Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

Final Rule

0910-0749
RIN 0910-AG81

ABSTRACT

The Food and Drug Administration (FDA) is issuing a final rule 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 intends to cease collecting this information in fiscal year 2015 (October 2014). Consistent with the requirements of the FD&C Act, FDA is requiring 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.

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SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is issuing a final rule 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 intends to cease 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 will require 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

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) 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.

In the Federal Register of May 31, 2013 (78 FR 32581), FDA issued a notice of proposed rulemaking (NPRM) to add 21 CFR part 1150 to require domestic tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the FD&C Act. This final rule requires domestic tobacco product manufacturers and importers to submit that information.

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 will be 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 (http://www.fda.gov/TobaccoProduct), 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.

This information is necessary to notify FDA of subsequent appeals.

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. Presently, USDA collects this information and provides FDA with the data FDA needs to calculate the amount of user fees assessed to tobacco product manufacturers and importers. USDA intends to cease collecting this information starting in fiscal year 2015 (October 2014). Beginning in fiscal year 2015, 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

In order to make reporting requirements for this collection easier for respondents, FDA is offering 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

FDA will not overlap the collection of this information with USDA. The information collected by USDA will continue to be available to FDA until USDA ceases collecting the information (October 2014).

There may be overlap with collections of excise tax and import information by TTB and Customs and Border Protection (CBP). Our understanding is that there are 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. Our

discussions included a discussion of the legal limitations on FDA's use of any taxpayer specific data provided by TTB. FDA intends to continue working with these parties to further develop means for the sharing of information that FDA could use to calculate and assess tobacco product user fees. In addition, we will explore whether it would be possible, in light of current legal restrictions on the use of individual taxpayer information, for FDA to rely solely on data received from TTB and CBP and thus eliminate the need for this information collection. We intend to report to OIRA on a quarterly basis beginning October 1, 2014, regarding the progress of these meetings until we reach a resolution, which shall be accomplished no later than July 1, 2016.

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. The cost of submitting this information to FDA is not greater than the current cost for small businesses to submit this information to USDA, and small businesses will cease submitting information to USDA when they begin submitting the information to FDA.

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) and is currently provided to USDA on a monthly basis, 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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of May 31, 2013 (78 FR 32581). OMB received no PRA-related comments. FDA received 12 sets of comments on this proposed rule from tobacco product manufacturers, trade associations, and individuals. One comment related to the PRA, suggested that FDA obtain data about product removals directly from TTB. The comment stated that monthly data submissions are unnecessary and unduly burdensome since this information is already collected by TTB. The comment indicated that FDA should require manufacturers to execute a release or waiver permitting TTB to report this information to FDA and that failure to execute such a release or waiver could be construed as an admission of adulteration under section 902(4) of the FD&C Act. However, the comment noted that manufacturers of regulated tobacco products that do not fit within TTB's excise tax structure could submit information directly to FDA. Another comment suggested that FDA seek a legislative amendment to ensure that FDA has access to excise tax data. In contrast, one comment supported FDA's transition plan for submitting data and noted that it should not be burdensome because manufacturers and importers are familiar with the reporting of this information and the submissions will continue to be made to a single Federal agency.

(Response) We agree with the comment that supported FDA's transition plan, because the rule requires that domestic manufacturers and importers submit to FDA the same information that they have been submitting to USDA (i.e., a summary form supported by the relevant tax forms), the impact of this rule should be minimal and not unduly burdensome. The summary form will enable us to efficiently identify the amount of tobacco product removed and subject to Federal excise tax, and the supporting tax forms will enable us to verify the accuracy of the information on the summary form. We believe that submission of information directly to FDA regarding removals and imports is important to ensuring that we have the information necessary to efficiently and accurately calculate the amount of user fees assessed.

In 2011 and 2012, FDA consulted with the USDA staff responsible for implementing the TTPP program. FDA currently has an MOU in place with USDA that addresses the sharing of information related to user fees, and FDA currently uses information that USDA collects as the basis for FDA's assessments and collections.

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's burden estimate is based on information gained from USDA in the collection of data that is similar to this collection of information. The estimated total hour burden of the collection of information is 10,150 hours (Table 1).

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

Table 1.--Estimated Annual Reporting Burden[1]					
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 (b)(2) and Form FDA 3852: General identifying information provided by manufacturers and importers of FDA-regulated tobacco products and identification and removal information (monthly)	200	12	2,400	3	7,200
1150.5(b)(3) Certified Copies (monthly)	200	12	2,400	1	2,400
1150.13 Submission of user fee information with user fee payment (Identifying information, fee amount, etc. (quarterly)	100	4	400	1	400
1150.15(a) Submission of user fee dispute (annually)	10	1	10	10	100
1150.15(d) Submission of request for further review of dispute of user fee (annually)	5	1	5	10	50
Total					**10,150**

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In Table 1, FDA estimates the total annual burden for this collection of information is 10,150 hours. Table 1 describes the annual reporting burden as a result of the provisions set forth in this final rule. FDA's estimated number of respondents is based on information FDA received from USDA regarding the number of reports it receives from domestic manufacturers and importers each month. The estimate of 200 respondents to provide the information requested from § 1150.5(a), (b)(1), and (b)(2), and Form FDA 3852 reflect both reports of no removal of tobacco products into domestic commerce and reports of removal of tobacco product into domestic commerce. Under § 1150.5(b)(3), these respondents are also expected to provide monthly certified copies to FDA of certain returns or forms related to the removal of tobacco products into domestic commerce and the payment of excise taxes. The estimate of 100 respondents to submit payment of user fee information under § 1150.13 reflects an average number of domestic manufacturers and importers who may be subject to fees each fiscal quarter. Although there were no comments on the number of appeals and requests for further review, after discussing internally, we increased our estimate of the number of appeals from 1 to 10, and requests for further review from 1 to 5 in an abundance of caution in case there is an increase in requests for review during the transition from USDA to FDA.

For § 1150.5(a), (b)(1), and (b)(2), and Form FDA 3852, FDA estimates that 200 domestic manufacturers and importers will each submit identifying information (e.g., mailing address, telephone number, e-mail address) and summarized tax information on a monthly basis (12 submissions annually) on Form FDA 3852, resulting in a total burden of 7,200 hours (200 respondents x 12 months x 3 hours). For § 1150.5(b)(3), FDA estimates that 200 domestic manufacturers and importers will each submit, on a monthly basis (12 times annually), 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, resulting in a total burden of 2,400 hours (200 respondents x 12 months x 1 hour per response.)

For § 1150.13, FDA estimates that 100 domestic manufacturers and importers will be submitting user fee payments on a quarterly basis. Therefore, the number of burden hours for this section is 400 hours (100 respondents x 4 submissions per year x 1 hour per response). FDA estimates that 10 of those respondents assessed user fees will dispute the amounts under § 1150.15(a), for a total amount of 100 hours. (10 respondents x 1 dispute submission x 10 hours per response). FDA also estimates that 5 respondents who dispute their user fees will ask for further review by FDA under § 1150.15(d), for a total amount of 50 hours (5 respondents x 1 dispute submission x 10 hours per response).

Total burden hours for this rule are estimated to be 10,150 hours (7,200 + 2,400 + 400 + 100 + 50 hours).

12b. <u>Annualized Cost Burden Estimate</u>

The analysis of impacts in the final rule estimates the annualized cost for compliance with the rule to be $512,981.

Estimates of the cost of the annual burden are based on an hourly wage rate of $26.60, doubled to $53.20 per hour to account for benefits and overhead. This rate is derived from the May 2012 Department of Labor's Bureau of Labor Statistics National Industry-Specific Occupational Employment and Wage Estimates for NAICS.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco product manufacturers and importers	10,150	$50.54	$512,981

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

All respondent burden is reflected in Item 12. 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

This is a new collection of information.

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.