United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 13, 2024 Decided January 24, 2025

No. 23-5220

CIGAR ASSOCIATION OF AMERICA, ET AL.,
APPELLEES

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,
APPELLANTS

Appeal from the United States District Court
for the District of Columbia
(No. 1:16-cv-01460)

Lindsey Powell, Attorney, U.S. Department of Justice, argued the cause for appellants. With her on the briefs were *Brian M. Boynton*, Principal Deputy Assistant Attorney General, *Mark B. Stern*, Attorney, *Samuel R. Bagenstos*, General Counsel, Department of Health and Human Services, and *Peter Dickos*, Associate Chief Counsel.

William B. Schultz and *Andrew N. Goldfarb* were on the brief for *amici curiae* Medical and Public Health Groups in support of appellants.

Michael J. Edney argued the cause for appellees. With him on the brief were *Brian T. Burgess* and *Andrew Kim*.

Michael Pepson was on the brief for *amicus curiae* Americans for Prosperity Foundation in support of appellees.

John J. Vecchione was on the brief for *amicus curiae* New Civil Liberties Alliance in support of appellees.

Jason S. Miyares, Attorney General, Office of the Attorney General for the Commonwealth of Virginia, *Erika L. Maley*, Solicitor General, *Kevin M. Gallagher*, Principal Deputy Solicitor General, *Steve Marshall*, Attorney General, Office of the Attorney General for the State of Alabama, *Ashley Moody*, Attorney General, Office of the Attorney General for the State of Florida, *Theodore E. Rokita*, Attorney General, Office of the Attorney General for the State of Indiana, *Brenna Bird*, Attorney General, Office of the Attorney General for the State of Iowa, *Russell Coleman*, Attorney General, Office of the Attorney General for the Commonwealth of Kentucky, *Lynn Fitch*, Attorney General, Office of the Attorney General for the State of Mississippi, *Austin Knudsen*, Attorney General, Office of the Attorney General for the State of Montana, *Alan Wilson*, Attorney General, Office of the Attorney General for the State of South Carolina, and *Ken Paxton*, Attorney General, Office of the Attorney General for the State of Texas, were on the brief for *amicus curiae* the Commonwealth of Virginia and 9 other States in support of appellees.

Macy D. Hanson was on the brief for *amicus curiae* the Heartland Institute in support of appellees.

Before: MILLETT and PAN, *Circuit Judges*, and RANDOLPH, *Senior Circuit Judge*.

Opinion for the court filed by *Senior Circuit Judge* RANDOLPH.

RANDOLPH, *Senior Circuit Judge*: This is an appeal from

the judgment of the district court, Mehta, J., vacating a regulation of the Food and Drug Administration to the extent it applied to "premium" cigars. In so ruling, Judge Mehta agreed with the plaintiffs—the Cigar Association of America, Cigar Rights of America, and the Premium Cigar Association—that as applied to this category of cigars, the FDA's regulation was arbitrary and capricious. *See Cigar Ass'n of Am. v. FDA* (*Cigar I*), No. 16-cv-01460, 2022 WL 2438512 (D.D.C. July 5, 2022); *Cigar Ass'n of Am. v. FDA* (*Cigar II*), No. 16-cv-01460, 2023 WL 5094869 (D.D.C. Aug. 9, 2023).

I.

The FDA promulgated its regulation pursuant to the 2009 Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776. The Act applies "to all 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" the Act. 21 U.S.C. § 387a(b). Those tobacco products specified in the Act, or brought within its coverage through an FDA regulation, are subject to comprehensive restrictions on sales, promotions, and distribution, including requirements of pre-market approval, information disclosure, age limits for purchasers, health warnings, and method-of-sale limitations. *See id.* §§ 387d(a)-(b), 387f(d), 387j(a), 123 Stat. at 1784–1812. The Tobacco Control Act, however, prohibited the FDA from promulgating regulations banning cigarettes or any other tobacco products, including cigars. *Id.* § 387g(d)(3).

In 2014, the FDA issued a Notice of Proposed Rulemaking in the exercise of its § 387a(b) so-called "deem[ing]" authority. *See* Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 23142 (Apr. 25, 2014). The FDA offered two options. Its first potential

approach—dubbed "Option 1"—proposed bringing all tobacco products within the agency's regulatory authority under the Tobacco Control Act. *Id.* at 23143. Its rulemaking notice stated, however, that although "all cigars are harmful and potentially addictive, it has been suggested that different kinds of cigars may have the potential for varying effects on public health . . . ." *Id.* The FDA therefore "proposed" a "second option" of excluding "premium cigars" "from the scope of this proposed rule." *Id.* The notice proposed to define a "premium cigar" under "Option 2" as a cigar that "(1) [i]s wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price . . . of no less than $10 per cigar . . . ; (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units." *Id.* at 23150.

Many commenters, including the plaintiffs in this case, supported Option 2, arguing that premium cigars are smoked less frequently than other cigars, leading to fewer adverse health effects and a less pressing need for regulation. As relevant here, these comments highlighted two pieces of data. *See, e.g.*, J.A. 527–29. One was a 2014 study published in the Centers for Disease Control's "Morbidity and Mortality" bulletin. *See* Catherine G. Corey et al., *Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012–2013*, 63 Morbidity & Mortality Weekly Rep. 650 (2014). Analyzing the 2012–2013 National Adult Tobacco Survey of 60,192 American adults, this study—the "Corey" study—found that only 3.3 percent of premium cigar smokers reported "every day" use, while 25.6 percent reported "some day" use and 71.2 percent reported "rare[]" use. *Id.* at 650, 652. Second was a 1998 study by the National Cancer Institute termed "Monograph No. 9." *See* Nat'l Cancer Inst., *Cigars: Health Effects and*

Trends Monograph No. 9 (1998). Monograph No. 9, as the district court put it, "found no statistically significant difference in the 'all-cause' mortality rate as between 'neversmokers' and those who smoked no more than two cigars per day." *Cigar I*, 2022 WL 2438512, at *3. Commenters, in discussing these two studies, stressed that the relatively infrequent use of premium cigars (typically less than once per day) resulted in fewer or lower health risks than usage of other tobacco products. *See, e.g.*, J.A. 523, 525, 527–29.

The FDA finalized the rule two years later, selecting the Option 1 regulatory approach covering all cigars without an exemption for premium cigars. *See* Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28974, 29020 (May 10, 2016) (codified at 21 C.F.R. pts. 1100, 1140, 1143). The FDA stated that it had conducted a "thorough review of the comments and the scientific evidence" and drew three principal conclusions: (1) "[a]ll cigars pose serious negative health risks," (2) the "available evidence" did not support a carve-out for premium cigars, and (3) premium cigars are used by youth. *Id.* To support the first and third conclusions, the final Rule extensively discussed the health risks of all cigars, citing statistics about the many Americans who smoke cigars and the resulting medical consequences. *See id.* at 29020–24.

Regarding a potential distinction between premium cigars and other cigars, the FDA lamented that, "despite [its] explicit requests in the NPRM, the comments did not include data indicating that premium cigar smokers [were] not subject to disease risk and addiction." *Id.* at 29024. Elsewhere, the Rule stated that the "FDA specifically sought comment on how the potential different patterns of use for premium cigars might result in different or decreased health impacts, but no such evidence was submitted." *Id.* at 29022. The FDA reported

several other times that there was "no data" about health differences, *id.* at 29020, and that commenters "ha[d] not substantiated their claims that the patterns of use for premium cigars preclude[d] . . . negative health effects," *id.* at 29027. The FDA therefore discerned "no appropriate public health justification to exclude premium cigars" from its Rule. *Id.* at 29020.

In the district court, the plaintiffs contended—as relevant here—that the Rule was arbitrary and capricious as applied to premium cigars. The district court found that the FDA "did not examine" the evidence the parties submitted, specifically Monograph No. 9 and the Corey study. *See Cigar I*, 2022 WL 2438512, at *4. Even though commenters had "already drawn" and "emphasized" a connection between those studies and the FDA's decision, *id.* at *5, the FDA simply repeated that all cigars were dangerous. This was "nonresponsive, circular reasoning," according to the district court. *Id.* at *6. The FDA, when it posed a choice between Option 1 and Option 2, "already knew" that "premium cigars, like standard cigars, produce toxic cigar smoke." *Id.* Thus, because the agency had spoken "in absolute terms that there [was] no evidence, it act[ed] arbitrarily and capriciously when there [was] in fact pertinent record evidence." *Id.* at *7. Then, after additional briefing on remedies, the district court vacated the Rule as applied to premium cigars. *See Cigar II*, 2023 WL 5094869. Given the "significance of the agency's error," the real possibility of FDA reaching a different conclusion on remand in light of new medical research, and the limited disruptive consequences of vacatur, the district court declined to remand without vacating. *Id.* at *4, *6. The court's opinion adopted a definition for "premium cigars" based on an FDA document from an earlier phase of the litigation. *See id.* at *6 n.7.

II.

The Administrative Procedure Act requires the "reviewing court" to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

The FDA's notice of proposed rulemaking asked a straightforward question: Option 1 or Option 2? The final Rule explained that the choice was driven by "public health justification[s]": do the "the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion"? 81 Fed. Reg. at 29020. From the beginning of this rulemaking, the FDA has taken as a given that "all cigars are harmful and potentially addictive." 79 Fed. Reg. at 23150. But the FDA also acknowledged that there could be significant differences in the degree of risk that premium cigars pose as compared to other tobacco products. And so the proposed rulemaking notice announced that the FDA would consider a premium-cigar carve-out because "different kinds of cigars may have the potential for varying effects on public health." *Id.* at 23143. In short, while the FDA believed that all cigars had some risks, premium cigars might have lower risks "based on possible differences [from] . . . frequency of use by youth or young adults." *Id.* The FDA made clear that it was "seeking comment on whether all cigars should be subject to deeming . . . taking into account what is appropriate to protect the public health." *Id.* at 23150. The agency thus narrowed the inquiry to the public health differences among cigars.

Plaintiffs provided evidence bearing directly on this question, but in its final rulemaking the FDA expressly stated that such evidence was not provided and did not exist. The agency wrote that it had "specifically sought comment on how the potential different patterns of use for premium cigars might

result in different or decreased health impacts, but no such evidence was submitted." 81 Fed. Reg. at 29022. Similar assertions were scattered throughout the Rule. For example, the FDA stated that, "no data indicat[ed] that premium cigar users are not susceptible to health risks," *id.* at 29020, and "despite our explicit requests in the NPRM, the comments did not include data indicating that premium cigar smokers are not subject to disease risk and addiction," *id.* at 29024. Yet the Corey study and Monograph No. 9 spoke to this precise question: the Corey study found that all but 3 percent of premium cigar users smoke fewer than one per day, and Monograph No. 9 found that smoking a cigar once or twice per day has no statistically significant impact on "all-cause" mortality. Taken together, those two data points provided evidence that premium cigar use poses a less urgent public health risk than that associated with any other tobacco product, including standard cigars. And it bears repeating: the notice of proposed rulemaking set up the central inquiry as whether "different kinds of cigars may have the potential for varying effects on public health." 79 Fed. Reg. at 23143.[1]

We agree with Judge Mehta that the FDA's final Rule was

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[1] While not central to how the parties argued this case, a different study in the record, also by Dr. Corey, contained comparative data on the average number of cigars smoked per day for different types of cigars. This study found that the average premium cigar smoker smoked 0.1 premium cigars per day. By contrast, the average smoker of nonpremium cigars smoked 0.4 such cigars per day, the average smoker of cigarillos smoked 0.3 per day, the average smoker of filtered cigars smoked 1.6 per day, and the average smoker of cigarettes smoked 10.1 per day. J.A. 151; Catherine G. Corey et al., *U.S. Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014*, 20 Nicotine & Tobacco Rsch. 1457, 1461 (2018).

arbitrary and capricious.

First, the FDA's rationale was factually incorrect. We have held that "agency action is arbitrary and capricious if it rests upon a factual premise that is unsupported by substantial evidence." *Genuine Parts Co. v. EPA*, 890 F.3d 304, 346 (D.C. Cir. 2018) (quoting *Ctr. for Auto Safety v. Fed. Highway Admin.*, 956 F.2d 309, 314 (D.C. Cir. 1992)). The FDA's explanation for its rejection of Option 2 in the final Rule rested on a false factual premise, as discussed above. That in itself constituted arbitrary agency action. *See, e.g.*, *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999).

Second, even if the FDA had said nothing about the supposed lack of evidence, its analysis of the choice between Option 1 and Option 2 shows that it did not "examine the relevant data," a defect rendering its action "arbitrary" within the meaning of APA section 706.[2] *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also, e.g.*, *Env't Health Tr. v. FCC*, 9 F.4th 893, 907 (D.C. Cir. 2021); *Viasat, Inc. v. FCC*, 47 F.4th 769, 776 (D.C. Cir. 2022); *Home Box Off., Inc. v. FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977).[3] In some cases, the relevance of the unexamined "data" might be debatable. But not here. As we have discussed, the FDA's notice of proposed rulemaking

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[2] While the FDA did *describe* elements of the Corey study and Monograph No. 9 when summarizing the comments it had received, the agency failed to *respond* to those studies' implications. Grappling with relevant data requires more than a mere recitation of unfavorable evidence without further explanation.

[3] Plaintiffs also argue that the FDA's discussion of youth usage of premium cigars was arbitrary and capricious. But the district court declined to reach that issue, *see Cigar I*, 2022 WL 2438512, at *8, and we decline to do so as well.

placed this sort of evidence at the heart of its inquiry.[4]

III.

This brings us to the question of remedy. Section 706 of the APA states that when the reviewing court finds "arbitrary" agency action, the court "shall . . . set aside" that agency action. *See* 5 U.S.C. § 706. Even so, precedents of our court have sanctioned the "exceptional remedy" of remand without vacatur in "limited circumstances," *Am. Great Lakes Ports Ass'n v. Schultz*, 962 F.3d 510, 518–19 (D.C. Cir. 2020), and "only if an agency's error is 'curable.'" *Bridgeport Hosp. v. Becerra*, 108 F.4th 882, 890 (D.C. Cir. 2024) (quoting *U.S. Sugar Corp. v. EPA*, 844 F.3d 268, 270 (D.C. Cir. 2016)).[5] Under *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Commission*, 988 F.2d 146 (D.C. Cir. 1993), the decision to vacate turns on two factors: the "seriousness of the [agency action's] deficiencies" and the "disruptive consequences" of vacatur. *Id.* at 150 (quoting *Int'l Union, United Mine Workers of Am. v. Fed. Mine Safety & Health Admin.*, 920 F.2d 960, 9667 (D.C. Cir. 1990)). Pursuant to circuit precedent, Judge Mehta's decision to vacate the contested portion of the final Rule must stand unless he abused his discretion to decide the appropriate remedy for the FDA's unlawful action. *See Great Lakes*, 962 F.3d at 518.

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[4] Before this court and in the district court, the FDA identified problems with the Corey study and Monograph No. 9. But as the district court determined, those points should have been made in the rulemaking. *See Cigar I*, 2022 WL 2438512, at *4.

[5] As we noted in *Bridgeport Hospital*, "[t]he conflict between 5 U.S.C. § 706(2)(A)'s command and our creation of remand without vacatur has been noted in more than one separate opinion." 108 F.4th at 890 n.5. But since vacatur is the appropriate remedy here, we need not reach that question.

The final Rule's deficiencies are serious. "In the past we have not hesitated to vacate a rule when the agency has not responded to empirical data or to an argument inconsistent with its conclusion." *Comcast Corp. v. FCC*, 579 F.3d 1, 8 (D.C. Cir. 2009). And in dicta, we have suggested that a court "*must vacate* a decision that 'entirely failed to consider an important aspect of the problem.'" *SecurityPoint Holdings, Inc. v. TSA*, 867 F.3d 180, 185 (D.C. Cir. 2017) (emphasis added) (quoting *State Farm*, 463 U.S. at 43). This case is a textbook example: the FDA did not respond to data speaking to the rulemaking's central question regarding the treatment of premium cigars.

As to the potential disruptive consequences of vacatur, the FDA cites the same parade of harms that it cited before the district court—i.e., the importance of age requirements, sample restrictions, vending machine prohibitions, and mislabeling rules to protect the public. The district court, however, carefully explained why the FDA's fears are overblown or unsubstantiated, *see Cigar II*, 2023 WL 5094869, at *5, and the FDA gives us no reason to disturb the district court's reasoned conclusion.

The FDA also raises the prospect of a disruption to the "detailed user fee scheme" that Congress imposed to fund tobacco regulation. *Cigar Ass'n of Am. v. FDA*, 5 F.4th 68, 78 (D.C. Cir. 2021) (describing the statutory framework). As relevant here, the user fee system uses a statutorily defined formula to allocate the FDA's costs among each type of tobacco product; the manufacturers of each type of product then bear their allocated share. *Id.* (citing 21 U.S.C. § 387s). As this scheme has been in place for seven years, the FDA worries that a vacatur order might necessitate the recalculation and reallocation of seven years worth of user fee payments.

In the past, we have often remanded without vacating in the

context of complex payment or fee schemes. For example, in *American Great Lakes*, vacatur could have required "attempting to recoup and redistribute funds that changed hands years ago in numerous separate transactions." 962 F.3d at 519. We emphasized that the "precise amount of each refund" was "unclear," rendering vacatur an "invitation to chaos." *Id.* (final excerpt quoting *Sugar Cane Growers v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002)). Thus, "a quintessential disruptive consequence arises" when vacatur would require "unravel[ing]" and "disrupt[ing] settled transactions." *Id.* Likewise, in *Allied-Signal*, we emphasized that if vacatur required an agency to refund user fees to some parties but left it unable to recover those fees in a future rulemaking, remand without vacatur was appropriate. 988 F.2d at 151.

Contrary to the FDA's contention, however, the presence of a user fee system in itself does not automatically require remand without vacatur. *American Great Lakes* and *Allied-Signal* indicate that when vacating would disturb "settled transactions," this is a factor in favor of remand without vacating. Here, this is a factor we need not consider. We read the district court's relief as applying only prospectively, without requiring an unwinding of past transactions.

In short, the district court did not abuse its discretion in vacating the FDA's Rule as applied to premium cigars, provided that the relief does not permit refunding past user fee payments.

IV.

One issue remains. The "FDA did not settle on a definition [of 'premium cigars'] . . . because it decided to regulate all cigars under Option 1." *Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d 256, 280 (D.D.C. 2020). The district court therefore took it upon itself to define "premium cigars," "[f]or purposes

of this ruling," using an eight-part definition. *See Cigar II*, 2023 WL 5094869, at *6 n.7. This definition departed somewhat from the FDA's proposal in its notice of proposed rulemaking. *Compare id.*, and *supra* p. 4, *with* 79 Fed. Reg. at 23150 (NPRM). For example, the district court's version eliminated the $10 price requirement, but it added a requirement that only tobacco, water, and vegetable gum could be used as ingredients. In addition, the district court's version included a few wording changes, specifying that the long filler tobacco requirement be measured by weight, generalizing the requirement that the cigar be "capped by hand" and "combin[ed] manually" to simply being "handmade or hand rolled," and changing the no "tip" requirement to "no nontobacco tip."

How did this definition come about? Its provenance traces back to a letter from the FDA to a different district court in a different case. But, suffice it to say, the FDA never formally defined the category of "premium cigars."[6] And so the FDA

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[6] More specifically, the district court adopted the definition used by a previous 2020 decision in this case. *See Cigar II*, 2023 WL 5094869, at *6 n.7 (citing *Cigar Ass'n*, 480 F. Supp. 3d at 281). That 2020 decision drew from a litigation notice filed on August 6, 2020. *See id.* (citing Notice of Filing, *Cigar Ass'n*, 480 F. Supp. 3d 256 (D.D.C. Aug. 6, 2020), ECF No. 209 at 3–4). The notice alerted the court below to a letter filed with the District of Maryland in a different challenge to the "Deeming Rule." The FDA's letter to the Maryland federal district court informed that court of a proposed agency guidance document on premium cigars—and *that* proposed guidance document contained the definition at issue. *See* Letter, *Am. Academy of Pediatrics v. FDA*, No. 18-cv-00883 (D. Md. Aug. 5, 2020), ECF No. 188. But the 2020 decision in this case was handed down before the District of Maryland could rule on the request, and the FDA later withdrew its proposed guidance document as moot. *See* Notice of Decision and Withdrawal of Motion, *Am. Academy of Pediatrics*, No. 18-cv-008833 (D. Md. Aug. 20, 2020), ECF. No. 192 at 1. As far as

complains that the district court's remedy usurped the FDA's role.

This is somewhat concerning because defining "premium cigars" was, or should have been, an issue in the rulemaking. But we recognize that the district court's determination that the FDA acted irrationally made it necessary to define "premium cigars" with some precision.

The rulemaking notice requested comment on the originally proposed definition, posing five questions about its specific elements. *See* 79 Fed. Reg. at 23150 ("We ask for comments . . . on the following questions regarding this issue: Is this proposed definition of 'covered cigar' appropriate . . . ?"); *see also id.* (requesting comments on the ingredient, price, and weight prongs). The FDA also asked whether an additional restriction based on production rate should be added. *Id.* Commenters weighed in with differing views, and the price prong was a particular area of disagreement. *See Cigar Ass'n*, 480 F. Supp. 3d at 280–81 (summarizing comments). Indeed, the three plaintiffs here disagreed with each other: Cigar Rights of America and the Premium Cigar Association supported the version the district court ultimately used; the Cigar Association of America opposed it. *Id.*

Unlike many cases in which the remedial question is distinct from the merits question—for instance, when a successful as-applied challenge leads a court to limit the applicability of a rule without affecting its substance—the scope of the remedy here poses the same question as the key merits issue. The definition of "premium cigar" in the final vacatur

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we can tell, the FDA never reissued the guidance containing the "premium cigar" definition used here.

order will determine which products are exempted from the Tobacco Control Act (pending any further rulemaking), precisely the issue this rulemaking sought to determine. As we have explained, the FDA set up a choice between Options 1 and 2, ignored the data supporting Option 2, and then chose Option 1. But the vacatur remedy incorporated a definition of "premium cigar" that the FDA never formally adopted.

Given the centrality of this issue, we think the parties should have the opportunity to express their views before the district court determines—in effect—the permissible scope of the FDA's existing rule. Accordingly, we reverse and remand only so that the district court can invite briefing on the appropriate definition of "premium cigars" before entering a final order. Of course, the FDA may separately begin a new rulemaking to redefine the "premium cigars" carve-out or it may seek to regulate these products once again. But until then, and with the understanding that vacatur will not permit revisiting past user fee payments, we otherwise affirm the district court's well-reasoned opinion in full.

So ordered.