Dear Industry Member –

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

On August 9, 2023, the U.S. District Court for the District of Columbia issued an order[1] vacating FDA's rule[2] deeming tobacco products to be subject to FDA's tobacco product authorities "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.

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.

As part of the monthly report, 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. CTP has recently received questions regarding the cigar data companies should submit as part of their monthly report. In light of these questions, CTP wants to clarify that **it is important that companies still report the volume and Federal excise taxes paid for *all* cigar removals (i.e., inclusive of both non-premium cigars and premium cigars) on their monthly FDA 3852 form**. This information allows FDA to reconcile monthly data and accurately assess the liability of each firm as part of the quarterly invoice process.

As such, if there are any monthly reports you did not previously submit or monthly reports you previously submitted that did not include removal information (i.e., volume and Federal excise taxes paid) for premium cigars—beginning with your August 2023 monthly report—please **submit or update these by September 20, 2024, and include removal information that is inclusive of both non-premium cigars and premium cigars**.

[1] Cigar Ass'n of Am. v. FDA, No. 16-cv-01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023), appeal filed No. 23-5220 (D.C. Cir. Sep. 29, 2023).
[2] *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).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
w ww.fda.gov

In your monthly reports, you may voluntarily break out removal information for non-premium and premium cigars. The FDA 3852 form, page 2, row 10 may be used to report this breakout by entering both the non-premium and premium cigar volume and Federal excise taxes paid in cells 10A through 10D as appropriate. FDA suggests you denote the data using NP for non-premium and P for premium.

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 to evaluate the evolving legal and practical circumstances surrounding premium cigars and will provide further information as it is available. In the meantime, FDA intends to continue to include notices with quarterly tobacco invoices generally explaining how the invoices are calculated and how industry should handle disputes related to premium cigars.

Here are additional resources:

- 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
w ww.fda.gov