Enclosed is the cigar assessment invoice for the first quarter of fiscal year 2026 (FY26 Q1 assessment). Because FDA has received inquiries about a recent court decision relating to "premium cigars," 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] Further, the court of appeals stated "[W]e read the district court's relief as applying only prospectively, without requiring an unwinding of past transactions." *Id*. Consistent with the foregoing language in the U.S. Court of Appeals decision, FDA does not intend to refund past premium cigar user fee payments for fiscal quarters preceding the district court's order.

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. FDA does not currently have information that would enable it to determine what portion of excise taxes paid by cigar manufacturers and importers were for "premium cigars," versus other cigars. Without that information, FDA is currently unable to determine the assessment amount that each manufacturer or importer would owe based on their percentage share, once "premium cigar" portions are excluded. For that reason, the enclosed invoice reflects the fee assessment for all products within the cigar class, including "premium cigars."

FDA does not intend to assess user fees for "premium cigars" for FY26, and if you are a manufacturer or importer of such products, **you may submit one dispute that covers an entire FY on that basis**, using the standard process explained on the assessment invoice. If you do so, your dispute must:

1. include the basis for the dispute

[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).

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2. be submitted in writing
3. be legible and in English
4. be received by FDA no later than 45 days after the date on the assessment notification.

You can submit a dispute by:

- Email (preferred): tobaccouserfees@fda.hhs.gov
- Fax: 301-595-1429 or 301-595-1430
- Mail: Food and Drug Administration
  Center for Tobacco Products
  Document Control Center
  Attn: OM, Division of Financial Management, User Fee Team
  Building 71, Room G335
  10903 New Hampshire Avenue
  Silver Spring, MD 20993-0002

If you are disputing an assessment on the basis of your manufacture or importation of "premium cigars," please add the phrase "Premium Cigars" to the subject line of your email or letter.

Consistent with 21 Code of Federal Regulations (CFR) § 1150.13(e), you may pay the full amount of your assessment now and submit your dispute of the assessment amount with respect to your "premium cigar" products. Alternatively, if you submit a dispute that includes good faith documentation establishing the portion of the assessment that is attributable to your manufacture or importation of "premium cigars," you may choose to withhold that portion of the assessment. In that situation, as an exercise of enforcement discretion, FDA does not intend to seek, or ask others to seek, interest, fees, or penalty charges, or to take any other enforcement or regulatory action relating to your failure to pay the total assessment amount. If, however, the Agency determines you have not sufficiently justified that the portion you withheld accurately reflects your manufacture or importation of "premium cigars," you will be obligated to pay the amount you incorrectly withheld. If it appears that any portion of your withholding and submission of a dispute did not have a good faith basis, FDA may seek, or ask others to seek, interest, fees, and penalties in accordance with the law, including those that accrued from not paying the relevant portion of the invoice in full by the due date.

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;

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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]

For disputes involving "premium cigars," please provide evidentiary documentation that demonstrates your cigars meet these elements.

Good faith documentation refers to evidence that:

- Illustrates the subject tobacco products meet all eight criteria for "premium cigars" set out in the U.S. District Court's August 9, 2023 order.
- Identifies the number of units of "premium cigars," as defined in the court order, removed and not tax exempt; and the Federal excise taxes assessed for those removals.

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."

The above information relates to "premium cigars." For disputing the assessment on any other grounds, as usual, please refer to the assessment invoice and 21 CFR §§ 1150.13(e) and 1150.15.

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.

[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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