

**“Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products”
(OMB Control Number 0910-0749)**

Date: September 2023

The Food and Drug Administration (FDA, us, or we) is submitting this non-substantive change request to incorporate edits to allow for the collection of additional information related to domestic manufacturers and importers of cigars report data for premium cigars. FDA made these edits based on the conforming changes related to the August 9, 2023, U.S. District Court for the District of Columbia order vacating FDA’s rule deeming tobacco products to be subject to FDA’s tobacco product authorities “insofar as it applies to premium cigars.”

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, FDA intends to issue a letter stating domestic manufacturers and importers of cigars may voluntarily report data for “premium cigars.”

As part of the current 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 make tobacco product user fee assessments. Beginning with August 2023 removals (reports that were originally due September 20, 2023), FDA would explain via a letter sent to domestic manufacturers or importers of cigar tobacco products identified that they may also submit the three data elements below for products that are “premium cigars” as defined in the court order:

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

FDA suggests domestic manufacturers and importers of cigars use the existing Form FDA 3852 form, page 2, row 10 to report additional information; they may enter both the non-premium and premium cigar volume and taxes in cells 10A through 10D as necessary (as shown above).

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

For the additional information collected from domestic manufacturers and importers of premium cigars, we estimate an average of 2.5 hours per response for approximately 100 respondents for a total of 3,000 hours.

Tracked Changed Supporting Statement


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