The FDA has received inquiries about a recent court decision relating to "premium cigars," so we are providing some additional information.

On August 9, 2023, the U.S. District Court for the District of Columbia issued an order vacating FDA's rule deeming tobacco products to be subject to FDA's tobacco product authorities[1] "insofar as it applies to premium cigars."[2] On January 24, 2025, the U.S. Court of Appeals for the District of Columbia Circuit largely affirmed the district court's order but reversed and remanded the case to the district court for the limited purpose of considering "the appropriate definition of 'premium cigars.'"[3]

As noted above, the *Cigar Association* case has been remanded to the district court, for further consideration of the appropriate definition of "premium cigars." While further litigation about that definition continues, until further notice, in reviewing disputes involving "premium cigars," FDA continues to intend to use the definition set out in the district court's August 9, 2023 order. In that order, the district court specified that "premium cigars" are those cigars that:

1. are wrapped in whole tobacco leaf;
2. contain a 100 percent leaf tobacco binder;
3. contain at least 50 percent (of the filler by weight) long filler tobacco;
4. are handmade or hand rolled;
5. have no filter, nontobacco tip, or nontobacco mouthpiece;
6. do not have a characterizing flavor other than tobacco;
7. contain only tobacco, water, and vegetable gum with no other ingredients or additives; and
8. weigh more than 6 pounds per 1,000 units.[4]

In light of the above developments, FDA intends to develop a mechanism by which it will not assess fees for "premium cigars." To assess and collect the full amount of tobacco product user fees authorized under federal law, *see* 21 U.S.C. § 387s(b)(1)(K), the Agency intends to consider what options are feasible and statutorily authorized for reallocating the fees that would otherwise have been collected for "premium cigars." In the meantime, however, the Tobacco Control Act and FDA's user fee regulations require FDA to issue assessment invoices on a quarterly basis. Accordingly, as a matter of practical necessity, in calculating and sending this assessment invoice, FDA used the process it has used since FDA's amended user fee regulations went into effect in 2016.

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[1] *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974 (May 10, 2016).
[2] *Cigar Ass'n of Am. v. FDA*, No. 16-cv-01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023) ("Cigar Association").
[3] *Cigar Ass'n of Am. v. FDA*, No. 23-5220, Document #2096141 (D.C. Cir. Jan. 24, 2025).
[4] *Cigar Ass'n of Am. v. FDA*, No. 16-cv-01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023).

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The Agency reserves the right to amend its FY26 Q1 assessments to the extent it is able to do so, including in light of the information it receives from manufacturers and importers regarding their "premium cigars" and as it continues to evaluate the evolving legal and practical circumstances surrounding "premium cigars."

Here are contacts if you have questions:

- For financial questions or questions regarding your payment or payment procedures, please contact FDA's User Fee Helpdesk at 301-796-7200 or userfees@fda.gov.
- For questions regarding the Tobacco User Fee Program and other questions concerning this assessment, please contact FDA's Center for Tobacco Products at tobaccouserfees@fda.hhs.gov.
- For general questions regarding the Family Smoking Prevention and Tobacco Control Act, please contact FDA's Center for Tobacco Products at 877-287-1373 or asktp@fda.hhs.gov.

You can also find additional information regarding the Tobacco User Fee Program at: https://www.fda.gov/tobacco-products/manufacturing/tobacco-user-fees.

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