Dear Industry Member –

You are receiving this notification because the FDA Center for Tobacco Products (CTP) identified you as a domestic manufacturer or importer of cigar tobacco products.

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." 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[2]

FDA recognizes that, absent further relief, it is bound by the District Court's order, and in light of that order, the Agency is working to develop a reporting mechanism that will allow for FDA to identify non-premium cigars which may include an update to Form FDA 3852. In the meantime, domestic manufacturers and importers of cigars may voluntarily report data for "premium cigars".

As part of the monthly report, the regulations require submitting "[t]he units of product, by class, removed and not tax exempt for the prior month and the Federal excise tax it paid, by class, for such removal." FDA uses this and other information to calculate tobacco product user fee assessments. Beginning with your August 2023 removals (reports that were due September 20, 2023), in addition to the currently required information, you may also submit the three data elements below for products that are "premium cigars" as defined in the court order (and described above):

- The number of units removed and not tax exempt (block 10A for manufacturers and 10C for importers)
- The Federal excise taxes assessed for those removals (block 10B for manufacturers and 10D for importers)
- The supporting documentation identifying those removals and associated Federal excise taxes (attached to FDA 3852)

[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).

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FDA suggests domestic manufacturers and importers of cigars use the existing FDA 3852 form, page 2, row 10 to report any additional information; they may enter both the non-premium and premium cigar volume and taxes in cells 10A through 10D as appropriate. Responders may use the current methods of submission for the monthly reports:

- Email: TobaccoUserFees@fda.hhs.gov (preferred method)
- 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

The Agency is continuing evaluate the evolving legal and practical circumstances surrounding premium cigars and will provide further information as it is available.

Here are additional resources if you have questions:

- For questions regarding the Tobacco User Fee Program and other questions concerning monthly reporting of removals 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 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

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