



Enclosed is the cigar assessment invoice for the fourth quarter of fiscal year 2023 (FY23 Q4 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<sup>1</sup> “insofar as it applies to premium cigars.” For purposes of its ruling, the 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.<sup>2</sup>

FDA recognizes that, absent further relief, it is bound by the District Court’s order, and in light of that order, the Agency intends to develop a mechanism by which it will not assess fees for cigars that fall within the court’s definition of “premium cigars” for FY23 Q4. 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 a cigar manufacturer or importer were for “premium cigars,” as defined by the court, 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 consistent with the court’s order. For that reason, the enclosed invoice reflects the fee assessment for all products within the cigar class, including “premium cigars.”

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<sup>1</sup> *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).

<sup>2</sup> *Cigar Ass’n of Am. v. FDA*, No. 16-cv-01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023).



It is not FDA's intent to assess user fees for "premium cigars" for FY23 Q4, and if you are a manufacturer or importer of such products, you may dispute the amount of this assessment 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
- (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 email a dispute to [tobaccouserfees@fda.hhs.gov](mailto:tobaccouserfees@fda.hhs.gov) or mail it to:

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 to 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.



Please note that the Agency presently intends and reserves the right to amend its FY23 Q4 assessments to the extent it is able to do so, in light of the information it receives from manufacturers and importers regarding their “premium cigars,” and its ability to develop a mechanism to exclude such fees. The Agency further reserves the right to revise its assessment approach relating to “premium cigars” for some or all of FY23 Q4, pursuant to any appeal of the court’s order or other basis, 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](mailto: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](mailto: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 [askctp@fda.hhs.gov](mailto:askctp@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>.