U.S. Food and Drug Administration
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 No. 0910-0749
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) was signed into law. The Tobacco Control Act amended the FD&C Act and granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors

The Food and Drug Administration (FDA) issued a final rule (81 FR 28707) that requires domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FDA expanded its authority by issuing a final rule (81 FR 28973), "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" (Deeming rule), deeming all products that meet the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the FD&C Act. The Deeming rule, among other things, subjected domestic manufacturers and importers of cigars and pipe tobacco to the FD&C Act's user fee requirements. Consistent with the Deeming rule and the requirements of the FD&C Act, this final rule requires the submission of the information needed to calculate user fee assessments for each manufacturer and importer of cigars and pipe tobacco to FDA.

Previously the Food and Drug Administration (FDA) issued a final rule (79 FR 39302) that requires domestic tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The United States Department of Agriculture (USDA) has been collecting this information and providing FDA with the data FDA needs to calculate the amount of user fees assessed to tobacco product manufacturers and importers. USDA ceased collecting this information in fiscal year 2015 (October 2014). USDA's information collection did not require OMB approval, per an exemption by Pub. L. 108-357 section 642 (b)(3). Consistent with the requirements of the FD&C Act, FDA now requires the submission of this information to FDA instead of USDA. FDA is taking this action to ensure that FDA continues to have the information FDA needs to calculate, assess, and collect user fees from domestic manufacturers and importers of tobacco products.

Background

Section 919(a) of the FD&C Act (21 U.S.C. 387s(a)) requires FDA to "assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products" subject to the tobacco product provisions of the FD&C Act (chapter IX of the FD&C Act). The total amount of user fees to be collected for each fiscal year is specified in section 919(b)(1) of the FD&C Act, and under section 919(a) FDA is to assess and collect a proportionate amount each quarter of the fiscal year. The FD&C Act provides for the total assessment to be allocated among the classes of tobacco products. The class allocation is based on each tobacco product class' volume of tobacco product removed[1] into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its share of the market for that tobacco product class.

In specifying how to determine each of these two allocations — to a class of tobacco products and then to a domestic manufacturer or importer within a particular class of tobacco products — section 919 of the FD&C Act references the Fair and Equitable Tobacco Reform Act of 2004 (FETRA, Pub. L. 108-357 (7 U.S.C. 518 *et seq*.)). In determining the user fees to be assessed on each class of tobacco products, section 919(b)(2)(B)(ii) of the FD&C Act provides that the applicable percentage for each tobacco product class "shall be the percentage determined under section 625(c) of [FETRA] for each such class of product for such fiscal year." In determining the user fee to be paid by each company, section 919(b)(4) of the FD&C Act directs that FDA use percentage share information "determined for purposes of allocations under subsections (e) through (h) of section 625 of [FETRA]."

FETRA provides for a Tobacco Transition Payment Program (TTPP) through which eligible former tobacco quota holders and tobacco producers receive payments in 10 equal installments in each fiscal year 2005 through 2014. FETRA provides for the establishment of quarterly assessments on each domestic manufacturer and importer of tobacco products to fund the 10-year TTPP. The last assessment under FETRA was in September 2014.

Under a Memorandum of Understanding (MOU) between FDA and USDA, USDA has been providing FDA with the information on percentage share by class of tobacco products and by individual company within each tobacco product class. In light of the sunset of the TTPP program, FDA is issuing this final rule consistent with section 919(b)(7) of the FD&C Act, which requires that no later than fiscal year 2015, FDA ensures that it will be able to make the determinations necessary for assessing tobacco product user fees.

The following sections of the final rule include collections of information.

§ 1150.5: Under paragraphs (a) and (b) of this section, domestic manufacturers and importers of FDA-regulated tobacco products are required to submit to FDA information that the Agency needs to calculate, assess, and collect user fees. The section provides continuity to domestic manufacturers and importers as it requires them to submit essentially the same information to FDA that they are currently submitting to USDA.

[1] Removal is defined at 26 U.S.C. 5702 as "the removal of tobacco products or cigarette papers or tubes, or any processed tobacco, from the factory or from internal revenue bond under section 5704, as the Secretary [of Treasury] shall by regulation prescribe, or release from customs custody, and shall also include the smuggling or other unlawful importation of such articles into the United States."

§ 1150.5(a): This paragraph describes when and in what manner domestic manufacturers and importers of FDA-regulated tobacco products are required to submit information to FDA. The cost and hourly burden for this section is covered under § 1150.5(b).

§ 1150.5(b)(1) and (b)(2): These paragraphs describe the information that domestic manufacturers and importers of FDA-regulated tobacco products are required to provide monthly. Under § 1150.5(b)(1), each domestic manufacturer and importer submits identifying information, including its name and address, contact name and telephone number, an email address and postal address for FDA notifications, Alcohol and Tobacco Tax and Trade Bureau (TTB) permit number, and Employer Identification Number. Under § 1150.5(b)(2), the manufacturer and importer submits information regarding the total amount of tobacco products, by class, removed into domestic commerce in the prior month and the Federal excise taxes paid, by class, for those removals. § 1150.5(b)(2) requires monthly reports from all domestic manufacturers and importers, and, as is currently required by USDA, entities that had no removals subject to tax during the reporting period are required to report that they had no removals. This type and frequency of reporting are almost identical to what USDA currently collects on its CCC-974 form. Moreover, FDA has available to domestic manufacturers and importers form FDA 3852, a form similar to the USDA CCC-974 form with minor changes reflecting that this information is to be submitted to FDA instead of USDA. The cost and hourly burden for this section contains burden from § 1150.5(a) and from Form FDA 3852.

Form FDA 3852: This form captures the monthly identification and removal information that domestic manufacturers and importers of FDA-regulated tobacco product are required to submit under § 1150.5(b)(1) and (b)(2). The form also directs manufacturers and importers to attach supporting documentation required by § 1150.5(b)(3) (described below). Thus, the burden for this form is covered under § 1150.5(b).

The information captured by § 1150.5(a), (b)(1), (b)(2), and Form FDA 3852 is necessary to provide FDA with the information needed to calculate the user fee to be assessed and collected from each domestic manufacturer and importer.

§ 1150.5(b)(3): This paragraph requires that domestic manufacturers and importers of FDA-regulated tobacco products provide monthly certified copies of the returns or forms related to the removal of tobacco products into domestic commerce and the payment of excise taxes. These reports and forms are referred to by the applicable Internal Revenue Code Authority. Because the specific names of external-to-FDA agency reports and forms may change over time, FDA does not name reports or forms in the final rule. FDA intends to specify the form names in FDA's quarterly notification of assessments to domestic manufacturers and importers, on its Web site, and in Form FDA 3852. Currently the forms are: TTB Form 5220.6; TTB Form 5210.5; TTB 5000.24; and CBP Form 7501.

This information is necessary because collecting the required information enables FDA to determine allocations and verify monthly summary information on which the allocations are based so FDA can accurately assess and collect user fees from domestic manufacturers and importers of FDA-regulated tobacco products. As has been USDA's approach, submission of the information in a summary form along with the supporting documents (i.e., copies of the relevant tax forms) helps ensure that FDA is able to efficiently and accurately identify the

amount of tobacco product removed and subject to Federal excise tax. FDA believes that the required information provides the information the Agency needs to effectively implement section 919 of the FD&C Act. The burden on reporting entities should be relatively low because they will be submitting copies of forms they are currently required to submit under separate laws along with a summary of information from those forms.

§ 1150.13: This section requires that a domestic manufacturer and importer pay an assessment by the last day of the quarter involved. If FDA has not notified the domestic manufacturer or importer of the amount that is required to be remitted 30 calendar days before the end of a fiscal year quarter, the final rule provides that no interest is assessed until 30 calendar days after the date FDA sent notification of the amount owed. This section also requires that payments be submitted in U.S. dollars and in the manner specified in the notification (e.g., check or online payment).

This information is necessary for the FDA to collect assessments, to identify which domestic manufacturers and importers have paid their assessments, and to calculate interest on unpaid manufacturer and importer assessments.

§ 1150.15(a): This section requires that domestic manufacturers and importers submit any dispute in writing, within 45 days of the date of the assessment notification, that the dispute be legible and in English, and that the dispute be sent to the address identified on FDA's tobacco products Web site. If FDA determines that an error occurs in the amount of the assessment, FDA will refund the amount. To ensure finality in FDA's accounts and potential refund obligations, FDA believes it is necessary to have a time limit on disputes over user fee assessments. FDA believes the timeframe identified is adequate to detect a dispute and prepare a written submission to FDA.

This information is necessary to notify FDA of domestic manufacturer or importer disputes. FDA will provide a dated, written response and FDA's response will provide information about how to submit a request for further Agency review.

§ 1150.15(d): This section provides that any request for further Agency review under 21 CFR 10.75 be submitted in writing within 30 days of the date of FDA's response to the dispute (submitted under § 1150.15(a)). FDA believes this timeframe is adequate to detect a continued dispute and to prepare a written submission to FDA. Along with the timeframe in § 1150.15(a), this timeframe ensures finality in FDA's accounts and potential refund obligations.

2. Purpose and Use of the Information Collection

The purpose of the information collection is to require each tobacco product domestic manufacturer or importer to submit to FDA information needed to calculate and assess user fees under section 919 of the FD&C Act. FDA will collect this information to ensure that it has the information needed to calculate, assess, and collect tobacco product manufacturer and importer user fees. In addition, the collection of information allows the domestic manufacturer or importer the ability to request further review of their assessment if there is a dispute over the amount of the user fee assessed by FDA.

3. Use of Improved Information Technology and Burden Reduction

To make reporting requirements for this collection easier for respondents, FDA offers respondents the ability to provide their user fee submission information via an electronic form (Form FDA 3852) which can be completed and mailed via electronic mail or printed and mailed to FDA. Although the form can be submitted either electronically or in paper format, FDA estimates that based on its past experience with submittals, approximately 90 percent of all respondents will submit the information in electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

As referenced in the previous terms of clearance, the data collected under this ICR overlaps with collections of excise tax and import information by Alcohol and Tobacco Tax and Trade Bureau (TTB) and Customs and Border Protection (CBP). However, the TTB and CBP data cannot currently be used by FDA for calculating user fees due to both logistical reasons and restrictions on the use of excise tax information that could be provided to FDA directly by TTB. FDA has had meetings with TTB about establishing a memorandum of understanding (MOU) with TTB to receive information directly from TTB regarding tobacco permit holders and excise tax payments and has fulfilled quarterly reporting requirements to notify OMB of outcomes of these interagency discussions. These meetings have led to the identification of certain legal restrictions that are outlined in the Internal Revenue Code law(s), specifically section 6103, that does not allow for the complete utilization of data received from the TTB and CBP to implement FDA's Tobacco User Fee Program. FDA continues to communicate with the TTB and CBP to obtain certain information from each organization that allows the CTP to verify and validate our records received from industry to ensure accurate tobacco user fee assessments.

5. Impact on Small Businesses or Other Small Entities

All domestic manufacturers and importers of tobacco products subject to regulation under chapter IX of the FD&C Act are affected by this rule, including small businesses. It is likely that about 90 percent of the affected entities would be small (approximately 180 small entities). The actual user fees paid by small entities are likely smaller than those paid by larger businesses because user fees are assessed based on the percentage share by class of tobacco products and by individual company within each tobacco product class.

FDA continues to pursue means of reducing the reporting burden for both small and large respondents to this collection of information and continues to employ the latest technology for receiving user fee information, consistent with the intent of the legislation.

FDA aids small businesses in dealing with the information submission requirements of this collection of information by providing technical, nonfinancial assistance in submitting the information required for user fees.

6. Consequences of Collecting the Information Less Frequently

The collection of information submitted is used to meet the requirements of section 919 of the FD&C Act regarding user fees. Because the information collection is derived from information collected monthly by other agencies (i.e., TTB and CBP), we believe that collecting this information less frequently will not allow FDA to meet its statutory obligations for collecting equitable user fees from domestic manufacturers and importers of tobacco products.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection that would be inconsistent with the regulation.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 09/11/2018 (83 FR 45937). One comment that was not PRA related was received.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift awarded to respondents of this collection of information.

10. Assurance of Privacy Provided to Respondents

All data will be collected with an assurance that the respondents' answers remain private to the extent allowed by law and consistent with the FDA Privacy Act System of Records #09-10-0021 (FDA User Fee System). Private information is protected from disclosure under the Freedom of Information Act (FOIA) under section 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the Agency's regulations (21 CFR part 20).

Privacy is assured by enacting procedures to prevent unauthorized access to respondent data and by preventing the public disclosure of the responses of individual participants.
All electronic data is maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35.

11. Justification for Sensitive Questions

FDA is not asking questions of a sensitive nature in this collection of information, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
1150.5(a), (b)(1) and (2), and Form FDA 3852; General identifying information provided by manufacturers and importers of FDA regulated tobacco products and identification and removal information (monthly)	658	12	7,896	3	23,688
1150.5(b)(3); Certified copies (monthly)	658	12	7,896	1	7,896
1150.13; Submission of user fee information (Identifying information, fee amount, etc. (quarterly)	329	4	1,316	1	1,316
1150.15(a); Submission of user fee dispute (annually)	5	1	5	10	50
1150.15(d); Submission of request for further review of dispute of user fee (annually)	3	1	3	10	30
Total					32,980

FDA estimates that 658 entities will submit tobacco product user fees. The entity count was derived from aggregate data provided by the Alcohol and Tobacco Tax and Trade Bureau (TTB), and reflects that in 2017 there were 192 total permitted manufacturers and 466 permitted importers over all tobacco product types for which TTB collects excise taxes (including cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco, excluding electronic nicotine delivery systems).

The estimate of 658 respondents to provide the information requested from § 1150.5(a), (b)(1) and (2) (21 CFR 1150.5(a), (b)(1) and (2)), and Form FDA 3852 reflects both reports of no removal of tobacco products into domestic commerce and reports of removal of tobacco product into domestic commerce. FDA estimates it will take 3 hours for each of these submission types for a total of 23,688 hours. Under § 1150.5(b)(3), these respondents are also expected to provide monthly certified copies of the returns and forms that relate to the removal of tobacco products into domestic commerce and the payment of Federal excise taxes imposed under chapter 52 of

the Internal Revenue Code of 1986 to FDA. We estimate that each monthly report will take 1 hour for a total of 7,896 hours. The estimate of 329 respondents to submit payment of user fee information under § 1150.13 reflects an average of half the number of domestic manufacturers and importers who may be subject to fees each fiscal quarter. FDA estimates the quarterly submission will take approximately 1 hour for a total of 1,316 hours.

FDA estimates that five of those respondents assessed user fees will dispute the amounts under § 1150.15(a), for a total amount of 50 hours. FDA also estimates that three respondents who dispute their user fees will ask for further review by FDA under § 1150.15(d), for a total amount of 30 hours. FDA has only received one dispute submission since fiscal year 2015. Based on this data, the Agency does not believe we will receive more than five disputes and three requests for further reviews in the next 3 years.

12b. Annualized Cost Burden Estimate

Estimates of the cost of the annual burden are based on an hourly wage rate of $25.28, doubled to $50.56 per hour to account for benefits and overhead. This rate is derived from the May 2017 Department of Labor's Bureau of Labor Statistics National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200. We estimate the annualized cost for compliance with this collection to be $1,667,469.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco product manufacturers and importers	32,980	$50.56	$1,667,469

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no capital, operating, or maintenance cost associated with this information collection.

14. Annualized Cost to Federal Government

Total annual cost to the Federal Government is $232,000, which is the annual salary costs of $116,000 for two Full Time Equivalent employees.

15. Explanation for Program Changes or Adjustments

FDA estimates the total annual burden for this collection of information is 32,980 hours and 17,116 annual responses. The estimated burden for the information collection reflects an overall increase of 16,058 hours and 8,387 annual responses. We attribute this adjustment to an increase in the number of entities submitting tobacco user fee information to FDA.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency has no plans for the tabulation and publication of this collection of information.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with this collection of information.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.