[DO NOT PUBLISH]

In the United States Court of Appeals

For the Eleventh Circuit

No. 21-13088

Non-Argument Calendar

SWISHER INTERNATIONAL, INC.,

Plaintiff-Appellant,

versus

UNITED STATES FOOD AND DRUG ADMINISTRATION,
ACTING COMMISSIONER OF FOOD AND DRUGS,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida
D.C. Docket No. 3:21-cv-00764-BJD-JBT

Before JORDAN, ROSENBAUM, and NEWSOM, Circuit Judges.

PER CURIAM:

This appeal of the denial of preliminary injunctive relief arises out of the U.S. Food and Drug Administration's ("FDA") decision in 2016 to include cigars, pipe tobacco, and electronic nicotine delivery systems (e-cigarettes) among the tobacco products subject to the regulatory framework of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009). As a result of that decision, nearly all tobacco products must receive FDA approval before being marketed. The premarket review requirements were deferred for a time for products that were already on the market at the time of the 2016 decision, but enforcement is now at the discretion of the FDA.

Appellant Swisher International, Inc., which manufactures and sells cigar products, argues that it will suffer irreparable harm without an injunction preventing the FDA from pursuing enforcement against it pending the resolution of its lawsuit, which challenges the validity of the 2016 decision and the FDA's failure to act on its timely submitted applications for FDA approval. The district

court denied a preliminary injunction, finding that the FDA was not likely to pursue enforcement related to Swisher's existing products while its applications remained pending. Because the district court did not abuse its discretion, we affirm.

I.

In 2009, Congress enacted the Tobacco Control Act, which established a comprehensive framework for the FDA to regulate "[t]obacco products." 21 U.S.C. § 387a(a); *see id.* § 321(rr)(1) (defining "tobacco product"). The Act applied to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the [FDA] by regulation deems to be subject to this subchapter." *Id.* § 387a(b).

In 2016, the FDA issued a rule deeming all products that meet the statutory definition of "tobacco product" (other than accessories of such products), including cigars, pipe tobacco, and e-cigarettes, subject to the Tobacco Control Act. Food and Drug Administration, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act*, 81 Fed. Reg. 28,973, 28,975, 28,982 (May 10, 2016) (codified at 21 C.F.R. §§ 1100, 1140 & 1143). We refer to this decision as the Deeming Rule.

As relevant here, the Tobacco Control Act requires manufacturers to obtain FDA authorization before marketing "new tobacco products," which are products that were not already on the market as of February 2007 or that were modified after that date. 21 U.S.C. § 387j(a). New tobacco products without premarket

authorization are deemed to be "adulterated" or "misbranded," *id.* §§ 387b(6), 387c(a)(6), and subject to civil and criminal penalties, injunctive relief, and seizure. *See id.* § 331 (prohibited acts); *id.* § 332 (injunctive relief); *id.* § 333 (penalties), *id.* § 334 (seizure).

A manufacturer can obtain premarket authorization by submitting a report showing that a product is "substantially equivalent" either "to a tobacco product commercially marketed" as of February 2007 or to a tobacco product previously determined to meet that test.[1] 21 U.S.C. § 387e(j)(1); *Id.* § 387j(a)(2)(i)(I). A new product is substantially equivalent if it "has the same characteristics" as the comparison or "predicate" product or if the "different characteristics" of the new product "do[] not raise different questions of public health" as the comparison product raises. *Id.* § 387j(a)(3)(A).

In issuing the Deeming Rule, the FDA stated it would defer enforcement of the premarket authorization requirements with respect to products that were on the market as of the effective date of the Deeming Rule. 81 Fed. Reg. at 29,010. As relevant here, the FDA stated that it did not intend to enforce those requirements for 18 months from the rule's effective date while manufacturers submitted the reports, and for up to an additional 12 months while the

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[1] Distinct premarket review processes apply to (1) new tobacco products without a substantially equivalent pre-2007 tobacco product, such as vaping products, and (2) products considered "exempt" due to minor modifications of tobacco additives.

FDA processed them. *Id.* at 29,010–12. In August 2017, the FDA extended those periods until August 2021 for combustible products (like cigars), and until August 2022 for noncombustible products (like most e-cigarettes). Food and Drug Administration, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule*, 82 Fed. Reg. 37,459 (Aug. 10, 2017).

In a later lawsuit, however, a federal district court in Maryland vacated the FDA's August 2017 extension. *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F.Supp.3d 461 (D. Maryland 2019). The court found that the FDA's decision to extend the deadlines across the board by up to five years was contrary to the Tobacco Control Act and violated the Administrative Procedure Act, because it was not an exercise of the FDA's case-by-case discretion. *See id.* at 493–94, 497–98. The court eventually ordered the FDA to require that premarket applications be filed by September 9, 2020. The court stated that new tobacco products subject to timely premarket applications "may remain on the market without being subject to FDA enforcement actions" until September 9, 2021.

In June 2021, the FDA held a public webinar related to deemed products in anticipation of the approaching deadline. FDA staff members acknowledged the substantial backlog of pending premarket review applications. Nevertheless, consistent with the Maryland district-court decision, they advised that new tobacco products "risk FDA enforcement" if not authorized by September 9, 2021, subject to the FDA's "discretion to defer enforcement

action against a particular product on a case by case basis" after that time.

II.

Swisher produces 173 different cigars, which make up nearly all its revenue. As a result of a Deeming Rule, it submitted 171 substantial-equivalence reports, covering most of its cigar portfolio, by the September 2020 deadline, investing thousands of hours and millions of dollars.

Having received no response or guidance from the FDA regarding its pending premarket review applications by August 2021, Swisher filed a lawsuit challenging the validity of the Deeming Rule and the FDA's failure to act. Swisher alleged, among other things, that the Deeming Rule violated the non-delegation doctrine, exceeded the FDA's statutory authority, and was arbitrary and capricious, and that the FDA violated the Administrative Procedure Act by failing to timely act on its substantial-equivalence reports.

Swisher also moved for emergency preliminary injunctive relief preventing the FDA from pursuing enforcement against its products pending the resolution of its claims. Swisher contended that, without an injunction, the FDA's "explicit, threatened enforcement," coupled with its inaction on Swisher's pending applications, would force Swisher to pull its products and "shutter its cigar business to avoid civil and criminal penalties" once the deferment period ended on September 9, 2021. It reasoned that it should

not be required to choose between pulling its products or risking FDA enforcement solely due to the FDA's inaction.

The record shows that, before filing suit, Swisher had written to the FDA making similar arguments and asking it to "exercise its case-by-case discretion to stay enforcement of the Tobacco Control Act for all Swisher products for which applications for pre-market review are currently pending." The FDA responded by letter dated August 12, 2021, stating that, "[a]t present, FDA has no intention of initiating an enforcement action against any of Swisher's products" that are the subject of this dispute "on the ground that they are being marketed contrary to" the premarket review requirements. The letter continued,

> If FDA were to later seek to initiate an enforcement action regarding 21 U.S.C. § 387j as to any of those products, it would first send a warning letter to Swisher, consistent with the agency's usual practice, and would afford Swisher 60 days to respond. The agency would then evaluate any arguments and evidence provided by Swisher in response to the warning letter before informing Swisher of any decision to initiate an enforcement action.

The district court held a hearing on Swisher's motion for a preliminary injunction on September 1, 2021. At the hearing, the attorney for the FDA reiterated the FDA's position from the August 12 letter, stating that the FDA had no present intent to bring an enforcement action against Swisher, but that Swisher would be

given 60 days' advance notice and an opportunity to respond if circumstances changed. So in the FDA's view, an injunction was not necessary to preserve the status quo. The attorney asserted that granting injunctive relief to Swisher could and likely would lead to a de facto reinstatement of the August 2017 guidance and an effective overruling of the Maryland district-court decision. In response to the court's questions, the attorney also explained that, if the FDA ultimately did send Swisher a warning letter, it would consider whether a substantial-equivalence report was pending, among other factors, and it would consider violations that occur after the date of the warning letter only, even if it had the authority to impose retroactive penalties.

For its part, Swisher said that the FDA would not have opposed its request for a preliminary injunction if the threat of enforcement was not real, and that it did not need to wait for a warning letter to obtain relief. And in addition to claiming that it would have to shutter its business without an injunction, Swisher asserted that it was being irreparably harmed by the "black cloud" hanging over its products. In support, Swisher pointed to evidence that one of its largest customers was considering no longer selling Swisher's products if Swisher could not certify its compliance with governing regulations by September 1, 2021.

The district court denied Swisher's motion on September 7, 2021. In sum and substance, the court found that Swisher would not be irreparably harmed if an injunction did not issue because the risk of FDA enforcement was not sufficiently imminent. The court

noted that the FDA's statements at the webinar indicated that "the risk of enforcement would be accompanied by case-by-case review and companies could obtain continued deferment." And given the FDA's August 12 letter to Swisher and its past conduct, according to the court, there was no credible reason to believe that an enforcement action was forthcoming, or, if one did come, that a court could not enjoin the FDA at that time. In particular, the court noted that the FDA was not required to take enforcement action or assess sanctions; that Swisher had not been "unambiguously" threatened and there was "no history of the FDA threatening Swisher for marketing products still under premarket review"; and that the FDA not only "indicated a willingness to delay any enforcement action, but it attempted to issue guidance affirmatively delaying such action."

Based on these observations, the district court concluded that the September 9, 2021, court-imposed deadline "exists merely as a possibility" and was "not sufficiently likely to be accompanied by imminent enforcement action, when considered along with the FDA's letter and past actions, to justify injunctive relief." The court was receptive to the gist of Swisher's position, stating that FDA enforcement against products subject to timely premarket review applications "appears on its face, as unjust, contrary to princip[le]s of due process, and potentially ruinous to Swisher." "But," in the court's view, the court continued, "that is not what is happening."

As for Swisher's reliance on harm stemming from its customer's concerns about the regulatory morass, the court found that

the asserted injury was not traceable to the FDA and that "an injunction would not preserve the status quo given the passage of the deadline given by the customer." This appeal followed.[2]

III.

We apply a "highly deferential" standard of review to a district court's denial of a preliminary injunction, reversing "only if we find that the court clearly abused its discretion." *Siegel v. LePore*, 234 F.3d 1163, 1178 (11th Cir. 2000) (*en banc*). We review the district court's findings of fact for clear error and its conclusions of law *de novo*. *Forsyth Cnty. v. U.S. Army Corps of Eng'rs*, 633 F.3d 1032, 1039 (11th Cir. 2011).

IV.

A district court may grant a preliminary injunction only if the movant shows that "(1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *Siegel*, 234 F.3d at 1176. "A preliminary injunction is an extraordinary and drastic remedy not to be granted unless the

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[2] In the same order, the district court also granted the FDA's motion to transfer this case to the United States District Court for the District of Columbia for consolidation with a previously filed case involving similar claims brought by the Cigar Association of America. Swisher does not appeal the transfer decision.

movant clearly established the burden of persuasion as to each of the four prerequisites." *Id.* (cleaned up). Indeed, "a preliminary injunction is 'an extraordinary remedy never awarded as of right.'" *Benisek v. Lamone*, 138 S. Ct. 1942, 1943 (2018).

We begin—and ultimately end—our discussion with irreparable injury, which is "the sine qua non of injunctive relief." *Id.* (quotation marks omitted). Even where a movant establishes a likelihood of success on the merits, the absence of a showing of irreparable injury "would, standing alone, make preliminary injunctive relief improper." *Id.*

For an injunction to issue, "the asserted irreparable injury must be neither remote nor speculative, but actual and imminent." *Id.* at 1176–77 (quotation marks omitted). In other words, irreparable harm must be "*likely* in the absence of an injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 21–22 (2008) (emphasis in original). "[A] possibility of irreparable harm" is not enough. *Id.*

The district court did not abuse its discretion in denying preliminary injunctive relief on the ground that Swisher was not likely to suffer irreparable harm without an injunction. The court reasonably concluded that Swisher did not "clearly establish[]" its burden of persuasion as to that factor. *See Siegel*, 234 F.3d at 1176.

At the outset, we acknowledge that FDA enforcement remains a possibility. According to the FDA, it retains case-by-case discretion to commence enforcement actions after September 9, 2021, even against products for which substantial-equivalence

reports remain pending. Because (as far as we know) the FDA has yet to act on Swisher's reports, there remains at least the possibility that Swisher will be subject to enforcement action for marketing products that have not passed the premarket review process.

But "a possibility of irreparable harm" is not enough. *Winter*, 555 U.S. at 21–22. And here, the record amply supports the district court's finding that FDA enforcement against Swisher's products once the deferment period ended on September 9, 2021, was neither "likely," *id.*, nor "actual and imminent," *Siegel*, 234 F.3d at 1176–77. In its August 12 letter to Swisher, FDA stated that it had "no intention of initiating an enforcement action against any of Swisher's products" that are the subject of this dispute "on the ground that they are being marketed contrary to" the premarket review requirements. The FDA's attorney reiterated that position at the hearing on the motion for a preliminary injunction. And that position is also consistent with the FDA's August 2017 guidance—later vacated by court order—deferring enforcement of the premarket review requirements.

That no enforcement action against Swisher was intended or even contemplated by the FDA once the deferment period ended is further supported by the lack of enforcement to date. It appears that the FDA has taken no steps to warn Swisher about its products or to institute an enforcement action against Swisher

since September 10.[3] Nor has Swisher suggested that it has removed any of its products from stores or taken other mitigatory measures in anticipation of such agency action.

Moreover, the district court reasonably concluded that, even if circumstances changed and the FDA decided to enforce, Swisher was unlikely to suffer irreparable harm because it would have an opportunity to seek to enjoin the FDA before any harm was realized. At the hearing on the motion for preliminary injunction, the FDA represented that, consistent with its general practices, it would not bring an enforcement action without providing 60 days' advance notice and considering Swisher's response, and that it would seek penalties for only those violations occurring after the warning letter. Swisher's objections that an FDA warning letter itself carries legal consequences, or that it would be too late to seek injunctive relief once a warning letter was issued, are not well taken. *See Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 943 (D.C. Cir. 2012) ("FDA's warning letters

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[3] On September 9, 2021, the FDA issued an update regarding its progress on reviewing applications for premarket approval. Consistent with its earlier statements, the FDA advised that new tobacco products without premarket authorization "are subject to enforcement action at FDA's discretion," but that the FDA's highest enforcement priorities concerned "[p]roducts for which no application [for premarket review] is pending." FDA, *Perspective: FDA's Progress on Tobacco Product Application Review and Related Enforcement* (Sept. 9, 2021), *available at* https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-tobacco-product-application-review-and-related-enforcement (last visited Jan. 26, 2019).

. . . neither mark the consummation of the agency's decisionmaking process nor determine the appellants' legal rights or obligations.").[4]

Nor are we persuaded on this record by Swisher's claims that the legal uncertainty surrounding its products is causing it irreparable harm. Swisher claims that it is losing customers and goodwill by being stuck in legal limbo through no fault of its own. While the "loss of customers and goodwill is an irreparable injury," *BellSouth Telecomms., Inc. v. MCIMetro Access Transmissions Servs., LLC*, 425 F.3d 964, 970 (11th Cir. 2005) (quotation marks omitted), Swisher's evidence does not show that it has lost customers or goodwill. Although a major customer had indicated that the legal uncertainty might lead it stop purchasing Swisher's cigars, Swisher's own briefing indicates that it "has been able to avoid that disaster as of now." Swisher asserts that such a disaster "could well materialize" and that it "fully expects other distributors to have similar concerns," but these claims are speculative and do not clearly show that injunctive relief is necessary.

On the whole, we cannot say that the district court clearly abused its discretion by concluding that an injunction was not necessary to preserve the status quo pending the resolution of Swisher's lawsuit. *See Siegel*, 234 F.3d at 1178. In our view, the

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[4] FDA, *Regulatory Procedures Manual*, ch.4, at 4 (Oct. 2021) ("A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action.").

district court reasonably found, based on the current record, that the likelihood of irreparable harm was too remote to justify granting preliminary injunctive relief.[5] We therefore affirm the denial of Swisher's motion for a preliminary injunction.

AFFIRMED.

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[5] The cases on which Swisher primarily relies do not require a different result. For the most part, these cases concern the requirements of Article III standing for pre-enforcement review where a plaintiff has expressed an intent to engage in proscribed conduct arguably protected by a constitutional interest, such as free speech. *See, e.g.*, *Wollschlaeger v. Governor, Fla.*, 848 F.3d 1293, 1303–06 (11th Cir. 2017) (*en banc*) (stating that a "credible threat of prosecution" is sufficient to confer standing in such a case); *Robinson v. Att'y Gen.*, 957 F.3d 1171, 1177–78 (11th Cir. 2020); *Socialist Workers Party v. Leahy*, 145 F.3d 1240, 1244 (11th Cir. 1998). They do not directly speak to the requirements for granting injunctive relief. Moreover, irreparable harm is not a legal determination like standing, but instead is an equitable one to be made based on the specific facts of the case. *See, e.g.*, *America's Health Ins. Plans v. Hudgens*, 742 F.3d 1319, 1334 (11th Cir. 2014) (describing irreparable harm as an "equitable factor[]"). And for the reasons we have explained, the district court did not abuse its discretion in finding, in the specific circumstances of this case, that Swisher would not be irreparably harmed without an injunction.

Perspective: FDA's Progress on Tobacco Product Application Review and Related Enforcement

By Mitch Zeller, Director of the FDA's Center for Tobacco Products (CTP)
September 9, 2021

Following updates provided in May (/tobacco-products/ctp-newsroom/update-fdas-application-review-pmta-list-posted-progress-metrics-updated) and February (/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline), as well as our initial perspective published in August 2020 (/tobacco-products/ctp-newsroom/perspective-fdas-preparations-september-9-submission-deadline), this piece describes the current status of our review of applications for "deemed" new tobacco products submitted by Sept. 9, 2020. Previously, we also created a webpage with general information and resources (/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products) related to the submission of tobacco product applications for these products.

*FDA's premarket review of tobacco products is an essential tool for ensuring that products on the market meet a set of legal standards set forth by Congress to protect public health, and that products that do not meet the legal standards are not marketed. Although different tobacco products have different levels of risk, all tobacco products are inherently dangerous. Whether they receive a marketing authorization or not—**there are no safe tobacco products**. People who do not currently use tobacco products, especially young people, should not start.*

Background

The Family Smoking Prevention and Tobacco Control Act (/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview) provided FDA with immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the agency, by regulation, deems to be subject to the law. When FDA's historic "Deeming Rule (https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-

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cosmetic-act-as-amended-by-the)" took effect in 2016, many of the regulatory and statutory requirements that had been in place for manufacturers of the originally regulated tobacco products since passage of the law in 2009, became applicable to the deemed products, including e-cigarettes and all other electronic nicotine delivery systems (ENDS), cigars, pipe tobacco, nicotine gels, hookah tobacco, and any future products meeting the statutory definition of "tobacco product." The applicable statutory provisions include the requirement that deemed products that meet the definition of a new tobacco product (https://www.fda.gov/node/370828#N) must receive premarket authorization from the FDA to be legally marketed.

In the deeming rule and subsequent guidance documents, FDA stated that it intended to defer enforcing the premarket review requirements, for a period of time, with respect to "deemed" new tobacco products that were on the market as of Aug. 8, 2016 (the effective date of the deeming rule). This policy did not extend to deemed new tobacco products that entered the market after the rule's effective date. Under a federal court order (/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline), manufacturers of deemed new tobacco products that were on the market as of the deeming rule's effective date were required to submit premarket review applications by Sept. 9, 2020. Following the court order, FDA accelerated its planning and preparation to receive a large number of applications by the premarket application deadline (/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products). FDA received thousands of submissions representing more than 6.5 million products by the deadline of Sept. 9, 2020. Per the court order (/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline), products for which applications were submitted by the deadline could generally remain on the market for up to a year from the date of the application—or until Sept. 9, 2021, at the latest—pending FDA review, although FDA retains enforcement discretion.

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Over the last year, the agency has worked to review premarket applications (/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product) for millions of products. The vast majority of the applications are for ENDS products. When reviewing premarket tobacco product applications (PMTAs) (/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications) for ENDS products, FDA's job is to assess the scientific evidence presented by the applicant and determine if permitting the marketing of the new tobacco product would be "appropriate for the protection of the public health" – the standard laid out by the statute. The agency makes this determination by following the direction Congress provided in the law to assess the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, as well as the increased or decreased likelihood that those who do not use tobacco products will start using such products. In making this determination, the impact of such products on youth initiation and use is a critical consideration.

FDA has made significant progress in reviewing premarket applications over the last year. This perspective piece provides an update on our work and information about what to expect after Sept. 9, 2021.

Review Progress

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As previously described (/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline), there are multiple phases in the review process which may differ by application pathway. The sections that follow describe where we are regarding each phase.

Receipt and Processing

Earlier this year, we completed the receipt and processing stage for all deemed new tobacco product applications submitted by the deadline via any of the three pathways to market: Substantial Equivalence (SE) Reports (/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence), Exemption from Substantial Equivalence Requests (EX REQ) (/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence), and Premarket Tobacco Product Applications (PMTA) (/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications).

Acceptance and Filing

As of September 2021, we have completed acceptance review for all applications submitted by the Sept. 9, 2020 deadline. More specifically:

- For the SE pathway, we have accepted applications for more than 5,200 products and issued Refuse-To-Accept (RTA) (https://www.federalregister.gov/documents/2016/12/29/2016-31370/refuse-to-accept-procedures-for-premarket-tobacco-product-submissions) letters for applications for roughly 1,900 products.
- For the EX REQ pathway, we have accepted applications for more than 240 products and issued RTA letters for applications for about 100 products.
- For the PMTA pathway, we have accepted applications for more than 6.5 million deemed products and issued RTA letters for applications for more than 200,000 products.

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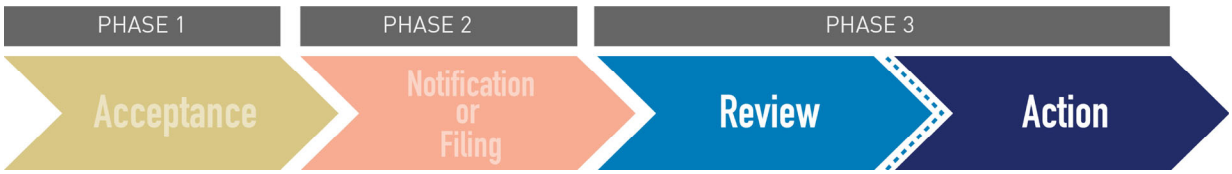
As of Sept. 8, we have completed filing review for about 90 percent of applications submitted via the PMTA pathway by the Sept. 9, 2020 deadline. Many of the accepted applications ultimately received a Refuse-To-File (RTF) letter at the filing stage of the review process because the application did not include required information. For example, companies received RTF letters for not including required content such as ingredient listings, labels for each product to be marketed, or adequate environmental assessments. One such RTF letter was issued on Aug. 9 (/tobacco-products/ctp-newsroom/fda-issues-refuse-file-rtf-letter-jd-nova-group-llc) to a single company for PMTAs associated with approximately 4.5 million products because their PMTAs lacked an adequate Environmental Assessment.

Review and Actions



As of Sept. 8, with respect to applications submitted by the September 9, 2020 deadline, FDA has issued SE marketing orders (/tobacco-products/substantial-equivalence/marketing-orders-se) covering more than 120 products and EX REQ marketing orders (/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se) covering more than 230 products.

On Aug. 26, we issued the first marketing denial orders (/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence) (MDOs) for ENDS products after determining the applications for about 55,000 flavored ENDS products lacked sufficient evidence that these products have a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products. The products from JD Nova Group LLC, Great American Vapes, and Vapor Salon subject to this action are flavored ENDS and they included flavors such as Apple Crumble, Dr. Cola and Cinnamon Toast Cereal. In total, the agency has issued 132 MDOs for over 946,000 flavored ENDS products (/media/151788/download) after reviewing those applications and concluding that they failed to provide sufficient evidence that those products will benefit adult smokers to an extent sufficient to justify their documented risks to youth.

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The FDA's review of new tobacco products before they can be legally marketed is required by statute and ensures that new products meet the standard Congress set in the law to protect the public health. In light of the public health threat posed by the well-documented, alarming levels of youth use of flavored ENDS, the agency reviewed each flavored ENDS application to determine whether it provided sufficient product-specific scientific evidence to demonstrate enough of a benefit to adult smokers to overcome the risk posed to youth. Based on existing scientific evidence and the agency's experience conducting premarket reviews, the evidence of benefits to adult smokers for such products would likely be in the form of a randomized controlled trial or longitudinal cohort study, although the agency does not foreclose the possibility that other types of evidence could be adequate if sufficiently robust and reliable. Because the Agency found the necessary, product-specific evidence absent in each of these applications, the FDA issued MDOs.

To date, FDA has taken action on a substantial majority—around 93 percent—of the applications submitted by the Sept. 9, 2020 deadline.

Marketing orders and other information about tobacco product application decisions are generally posted on our Tobacco Product Marketing Orders (/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders) webpage and organized by pathway. Due to legal requirements to redact confidential commercial information (CCI) and ensure documents posted to the FDA website are accessible to everyone, the full decision summary and order letters may not be posted to the website until a later date.

In addition to the applications on which we've already taken actions, FDA continues review on thousands of applications for tobacco products across all product classifications. FDA intends to continue to devote significant resources to responding to the remaining pending applications expeditiously and will issue our decisions on a rolling basis.

We have also updated our Metrics & Reporting page (/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting) with the complete set of metrics for all review phases of all pathways, which provide aggregate numbers showing our progress within each phase of application review. We will continue to update these metrics every other month.

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Update on Compliance and Enforcement

While our review of premarket applications is ongoing, we remain vigilant in overseeing the market and continue to prioritize the use of our enforcement resources to curb the unlawful marketing of tobacco products.

As such, FDA has been closely monitoring retailer, manufacturer, importer, and distributor compliance with the premarket authorization requirement. Since January 2021, we have issued a total of 170 warning letters (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/tobacco-retailer-warning-letters) to firms that collectively have listed more than 17 million ENDS products with the FDA and that did not submit premarket applications for these products by Sept. 9, 2020. Among those warning letters, FDA issued a warning letter in July (/news-events/press-announcements/fda-brief-fda-warns-firm-over-15-million-products-listed-fda-remove-unauthorized-e-cigarette) to a single company that did not submit an application and has more than 15 million products listed with FDA (/tobacco-products/manufacturing/biannual-tobacco-product-listing-deadline-what-does-deadline-mean-you-and-how-fda-helping-you-comply).

FDA requests that firms that receive warning letters respond to the agency within a specified time period, typically 15 working days, and provide an explanation of the steps they will take to address any violations and their plan for maintaining compliance with the law. Failure to address any violations may lead to regulatory action, including injunctions, seizure, and civil money penalties (/tobacco-products/compliance-enforcement-training/ctp-compliance-enforcement#civilmoneypenalty).

What Happens on Sept. 10 and Beyond?

A small percentage of the more than 6.5 million products that were the subject of timely-submitted applications still remain under review after Sept. 9, 2021. We continue to work expeditiously on the remaining applications, many of which are in the final stages of review, and will issue our decisions on a rolling basis.

Consistent with FDA's January 2020 (revised April 2020) enforcement guidance (/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market), we will continue to make enforcement decisions on a case-by-case basis according to our enforcement priorities and individual circumstances, recognizing that we are unable, as a practical matter, to take enforcement action against every illegally marketed

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tobacco product, and that we need to make the best use of Agency resources. All new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action at FDA's discretion, as recognized in the court's order regarding the Sept. 9, 2020 premarket application deadline.

As described in FDA's enforcement guidance, we have identified flavored products that appeal to youth as enforcement priorities. Available data, including from the National Youth Tobacco Survey (/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey), suggest that tobacco-flavored ENDS products, unlike products with other characterizing flavors, are used by relatively few youth. Products for which no application is pending, including, for example, those with a Marketing Denial Order and those for which no application was submitted, are among our highest enforcement priorities. If such products are not removed from the market, the Agency intends to follow its usual enforcement practices in these circumstances and will issue a warning letter before initiating regulatory action (such as civil money penalties, seizure, or injunction) and afford the recipient an opportunity to respond.

Conclusion

FDA regulates the manufacturing, marketing, and distribution of tobacco products to protect public health. Premarket review of new tobacco products before they can be legally marketed is one of the most important responsibilities of the FDA's Center for Tobacco Products (CTP). We will continue to assess whether applicants meet the applicable statutory standard to market their new products.

The large number of applications submitted by the Sept. 9, 2020 deadline was unprecedented. However, over the last year, we've taken action on a significant number of the applications we received by Sept. 9, 2020. After the Sept. 9, 2020 deadline, FDA received additional applications for more than 1 million products. We will continue working to review all pending and incoming applications.

FDA remains committed to providing continued regular updates to the public about our premarket review as well as compliance and enforcement actions related to deemed tobacco products. For the latest information, please check our metrics and reporting (/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting) and the products list (/tobacco-products/market-and-distribute-tobacco-product/deemed-new-tobacco-produci-

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applications-lists) pages regularly and sign up for email updates (/tobacco-products/ctp-newsroom/subscribe-fda-center-tobacco-products-ctp-email-newsletters) from CTP.

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