format alternatives that would reduce the burden associated with the submission and review of an application"). For example, commenters suggested that the FDA should accept PMTAs that provide "summaries of the relevant scientific literature" and "limited product-specific testing" tailored to e-vapor products. Tennessee Smokefree Ass'n Comment at 7 (Dec. 16, 2019), https://www.regulations.gov/comment/FDA-2019-N-2854-1104.

F. 2020 Deluge of PMTAs and SE Reports

71. After the FDA issued the Proposed PMTA Rule in September 2019 but before it was finalized, the District of Maryland's September 2020 deadline for submitting PMTAs caused the FDA to receive "thousands of tobacco products submissions covering *millions* of tobacco products." *Deemed Product Review: A Conversation with the Center for Tobacco Products Office of Science* ("June 11 Conversation"), FDA (June 11, 2021), Tr. at 6 (emphasis added), https://bit.ly/3jA0AUb. In total, the FDA received SE Reports for 6,800 products; SE exemption requests for 350 products; and PMTAs for *4.8 million* products (primarily e-vapor products). *See* Mitch Zeller, *Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline*, FDA (Feb. 16, 2021), https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline [hereinafter *Perspective*]. "[T]he submissions varied substantially in number of tobacco products contained in each submission, size, format and organization." *Id.*

72. This flood of reports and applications was entirely predictable, as commenters warned the FDA even before the FDA adopted the Deeming Rule in 2016. The reason was obvious: The Deeming Rule subjected millions of products that were already on the market to the FDA's complex "premarket review" process that had already resulted in massive backlogs over the preceding decade.

73. Notwithstanding this record, the FDA was totally unprepared for the tidal wave of reports and applications it received. In February 2021—nearly six years after the Deeming Rule was finalized—the FDA cited "the unprecedented number of applications" it had received and admitted that "the likelihood of FDA reviewing all the applications by *Sept. 9, 2021* is low," even though the TCA's 180-day deadline required the FDA to review the applications filed pursuant to the District of Maryland's order by *March 2021*. FDA, *Perspective: FDA's Progress on Review of Tobacco Product Applications* (May 20, 2021) (emphasis added).[5] By mid-January 2021—five months after receiving these applications, and almost halfway through the one-year period in which the FDA projected it could review *all* of them—the FDA had taken preliminary steps on PMTAs for only about 29,000 products, representing 0.6% of the PMTAs the agency received. *Id.* And although it indicated that it had "commenced substantive review on hundreds of products submitted through the PMTA pathway," the agency had not taken final action on *any* applications. *Id.* Still, the FDA cautioned regulated parties that selling unauthorized products would subject them to enforcement actions. *Id.*

74. In June 2021, the FDA admitted that "given the unprecedented number of applications"—a problem caused by the Deeming Rule—"the likelihood of FDA reviewing all of the

[5] https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline.

applications" in accordance with statutory and court deadlines was "extremely low." June 11 Conversation, Tr. at 19. Although commenters had warned the FDA of this exact problem, the FDA again simply responded that the "number of applications exceeds anything that we've ever seen by orders of magnitude" and that it has been "very challenging due to the size, complexity and diversity of these submissions." June 11 Conversation, Tr. at 8.

75. Of course, these were precisely the problems that commenters flagged *before* the FDA adopted the Deeming Rule that caused the flood of applications the FDA then failed to review in accordance with the TCA. Accordingly, they were known to the FDA in 2016 and were then greatly exacerbated by the flood of applications precipitated by the Deeming Rule. The FDA expressly acknowledged and attempted to address these problems in the discretionary enforcement relief it defended from 2017 to 2019, and commenters then highlighted the agency's inability to comply with the TCA's review deadlines in the comment record on the PMTA Rule that the FDA proposed in 2019.

G. The Final 2021 PMTA Rule

76. In the two years before the FDA finalized that rule, the agency received a total of 25,378,715 PMTAs. *PMTA Metrics for Acceptance, Filing and Review/Action Phases*, FDA (data as of Mar. 31, 2026), https://www.fda.gov/media/192290/download?attachment. By the end of those two years, the FDA had issued an order granting or denying marketing authorization—the order the TCA requires—for less than 5% of the applications (only 1,201,826). *Id.* During the same period, the FDA refused to accept 1,311,559 applications, refused to file another 5,089,883, and authorized only three new tobacco products for marketing. *Id.* Approximately 17 million PMTAs remained pending. *Id.* Accordingly, over a year after manufacturers subject to the District of Maryland's September 2020 deadline had submitted their applications, the FDA faced a far worse backlog of PMTAs than when it proposed the PMTA rule in 2019.

77. The backlog that the FDA experienced in late 2021 was a direct result of the agency's decision to "deem" new products subject to premarket review with procedures in place that ensured that the FDA could never conduct those reviews in accordance with the TCA's deadlines.

78. Nevertheless, in 2021 the FDA finalized the 2021 PMTA Rule over objections and undisputed record evidence that it would make the problem worse and result in a review process that violated the TCA's text and public health mandate. *See* 86 Fed. Reg. 55,300.

79. Instead of offering a meaningful response to these comments or conducting a proper regulatory impact analysis, the FDA simply claimed that the final 2021 PMTA Rule would "improve the efficiency of the submission and review of PMTAs." 86 Fed. Reg. at 55,301. The agency did not explain how the Rule would allow the FDA to review pending applications within the TCA's 180-day statutory deadline, particularly given the Rule's broadening of the requirements for PMTA submissions and review. Nor did the agency adopt any of commenters' alternative proposals for creating a more efficient PMTA process aligned with the statutory timeframe. The agency simply rejected these proposals, even though it published the final Rule *after* the flood of PMTAs precipitated by the District of Maryland's deadline, which should have made crystal clear to the FDA that it needed a process that was *less* cumbersome and time-consuming, not more so.

80. For example, the 2021 PMTA Rule finalized, largely without change, the proposed requirements that applicants must submit a massive amount of information about the tobacco product, including descriptive information, product formulations, design parameters, test data and protocols, and behavioral and pharmacological studies. 86 Fed. Reg. at 55,331 (behavioral studies); *id*. at 55,332–54 (product formulation requirements); *id*. 55,336 (test data and test protocols); *id*.

at 55,336–50 (design parameters); *id*. at 55,354–55 (description of typical use); *id*. at 55,363 (pharmacological studies); *see* 21 C.F.R. § 1114.7 (prescribing the "required content and format" of PMTAs). By requiring this extensive information, the FDA was mandating the submission of applications it could not review within the TCA's statutory deadline.

81. In 2021, the FDA also finalized its departure from the TCA's statutory time periods by splitting the review process into an "acceptance" phase, a "filing" phase, and a substantive-review phase. 86 Fed. Reg. at 55,379–81; *see* 21 C.F.R. § 1114.27(a)–(c). Specifically, the FDA "decline[d] to set a deadline for acceptance and filing reviews both because it would not affect the 180-day review period and because FDA wishes to retain some amount of flexibility in its review process as it gains more substantial experience in reviewing PMTAs." 86 Fed. Reg. at 55,381.

82. The FDA's Final 2021 PMTA Rule thus guaranteed the agency's departure from the TCA's express review deadlines. The Rule declared (incorrectly) that the "event that starts the 180-day review clock" under the statute "is the receipt of an application that meets the requirements of [Section 387j(b)(1) of the TCA] *which also includes information required by the rule*," such as product samples, that the statute does not even mention. 86 Fed. Reg. at 55,282 (Response 100) (emphasis added).

83. As predicted in warnings from commenters, the FDA used these extra-statutory requirements to delay product reviews in violation of the TCA. Notably, the 2021 PMTA Rule starts the statutory 180-day clock only after applicants submit product samples, which the applicants cannot submit until their application has been accepted for review and the FDA has requested the samples. 86 Fed. Reg. at 55,321; *see* Altria Comment at 12. In response to objections to this practice, the FDA reaffirmed that it would not start the 180-day statutory clock until it received such product samples and attempted to justify its decision by stating that the Rule would allow the

FDA to decide whether samples are needed and avoid the cost of submitting unnecessary samples. *Id.* But in the same breath, the FDA asserted that "an applicant should be prepared to submit" samples because the FDA "generally expects . . . samples will be required." *Id.* at 55,321. The agency therefore left it to applicants either to: (1) incur unnecessary expenses storing samples in anticipation of a request that may never occur or (2) risk delaying the FDA's review of its application should the applicant have to prepare samples after receiving a request from the FDA.

84. The Final 2021 PMTA Rule also declined to exempt from the PMTA pathway e-vapor or pouch products or to create a streamlined pathway for the authorization of such smoke-free products. 86 Fed. Reg. at 55,315. Commenters had explained that these alternatives would have greatly reduced the number of PMTAs submitted to the FDA and increased the likelihood that the FDA could meet its statutorily mandated 180-day review deadline. After all, the majority of PMTAs were for e-vapor products. *See* FDA, *Final Regulatory Impact Analysis* at 78, Deeming Rule, Docket No. FDA-2014-N-0189, *available at* https://www.fda.gov/media/97875/download. Nevertheless, the FDA rejected these alternatives based on the conclusory assertion that having "less information" would prevent the FDA from assessing the product's safety. 86 Fed. Reg. at 55,315.

85. At no point did the FDA explain how, in light of the 2021 PMTA Rule's requirements and the existing backlog of PMTAs, the agency could possibly plan to review all the PMTAs it had received (and would continue to receive) within 180 days. Instead, the FDA simply professed its intent to do so. "Within 180 days after receipt of an application," the agency declared, the "FDA intends to complete its review of a PMTA." 86 Fed. Reg. at 55,382.

H. The Final 2021 PMTA Rule's Exacerbation of the FDA's Departures from the TCA

86. As predicted, the Final 2021 PMTA Rule all but guaranteed the FDA's inability to comply with the TCA's statutory requirements for PMTA reviews.

87. One year after the FDA promulgated the Final 2021 PMTA Rule, the Inspector General for Health and Human Services found that the FDA still had a backlog of 53,128 e-vapor product applications it had received two years earlier (in September 2020). *The FDA Needs to Improve the Premarket Tobacco Application Review Process for Electronic Nicotine Delivery Systems to Protect Public Health*, HHS-OIG (Nov. 8, 2023), https://oig.hhs.gov/reports/all/2023/the-food-and-drug-administration-needs-to-improve-the-premarket-tobacco-application-review-process-for-electronic-nicotine-delivery-systems-to-protect-public-health/. Moreover, the FDA still routinely took longer than the statutory 180-day review period to issue an order. *Id.* (noting that the FDA "had outlined a timeline to meet the 180-day deadline" but "it encountered delays and was unable to comply"); *see also*, *e.g.*, Reagan-Udall Foundation, *Operational Evaluation of Certain Components of FDA's Tobacco Program* at 3 (Dec. 2022), https://tinyurl.com/yeywhmy6 (finding that FDA has "struggled to function as a regulator in part due to some of its policy choices," including the "scope of the product review regulations" that "have been difficult for both stakeholders and [the agency] to apply in practice").

88. An independent government audit confirmed that the FDA's PMTA process made it virtually impossible to comply with the TCA's review deadlines and that the FDA had chosen to calculate the deadline in ways that rendered this important statutory provision meaningless. As the audit explained, the FDA had broken its review process into three discrete phases after receiving a PMTA: "Phase 1" is "[a]cceptance," "Phase 2" is "[f]iling," and "Phase 3" is "[s]ubstantive [r]eview." HHS-OIG, *The FDA Needs to Improve* at 5. But the FDA was not starting the TCA's

180-day clock when it received a PMTA that contained the information in Section 387j(b), as the statute requires. The FDA apparently also was not starting its 180-day clock when it received the purported last piece of required information in an application, as the 2021 PMTA Rule promised. *See supra*, at 26-27. Instead, the FDA "decided to start the 180-day statutory deadline once a PMTA started phase 3 of the review process." HHS-OIG*, The FDA Needs to Improve* at 10. The FDA played fast and loose with the statutory deadline "because [it] received PMTAs for millions of products within a short period of time and reviewing those within the 180-day timeframe was believed to be almost impossible," *id.*, exactly as commenters had warned *before* the FDA finalized the PMTA Rule in 2021, *see supra*, at 21-22.[6]

89. Even under the FDA's own view of when its 180-day review period began, it was unable to comply with the statutory deadline. As the audit found, the FDA took nearly triple the statutory time period to authorize just over a dozen products. For the 15 tobacco products that were authorized, the FDA "took from 483 to 633 days to conduct" its substantive review alone, *after* the additional time the agency initially took to accept and file the applications. HHS-OIG, *The FDA Needs to Improve* at 15.

90. The complexity of the product reviews the 2021 PMTA Rule requires persists to this day. At the FDA's February 10, 2026 *Roundtable on Premarket Tobacco Application Submissions for Electronic Nicotine Delivery Systems Products*, agency scientific staff detailed the many distinct layers of review to which each ENDS PMTA is subject under the 2021 Rule—

[6] Apparently recognizing that it had utterly failed to live up to its own commitments in the 2021 PMTA Rule, the FDA "began tracking the 180-day requirement when the PMTA entered acceptance review" for "PMTAs received after [the government] audit period." HHS-OIG, *The FDA Needs to Improve* at 15 n.17.

including exhaustive product characterization (design specifications, ingredients, harmful and potentially harmful constituents, and stability testing), validation and verification of analytical test methods, extractables and leachables studies, complete manufacturing and quality-system documentation, clinical pharmacokinetic studies of abuse liability, product-specific evidence of adult benefit for flavored products, and multi-tiered toxicological risk assessments, including excess lifetime cancer risk calculations. This multidisciplinary review—spanning chemistry, engineering, pharmacology, toxicology, and epidemiology—confirms both the breadth of information the Rule demands of applicants and the corresponding burden the Final 2021 PMTA Rule imposes on agency reviewers, which the agency cannot discharge within the TCA's 180-day deadline.

91. As of March 2026—the last date for which the FDA has reported data—the FDA still faced a massive backlog of about 130,000 PMTAs. *See* FDA, *PMTA Metrics* (Mar. 31, 2026) https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting.[7] Among that backlog are Helix's applications for *on!* pouches, which were submitted on May 15, 2020 and have been pending for more than 2,270 days.

I. The 2021 Rule's Facilitation of Foreign Illicit Sales to U.S. Consumers

92. The 2021 PMTA Rule's process for reviewing new product applications violates several express provisions of the Act and harms public health by depriving adult consumers of access to regulated alternatives to cigarettes, including new versions of Helix pouch products that are made in the United States and are substantially similar to the few products FDA has authorized for marketing.

[7] Specifically, the FDA has not acted on 130,900 PMTAs. That number is calculated by adding up all of the "applications received" by the FDA from October 2019 through March 2026, and subtracting from that number all of the FDA's decisions in that same time period refusing to accept, refusing to file, granting marketing authorization, or denying marketing authorization, as well as the applications that were withdrawn or closed.

93. To make matters worse, while Helix, NJOY, and many other companies waited for the FDA to act on their PMTAs, others—including many Chinese manufacturers—have been selling products without FDA review by using foreign labor to produce vaping devices and pouches for U.S. sale through black-market channels. The FDA's delays thus created precisely the illicit market for foreign-made products the TCA identifies in other contexts as a factor for setting or revising tobacco product standards and harmed both Plaintiffs and American consumers. The FDA's June 2026 proposed rule directly acknowledges this harm. As the proposed rule explains, the lack of registration and listing requirements for foreign-owned or -operated tobacco product establishments creates gaps that prevent the agency from identifying non-compliant products—including unauthorized ENDS—distributed or imported into the United States. 91 Fed. Reg. at 39,168-69.

J. The FDA Has Not Timely Acted on Several Helix and NJOY Applications

94. Plaintiffs Helix and NJOY have experienced first-hand how the FDA's failure to adopt a process that complies with the TCA's 180-day statutory deadline leaves products in regulatory limbo for too long.

95. Helix and NJOY have submitted PMTAs for various pouch and e-vapor products both before and after the FDA finalized its 2021 PMTA Rule. As discussed above, Helix and NJOY's pouch and e-vapor products protect the public health. For example, the FDA agrees that "nicotine pouches generally belong toward the lowest end of the continuum of risk of tobacco products" and "can support behavioral change (e.g., product substitution)," by encouraging users of combustible products to switch to nicotine pouches over time. *Technical Project Lead (TPL) Review of Nicotine Pouch PMTAs*, FDA, at 4, 16, 20-21 (Dec. 19, 2025), https://www.accessdata.fda.gov/static/searchtobacco/helix/Multiple-STNs-TPL-Review-HelInn-Dec-2024-B1-Redacted.pdf. And the FDA previously authorized several NJOY e-cigarette products because

they were "appropriate for the protection of the public health." FDA Press Release, *FDA Issues Marketing Decisions on NJOY Ace E-Cigarette Products* (Apr. 26, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-njoy-ace-e-cigarette-products. As the agency noted, people who use only the NJOY products have "lower levels of exposure to [harmful and potentially harmful constituents] compared to" those who use cigarettes. *Id*. Helix and NJOY also undertake specific measures to restrict youth access to their products. *Id.* As a result, the FDA concluded that "the potential benefit to adult smokers who switch completely or significantly reduce their cigarette use" "outweigh[ed] the risk to youth." *Id*.

96. Yet the FDA has not taken the statutorily required action (a Marketing Granted Order or Marketing Denial Order) on any of Helix and NJOY's PMTAs within the TCA's 180-day deadline. To the contrary, every marketing granted order the FDA has issued on Helix's and NJOY's applications came between 361 and 1,564 days after submission—for NJOY's ACE and DAILY e-vapor products (777 to 1,564 days after submission), the Verve product (1,184 days), and certain of Helix's *on!* flavor (678 days) and *on!* PLUS (361 days) pouch products—two to nearly nine times the TCA's 180-day limit. That delay was a product of the 2021 PMTA Rule: The applications had to include thousands of pages of documentation and information to meet the FDA's requirements. Five examples illustrate the problem, which has affected several products Helix and NJOY recently asked the agency to list as non-priorities for enforcement if they are marketed while their PMTAs remain pending. Helix and NJOY made those requests consistent with the enforcement-priority framework the FDA set out in its May 2026 Guidance.

97. *First*, on May 15, 2020, Helix submitted 45 PMTAs for its original *on!* pouch products. All those applications have been pending for more than 2,270 days and remain pending *to this day*.

98. *Second*, Helix subsequently created newer versions of those pouch products called *on!* PLUS. On June 24, 2024, Helix submitted PMTAs for 6-mg, 9-mg, and 12-mg *on!* PLUS nicotine pouches in mint, tobacco, and wintergreen flavors. Helix resubmitted PMTAs for all of those products on December 23, 2024. FDA's statutory deadline to act on those applications was no later than June 21, 2025. In late 2025, the agency (tardily) authorized Helix's PMTAs for the 6-mg and 9-mg strengths. But the agency has still failed, more than one year after its statutory deadline lapsed, to issue an order granting or denying the 12-mg strength products as the TCA requires—despite these products being in the "expedited review pilot program" that the FDA predicted would result in decisions by December 2025.

99. *Third*, in September 2024, Helix submitted nine PMTAs for additional *on!* pouch products in 2-mg, 4-mg, and 8-mg varieties for three flavors. On August 4, 2026—678 days later—the FDA authorized Helix's PMTAs for three flavors in 2-mg strength and three flavors in 4-mg strength. The remaining PMTAs remain pending.

100. *Fourth*, on November 18, 2025, Helix submitted PMTAs for six additional *on!* PLUS flavors, including some in the 6-mg and 9-mg strengths that the FDA authorized in mint, tobacco and wintergreen flavors. The FDA's deadline to act on those applications was May 17, 2026. But the FDA still has not issued any orders.

101. *Fifth*, NJOY submitted supplemental PMTAs for its ACE e-vapor device and NJOY ACE pods on November 19, 2025. The FDA's deadline to act on these applications was May 18, 2026, but it still has not issued orders on these products. Moreover, even measured from NJOY's February 11, 2026 resubmission of the application for the ACE device, the FDA's deadline to act was no later than August 10, 2026. That deadline, too, has passed without any order.

102. For all five of these product categories, the FDA's review of Helix's and NJOY's products under the PMTA Rule has violated the TCA while illicit trade in unauthorized competing products continues to grow.

K. The D.C. Circuit's January 2025 Decision in *Cigar Association v. FDA*

103. In January 2025 the D.C. Circuit validated the problems with the FDA's premarket regulatory regime that have caused many of the statutory violations and associated injuries Plaintiffs allege in this suit. *See Cigar Ass'n of Am. v. FDA*, 132 F.4th 535 (D.C. Cir. 2025). It affirmed a district court's decision holding that the FDA acted arbitrarily and capriciously in violation of the APA when it adopted the Deeming Rule without a proposed carve-out for premium cigars despite evidence that these products posed different health questions than many other deemed products. *Id*. at 540-41. On this record, the D.C. Circuit agreed that the FDA unlawfully disregarded evidence that premium cigars should not be subject to TCA regulation at all. *Id*.

104. A similar analysis applies to the smoke-free products and record addressed in this suit. The FDA has repeatedly recognized that certain regulated pouch and other smoke-free products can reduce health risks associated with adult use of combustible tobacco products, and health risks associated with adult and youth usage of illicit smoke-free products. *See, e.g.*, FDA Press Release, *FDA Authorizes 6 Nicotine Pouch Products, Completing Review in Record Time* (Dec. 19, 2025), https://tinyurl.com/43982dv2 (acknowledging that nicotine pouches are "lower-risk alternative tobacco product[s]"). Yet the PMTA Rule failed adequately to address these product differences or associated statutory options for expedited review of different product categories before it was finalized in 2021, which has since caused the FDA to commit further violations of the TCA including with respect to its untimely review of several of Helix's and NJOY's product applications.

L. The FDA's 2025 Pilot Program to Streamline Review of Certain Products and May 2026 Guidance

105. In late 2025, the FDA correctly recognized that its premarket-review process was delaying new product reviews in violation of the TCA's timing and public health goals. The FDA adopted a pilot program to fast track review of certain products, including some new Helix nicotine pouches.

106. Specifically, in September 2025, the FDA launched a pilot program that aimed to "increase efficiency and streamline the review process" for PMTAs "for nicotine pouch products." FDA Press Release, *FDA Launches Program To More Efficiently Review Nicotine Pouch Applications* (Sept. 18, 2025), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-launches-program-more-efficiently-review-nicotine-pouch-applications. The FDA explained that the pilot program would "feature increased real-time communication between FDA and applicants with the goal of providing more frequent feedback and shorter review timeframes." *Id.*

107. The pilot program got off to a promising start. In December 2025, the FDA authorized six Helix *on!* PLUS pouch products for marketing. *See* FDA, *FDA Authorizes 6 Nicotine Pouch Products, supra*. Those authorized products are 6- or 9-milligram pouches in mint, tobacco, and wintergreen flavors. *Id.* The FDA explained that these products contain "lower levels of most harmful and potentially harmful constituents" compared to other tobacco products and have the "potential to provide a benefit to adults who smoke cigarettes and/or use other smokeless tobacco products that is sufficient to outweigh the risks of the products, including to youth." *Id.*

108. More broadly, by May 2026, the FDA announced that, for the "first time in years," there was no "queue for applications pending Acceptance Review." CTP Acting Director Statement, *New Steps Forward in Accelerating Innovation and Efficiency in Product Review*, FDA

(May 7, 2026), https://www.fda.gov/tobacco-products/ctp-newsroom/ctp-acting-director-statement-new-steps-forward-accelerating-innovation-and-efficiency-product.

109. But the pilot program's limited progress only confirmed the need for permanent, structural regulatory changes to fix the problems that the 2021 PMTA Rule codified and exacerbated. Indeed, the FDA touted the 361 days it took to authorize Helix's *on!* PLUS pouch products in December 2025 as "completing review in record time," suggesting that the agency's fastest authorization decision in history required *double* the time Congress mandated. FDA, *FDA Authorizes 6 Nicotine Pouch Products, supra*. Several of Helix's and NJOY's products that were put in the pilot program in December 2025 are still languishing in FDA review, well past the TCA's 180-day deadline. *See supra*, at 33. In May 2026, the FDA stated that "[n]o additional products will be added to the nicotine pouch pilot," and did not transform the pilot into a full-scale program. CTP Acting Director Statement, *New Steps Forward*, *supra*. Accordingly, although the FDA had eliminated the queue for *accepting* PMTAs during the pilot program, it has been discontinued and the FDA is back to imposing unlawful delays in *reviewing* PMTAs. *Id.*

110. In May 2026, the FDA again recognized the statutory and other problems with the backlog of applications the 2021 PMTA Rule created, particularly for new smoke-free products, and issued guidance for de-prioritizing enforcement action against products in certain categories. *See* 91 Fed. Reg. 25,892; FDA, *Guidance for Industry*, *supra*. But the FDA's discretionary enforcement moratoria on certain (thus far unidentified) products is no substitute for the decisions that the TCA requires the FDA to make within 180 days. The May 2026 Guidance confirms the point: the FDA issued it as a statement of the agency's enforcement policies that remains subject to public comment and potential agency reconsideration, not as the final marketing decisions the TCA commands on the authorization or denial of specific applications for specific products.

111. Meanwhile, the FDA's 2025 Pilot Program for fast-track authorization of certain pouch products has expired, illicit trade in unregulated smoke-free products continues, and Helix's and NJOY's competing products and applications remain mired in the same unlawful PMTA Rule process that created the problems the FDA's May 2026 Guidance expressly cites. The FDA's June 2026 proposed rule to extend establishment registration and product listing to foreign tobacco product manufacturers confirms that the current domestic-only system leaves the agency blind to the foreign establishments driving much of the illicit market. But subjecting these products to FDA review will simply result in more applications the agency cannot review in compliance with the TCA's deadlines unless the 2021 Rule is vacated and replaced with a workable process for assessing new tobacco products under the statute. *See* 91 Fed. Reg. 39,168.

112. The FDA's pilot program, the Administration's focus on more efficiently evaluating PMTAs, and the May 2026 Guidance all underscore that the FDA is not currently able to review new product applications in accordance with the TCA, and that this problem will persist until the 2021 PMTA Rule is vacated and replaced with a compliant review process.

Count One:

The 2021 PMTA Rule Exceeds the FDA's Statutory Authority and Is Contrary to Law in Violation of 5 U.S.C. § 706(2)(A), (C)

113. Plaintiffs incorporate by reference the allegations of paragraphs 1–112.

114. Under the APA, courts shall hold unlawful and set aside agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (C).

115. The PMTA Rule exceeds the FDA's statutory authority and is contrary to law.

116. For example, and without limitation, the TCA requires the FDA to issue an authorization or denial order "in no event later than 180 days after the *receipt* of an application." 21 U.S.C. § 387j(c)(1)(A) (emphasis added). The ordinary meaning of "receipt" is the "act of receiving something" or the "fact of being received." *Receipt*, Am. Heritage Dictionary 1032 (1991). The ordinary meaning of "receive" is "[t]o take or acquire," or to "acquire knowledge of or information about." *Receive*, Am. Heritage Dictionary 1032. The TCA's 180-day deadline therefore begins when the FDA receives a company's application, not at some later date.

117. Further, the TCA expressly states that the clock starts to run on the date the FDA receives an application that contains the information in Section 387j(b)(1) of the Act. Under the PMTA Rule, however, the 180-day review period typically does not begin until the FDA receives the purported "last piece" of information the FDA may decide to request long after it receives an application that complies with Section 387j. 86 Fed. Reg. at 55,382 (Response 100); *see* 21 C.F.R. § 1114.27(c)(1) (providing that FDA will complete its review of the PMTA and act on the application "within 180 days of receipt of an application . . . meeting the filing requirements set out in" FDA regulations). Because the FDA controls the timing of these information requests, the PMTA Rule effectively nullifies the TCA's 180-day deadline. For example, the PMTA Rule prohibits applicants from submitting product samples with an application. The FDA decides whether product samples are required only *after* it has conducted an initial review and accepted an application. In the FDA's words, "product samples are likely to be required after application acceptance." 86 Fed. Reg. at 55,382. So in practice, the 180-day statutory "review period would typically begin, at the earliest, when FDA receives product samples." *Id.* "Similarly, if an application is missing other pieces of required information, the review period would begin only upon receipt of that information." *Id.*

118. The PMTA Rule therefore exceeds the FDA's statutory authority and is contrary to law, in violation of the plain language of the APA and the TCA's express mandate that the FDA issue orders on marketing applications "[a]s promptly as possible, but ***in no event later than 180 days after the receipt of an application***." 21 U.S.C. § 387j(c)(1)(A).

119. In light of these statutory violations and precedents holding that the FDA cannot cure them merely by exercising enforcement discretion, the Court should vacate the PMTA Rule. *See* 86 Fed. Reg. 55,300 (codified at 21 C.F.R. §§ 1114.1–.49). If agency action is unlawful, the court "*shall* . . . hold unlawful and set aside" that action. 5 U.S.C. § 706(2) (emphasis added); *see Tex. Med. Ass'n v. HHS*, 110 F.4th 762, 780 (5th Cir. 2024) (under the APA, "universal vacatur" is "required").

120. The Court also should remand for the FDA to adopt a new process for reviewing applications for tobacco product marketing that is consistent with the TCA's 180-day deadline, considers the TCA's authorization of exemptions and expedited review pathways to ensure compliance with the deadline, and considers illicit demand as a relevant factor.

121. The Court should also enjoin the FDA from enforcing the TCA, including its premarket-review requirements, against products for which Helix and NJOY have had a pending application for more than 180 days. This "additional equitable relief is warranted and necessary to grant [Plaintiffs] a complete remedy." *Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d 256, 281 (D.D.C. 2020), *aff'd*, 5 F.4th 68 (D.C. Cir. 2021) (enjoining the FDA from "enforcing the premarket review requirement" against certain tobacco products after finding that an FDA rule arbitrarily failed to create a streamlined SE review process for those products); *see also, e.g.*, *Coal. for Gov't Procurement v. Fed. Prison Indus., Inc.*, 365 F.3d 435, 460 (6th Cir. 2004) (explaining that courts "may craft declaratory and injunctive relief designed to preclude a federal agency from

acting in contravention of its statutory and regulatory authority" and "require an agency to modify its current or future practices in order to account for past violations of its statutes or regulations"). This additional equitable relief also serves the public interest because Helix's and NJOY's first-generation e-vapor and pouch products are among the few products FDA has authorized as appropriate for the protection of public health. *See supra*, at 31–32; *see also* Order at 24, *C Store Depot, Inc. v. FDA*, No. 26-cv-483 (M.D. Fla. June 8, 2026) (concluding that permitting plaintiffs to sell pouch products pending litigation against PMTA Rule "will not pose significant harm to the public interest").

Count Two:

The 2021 PMTA Rule Is Arbitrary and Capricious in Violation of 5 U.S.C. § 706(2)(A)

122. Plaintiffs incorporate by reference the allegations of paragraphs 1–112.

123. Under the APA, courts shall hold unlawful and set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

124. For example, and without limitation, the PMTA Rule is arbitrary and capricious in at least five ways.

125. *First*, even if the FDA's interpretation of "receipt" were permissible under the statute, the FDA was arbitrary and capricious in deciding to start the statutorily mandated 180-day review period long after the FDA "receives" an application. An agency's "approach" cannot be "inconsistent with the intent of Congress," *Tex. Power & Light Co. v. FCC*, 784 F.2d 1265, 1272 (5th Cir. 1986), and cannot create the very problem "that Congress sought to avoid," *Tex. Oil & Gas Ass'n v. EPA*, 161 F.3d 923, 939 (5th Cir. 1998) (rejecting arguments that would recreate the "administrative headache[s]" Congress remedied).

126. Here, the FDA's review process routinely results in the FDA starting the 180-day clock long after the FDA receives a PMTA and incentivizes the agency to ask for more information to delay the start of the 180-day period. As a result, the FDA routinely takes longer than 180 days to grant or deny a PMTA. That is inconsistent with the purpose of the TCA's mandate to act on PMTAs "in no event later than" 180 days after the FDA receives an application. 21 U.S.C. § 387j(c)(1)(A). It is also inconsistent with Congress's directive to "promulgate regulations for the *efficient* enforcement of" the TCA. *Id.* § 371(a) (emphasis added).

127. The FDA's attempt to justify its decision relied on internally inconsistent reasoning. The FDA stated that the PMTA Rule would allow the FDA to decide whether product samples are needed and avoid the cost to applicants of submitting unnecessary samples. 86 Fed. Reg. at 55,321. But in the same Rule, the FDA asserted that "an applicant should be prepared to submit" samples because the FDA "generally expects . . . samples will be required." *Id.* Such "[u]nexplained inconsistenc[ies]" make an agency's decision arbitrary and capricious. *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005); *see also Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) (similar).

128. Further, it was unreasonable for the FDA not to start the 180-day review period until it received the samples. Commenters suggested that the PMTA Rule start the 180-day review period when an application is complete except for the samples, or that the FDA permit applicants to submit samples with initial PMTAs to avoid delays. But the PMTA Rule rejected these alternatives and left it to applicants either to incur unnecessary expenses storing samples in anticipation of a request that might never occur, or to risk delaying review of their applications in the event they received a request for samples they would then have to manufacture or otherwise prepare.

129. *Second*, the administrative record confirms that the PMTA Rule fails to reasonably account for the TCA's express 180-day deadline or to provide a "reasoned response" to commenters who explained that the Rule was inconsistent with that deadline. *Ohio v. EPA*, 603 U.S. 279, 294–95 (2024). In this respect, too, the PMTA Rule is contrary to law and arbitrary and capricious.

130. When the FDA proposed the PMTA Rule, commenters warned that the proposal would not allow the agency to review PMTAs in accordance with the TCA's timeline and other directives. *See, e.g.*, Altria Comment at 12; RAI Servs. Co. Comment at 10; E-Alternative Solutions Comment at 14. These comments became even more important by the time the FDA finalized the PMTA Rule, because the agency was facing a new backlog of millions of pending PMTA applications due to a recent court order invalidating its 2017 guidance for reviewing the vast number of new tobacco products it "deemed" subject to TCA review in 2016.

131. But the FDA disregarded these comments and the record, and finalized a PMTA Rule that made the situation worse. The FDA never grappled with the obvious consequences of those choices on its ability to review applications in the statutory timeline, and the FDA's new rule made it even more difficult to comply with Congress's directive. Although the FDA gave lip service to its statutory obligation "to complete its review of a PMTA" and act "[w]ithin 180 days after receipt of an application," 86 Fed. Reg. at 55,382 (Response 99), the FDA failed to provide a reasoned explanation for how it could possibly do that in light of the backlog it faced and the unnecessarily cumbersome procedures it had just piled on top of an already unworkable process.

132. *Third*, the FDA failed to consider reasonable alternatives or provide a reasoned explanation for rejecting alternatives proposed by commenters. *See Spirit Airlines, Inc. v. DOT*, 997 F.3d 1247, 1255 (D.C. Cir. 2021) ("[T]he failure of an agency to consider obvious alternatives has led uniformly to reversal." (quotation marks omitted)); *Am. Radio Relay League, Inc. v. FCC*,

524 F.3d 227, 242 (D.C. Cir. 2008) (holding unlawful agency action where agency did not "consider responsible alternatives to its chosen policy and . . . give a reasoned explanation for its rejection of such alternatives" (quotation marks omitted)).

133. For example, commenters urged the FDA to exempt smoke-free products from PMTA review or create "a streamlined pathway" for them. 86 Fed. Reg. at 55,315 (Comment 15); *see, e.g.*, Altria Comment at 4 ("FDA should continue to develop PMTA format alternatives that would reduce the burden associated with the submission and review of an application" (quotation marks omitted)). These commenters explained that because smoke-free products "do not contain tobacco *per se* and are not combusted, they expose users to fewer chemicals of concern." Tennessee Smokefree Ass'n Comment at 7–8. Accordingly, these commenters suggested that the FDA should accept PMTAs that provide "summaries of the relevant scientific literature" and "limited product-specific testing" tailored to smoke-free products, rather than full-blown studies and testing that the FDA proposed to require. *Id.* at 7.

134. The FDA rejected these proposals because they would purportedly "result in FDA having insufficient information to make its statutorily required determinations under" the TCA. 86 Fed. Reg. at 55,315. But beyond that conclusory explanation, the FDA never justified its approach or considered all of the factors the APA says it must. The FDA did not explain why every piece of information that would be included in PMTAs for smoke-free products was the absolute minimum amount of information *required* to determine whether those products would "be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). "Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decision-making." *Texas v. Biden*, 10 F.4th 538, 555 (5th Cir. 2021) (quotation marks omitted); *see also, e.g.*, *Texas v. Becerra*, 575 F. Supp. 3d 701, 723 (N.D. Tex. 2021) (concluding that agency

rule adopting "'one-size-fits-all' solution" to complex problem was arbitrary and capricious); *Cigar Ass'n of Am.*, 480 F. Supp. 3d at 278 (concluding that the FDA "failed to meaningfully respond" to comments proposing a "streamlined premarket review scheme for premium cigars").

135. At a minimum, the FDA could have exempted new smoke-free products from the PMTA pathway until the FDA had cleared out its backlog of already pending PMTAs—but the agency failed to consider that alternative. When the FDA promulgated the PMTA Rule, it faced a backlog of millions of pending PMTAs that the agency could not possibly review within the TCA's 180-day deadline. The PMTA Rule could have exempted many new tobacco products from the full PMTA review it imposed—and, correspondingly, allowed them to be marketed lawfully—until the FDA was ready to act on their applications within the required 180 days. But the FDA did not meaningfully consider that (or other) "viable and obvious alternatives." *Clarke v. CFTC*, 74 F.4th 627, 641 (5th Cir. 2023) (quotation marks omitted).

136. *Fourth*, the FDA's application of the PMTA Rule to Helix's and NJOY's next-generation pouch and other smoke-free products failed to account for material differences among new tobacco products or less burdensome statutory alternatives for marketing authorization that would advance American public health and adhere to statutory deadlines. Reasonable alternatives were available in 2021, including product-category-specific standards, a streamlined PMTA pathway for non-combustible products similar to those the FDA already authorized, staged effective dates of agency rules tied to statutory review deadlines, a safe harbor for timely applications that remain pending, expedited procedures for modifications to authorized products, and standardized templates, cross-references, and sample protocols for specific product categories.

137. The TCA's focus on evolving data about public health and general principles of reasoned decisionmaking required the FDA to consider the public-health benefits of smoke-free

tobacco products when deciding whether to adopt any of the foregoing alternatives. The Act states that the "Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data." 21 U.S.C. § 387g(a)(5). And it requires the Secretary to consider the "effects of" current "tobacco product standard[s] on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand." *Id.* § 387g(b)(2). Although these provisions deal with tobacco product standards, they confirm that scientific evidence about the public-health benefits and use of specific products are important aspects generally when the FDA makes decisions.

138. *Fifth*, the FDA did not reasonably address the economic costs of the PMTA Rule. In the PMTA Rule's regulatory impact analysis, the FDA "attribute[d] any costs that result from the requirement to prepare and submit PMTAs for deemed new tobacco products to the Deeming Final Rule and not this rule." FDA, *Final Regulatory Impact Analysis* at 12, Dkt. No. FDA-2019-N-2854 (Oct. 5, 2021), https://www.fda.gov/media/152622/download?attachment. But the Deeming Rule in 2016 could not—and did not—analyze the costs of the new PMTA Rule the FDA promulgated years later, *after* the Deeming Rule resulted in what FDA itself described as an unprecedented backlog of applications. Indeed, the FDA explained in the Deeming Rule's regulatory impact analysis that in 2016, the agency was "*unable* to quantify the costs [of that rule] for novel tobacco products"—a catchall term for tobacco products other than cigarettes, cigars, pipe tobacco, and waterpipe tobacco—"other than ENDS due to lack of data." FDA, *Final Regulatory Impact Analysis of Deeming Rule* at 76, Dkt. No. FDA-2014-N-0189 (May 2016), https://www.regulations.gov/document/FDA-2014-N-0189-83196 (emphasis added); *see also id.* at 115 (similar).

139. The data now exists and shows that particularly for pouch products, the regulatory impact of the FDA's PMTA Rule vastly exceeded any possible benefit, and the Rule affirmatively harms Plaintiffs and other U.S. businesses as well as American public health. Accordingly, and because "the FDA improperly attributed costs derived from the PMTA Rule to the Deeming Rule even though the PMTA rule created new cost burdens," the FDA failed adequately to analyze the costs the PMTA Rule imposed on regulated businesses. Order at 16, *C Store Depot*, *supra*; *see Nat'l Tel. Co-Op Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009) (a "regulatory flexibility analysis is, for APA purposes, part of an agency's explanation for its rule"). The PMTA Rule is arbitrary and capricious for this reason as well.

140. *Sixth*, the FDA acted arbitrarily and capriciously by failing to consider and allow for comment on the comparative-efficacy test it was developing prior to promulgating the final PMTA Rule. In 2020, the FDA internally developed a comparative-efficacy test for flavored vapes to determine whether a given flavor was more effective than others at helping smokers stop using combustible cigarettes. The Fifth Circuit held that the comparative-efficiency standard must be imposed, if at all, through notice and comment rulemaking, yet the FDA did not include the comparative-efficacy test in the text of the PMTA Rule. Instead, the agency "us[ed] informal adjudication to promulgate a substantive rule." In doing so, the FDA improperly "sidestepped the notice-and-comment rulemaking requirement of the APA." *NicQuid, L.L.C. v. FDA*, 2026 WL 2425806, at *6 (5th Cir. Aug. 19, 2026).

141. For any or all of the foregoing reasons, the Court should vacate the PMTA Rule. If agency action is unlawful, the court "*shall* . . . hold unlawful and set aside" that action. 5 U.S.C. § 706(2) (emphasis added); *see Tex. Med. Ass'n*, 110 F.4th at 780.

142. The Court should thus vacate the 2021 PMTA Rule and also remand for the FDA to adopt a new process for reviewing new tobacco products that: (i) respects the TCA's requirement to decide even the most complex PMTAs within 180 days; (ii) properly considers the more streamlined authorization pathways the statute authorizes for new products with health profiles or history that support expedited review, such as the substantial-equivalence pathway and the substantial-equivalence exemption pathway; and (iii) considers all relevant factors, including illicit market development, in promulgating revised review processes.

143. The Court should also enjoin the FDA from enforcing the TCA, including its premarket-review requirements, against products for which Helix and NJOY have a pending PMTA for more than 180 days. *See Cigar Ass'n of Am.*, 480 F. Supp. 3d at 281. This additional equitable relief also serves the public interest because—as the FDA concedes—Helix's and NJOY's e-vapor and pouch products are appropriate for the protection of public health. *See supra*, at 31–32.

Prayer for Relief

144. The Court should enter an order and judgment:

a. Declaring that the 2021 PMTA Rule is unlawful;

b. Vacating and setting aside the 2021 PMTA Rule;

c. Remanding and ordering the FDA to adopt a new rule or process for TCA reviews that accords with statutory deadlines;

d. Issuing all other process necessary and appropriate to postpone further implementation of the 2021 PMTA Rule pending the conclusion of this case, including but not limited to a stay pending final judgment, *see* 5 U.S.C. § 705;

e. Granting preliminary and permanent injunctive relief preventing the FDA from enforcing the TCA, including its premarket-review requirements, against Helix's and NJOY's products that are subject to a pending PMTA for more than 180 days;

f. Awarding Plaintiffs their reasonable costs, including attorneys' fees, incurred in bringing this action under 28 U.S.C. § 2412 or other applicable law; and

g. Granting such other and further relief as this Court deems just and proper.

Dated: September 2, 2026

Respectfully submitted,

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