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

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 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 recently expanded its authority by issuing a final rule, "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 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 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.

[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: 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.

§ 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.

The following sections are revisions to the codified as part of the second final rule.

We are finalizing portions of the proposed rule with only minor changes. We amended § 1150.7(a)(1) and (2) to include language from the proposed rule specifying the calculations that

FDA will perform to determine the yearly class allocation for cigars. Moreover, we added § 1150.9(a)(2) to codify the method by which FDA will calculate the percentage share for each domestic manufacturer and importer of cigars. In the proposed rule, we specifically discussed this proposed methodology, requested comment, and reserved § 1150.9(a)(2) for the purpose of including the calculations for manufacturers and importers in the cigar class if they became subject to chapter IX of the FD&C Act. After reviewing comments on the proposed rule, FDA is adding this methodology for cigars to § 1150.9(a)(2) without changes.

We added paragraph (c) to § 1150.5 to require that domestic manufacturers and importers of cigars report data for each prior month in the fiscal year in their first submission under this rule. Once deemed, cigars and pipe tobacco will be subject to user fees under section 919 of the FD&C Act. However, domestic manufacturers and importers of cigars and pipe tobacco will start being assessed fees only at the start of the fiscal year following the effective date of this rule because we can only perform class allocations on a full fiscal year basis. As we discussed in section I.B. of the User Fee proposed rule (78 FR 32583), section 919(b)(5) of the FD&C Act requires FDA to allocate user fees within the cigar class to cigar firms based on the amount of excise taxes those firms paid in the prior fiscal year. This addition to § 1150.5 will ensure that FDA has data for the prior fiscal year necessary to calculate, assess, and collect user fees for domestic manufacturers and importers of cigars in the first fiscal year in which they are assessed fees. We do not need data for the full prior fiscal year from domestic manufacturers and importers of other tobacco products subject to user fees, including pipe tobacco, because percentage share calculations for those classes only requires prior fiscal quarter data.

We added paragraph (d) to § 1150.5 to require that domestic manufacturers and importers of pipe tobacco begin their monthly reporting of data in August, 2016. As noted above, FDA makes percentage share calculations for tobacco products other than cigars using prior fiscal quarter data. Because FDA will begin making percentage share calculations for domestic manufacturers and importers of pipe tobacco beginning in the first fiscal quarter of 2017, FDA does not need pipe tobacco firms to submit data for months prior to the fourth fiscal quarter of 2016. Requiring domestic manufacturers and importers of pipe tobacco to make their first submission of prior month data by the 20th day of August, 2016, ensures FDA will have data for each month of the fourth fiscal quarter in 2016 and will be able to complete percentage share calculations for pipe tobacco firms for the first fiscal quarter of 2017.

Further, in light of the Deeming rule subjecting cigars and pipe tobacco to user fee requirements, we added 21 U.S.C. 387a and 21 CFR 1100.1 to the authority section. Finally, we amended § 1150.5(a) by removing the phrases “that are part of a class of tobacco products that is subject to regulation under chapter IX of the Federal Food, Drug, and Cosmetic Act” and “beginning October 2014.” We made these changes because all classes of tobacco products that are included in the definition of “class of tobacco products” are subject to chapter IX of the FD&C Act and it is no longer necessary to make such a distinction, and because the October 2014 compliance date has passed.

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 ceased in 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). FDA received 12 sets of comments on this proposed rule from tobacco product manufacturers, trade associations, and individuals. We addressed a majority of the comments in the User Fee final rule. We declined to address comments relating to cigars, pipe tobacco, and other deemed products in that document because they were outside of FDA's jurisdiction at the time. Now that the Deeming rule has expanded FDA's authority to cover those products, we address the comments on assessing user fees on tobacco products that FDA deemed subject to chapter IX of the FD&C Act in this section. Additionally, FDA provided an opportunity for public comment on the information collection requirements of the Deeming proposed rule that published in the FEDERAL REGISTER of April 25, 2014 (79 FR 23142). FDA has responded to the comments

received in the preamble to the final rule, and the supporting statement for the Deeming information collections under OMB control number 0910-0768.

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:

Existing Burden

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					**0**

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

New Burden

Table 2.--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), (b)(2), and FDA Form 3852 (Ref. 2) General identifying information provided by manufacturers and importers of FDA regulated tobacco products and Identification and removal information (monthly)	135	12	1,620	3	4,860
1150.5(b)(3) Certified Copies (monthly)	135	12	1,620	1	1,620
1150.13 Submission of user fee information (Identifying information, fee amount, etc. (quarterly)	68[2]	4	272	1	272
1150.15(a) Submission of user fee dispute (annually)	1	1	1	10	10
1150.15(d) Submission of request for further review of dispute of user fee (annually)	1	1	1	10	10
Total					**6,772**

Final Burden

Table 3.--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), (b)(2), and FDA Form 3852 (Ref. 2) General identifying information provided by manufacturers and importers of FDA regulated tobacco products and Identification and removal information (monthly)	335	12	4,020	3	12,060
1150.5(b)(3) Certified Copies (monthly)	335	12	4,020	1	4,020
1150.13 Submission of user fee information (Identifying information, fee amount, etc. (quarterly)	168[2]	4	672	1	672
1150.15(a) Submission of user fee dispute (annually)	11	1	11	10	110
1150.15(d) Submission of request for further review of dispute of user fee (annually)	6	1	6	10	60
Total					**0**

[2] This figure was rounded to the nearest tenth.

Table 2 describes the annual reporting burden of 6,227 hours as a result of the provisions set forth in this proposed rule. Our estimated number of 135 newly deemed respondents (335 total tobacco entities) is based on 2013 summary information obtained from the Alcohol and Tobacco Tax and Trade Bureau (TTB) regarding the number of permitted manufacturers and importers.

As referenced previously, the PRA burden for currently regulated products was previously approved by OMB. The burden analysis for that collection assumed 200 respondents would submit user fees. Therefore given our updated estimate of 335 entities, the total number of new deemed tobacco entities is 135 (335 minus 200 = 135). FDA estimates that there are 113 cigar manufacturers and 74 pipe tobacco manufacturers, as well as 216 importers of cigars and 43 importers of pipe tobacco. However, these estimates from TTB reflect that in 2013 there were 135 total permitted manufacturers and 200 permitted importers over all tobacco product types for which TTB collects excise taxes (including cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-you-own tobacco, excluding electronic nicotine delivery systems). This total is less than the sum across all tobacco product types because some manufacturers and importers produce or import more than one type of tobacco product (we subsequently refer to these entities as poly-manufacturers and poly-importers). As the number of cigar and pipe tobacco manufacturers cannot exceed the number of permitted entities, we use 335 as an upper bound estimate of the number of affected entities. The estimate of 135 respondents reflects both reports of no removal into domestic commerce and reports of removal of tobacco product into domestic commerce. The estimate of 68 respondents reflects an average number of domestic manufacturers and importers who may be subject to fees each fiscal quarter. FDA assumes half the number of respondents will submit quarterly payments to the Agency. Based on our experience with the assessment of user fees for other FDA-regulated products, we estimate that approximately one respondent might appeal an assessment, and one respondent will request for further review of their dispute.

In Table 3, FDA estimates the total annual burden for the new collection of information is 16,922 hours. Table 2 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 335 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 168 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. Our estimate of the number of appeals is 11, and requests for further review are 6 respondents.

For § 1150.5(a), (b)(1), and (b)(2), and Form FDA 3852, FDA estimates that 335 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 12,060 hours. For § 1150.5(b)(3), FDA estimates that 335 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 4,020 hours.

For § 1150.13, FDA estimates that 168 domestic manufacturers and importers will be submitting user fee payments on a quarterly basis. Therefore, the number of burden hours for this section is 672 hours (168 respondents x 4 submissions per year x 1 hour per response). FDA estimates that 11 of those respondents assessed user fees will dispute the amounts under § 1150.15(a), for a total amount of 110 hours. FDA also estimates that 6 respondents who dispute their user fees will ask for further review by FDA under § 1150.15(d), for a total amount of 60 hours.

Total burden hours are estimated to be 24,962 hours.

12b. Annualized Cost Burden Estimate

The analysis of impacts in the final rule estimates the annualized cost for compliance with the rule to be $855,238.

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	16,922	$50.54	$855,238

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

The burden for this collection of information is expected to increase by 6,772 reporting hours due to an expected increase in the number of Tobacco respondents. This adjustment is a result is FDA issuing a final rule 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). Additionally, FDA is extending the Agency's "tobacco product" authorities in the FD&C Act to all other categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products.

The estimated number of respondents will increase by 954 (from 515 to 1,469 respondents) and the annual responses will increase by 3,514 (from 5,215 to 8,729). The currently OMB approved

burden estimate of 10,150 hours will increase by 6,772 hours to equal a total of 16,922 total burden hours.

Activity	Number. of respondents	Total annual responses	Average burden per response	Total hours
1150.5(a), (b)(1), (b)(2), and FDA Form 3852 General identifying information provided by manufacturers and importers of FDA-regulated tobacco products and identification and removal information (monthly) **(Existing)**	200	2,400	3	7,200
1150.5(a), (b)(1), (b)(2), and FDA Form 3852 General identifying information provided by manufacturers and importers of FDA-regulated tobacco products and identification and removal information (monthly) **(New)**	135	1,620	3	4,860

1150.5(a), (b)(1), (b)(2), and FDA Form 3852 General identifying information provided by manufacturers and importers of FDA-regulated tobacco products and identification and removal information (monthly) (**Final)**	335	4,020	3	**12,060**
1150.5(b)(3) Certified Copies (monthly) **(Existing)**	135	1,620	1	1,620
1150.5(b)(3) Certified Copies (monthly) **(New)**	135	12	1,620	1
1150.5(b)(3) Certified Copies (monthly) **(Final)**	335	4,020	1	**4,020**
1150.13 Submission of user fee information. (quarterly) **(Existing)**	100	400	1	400
1150.13 Submission of user fee information. (quarterly) **(New)**	682	272	1	272
1150.13 Submission of user fee information. (quarterly) **(Final, Existing and Deeming**	168	672	1	**672**

Combined)				
1150.15(a) Submission of user fee dispute (annually) **(Existing)**	10	10	10	100
1150.15(a) Submission of user fee dispute (annually) **(New)**	1	1	10	10
1150.15(a) Submission of user fee dispute (annually) **(Final, Existing and Deeming Combined)**	11	11	10	**110**
1150.15(d) Submission of request for further review of dispute of user fee (annually) **(Existing)**	5	5	10	50
1150.15(d) Submission of request for further review of dispute of user fee (annually) **(New)**	1	1	10	10
1150.15(d) Submission of request for further review of dispute of user fee (annually) **(Final, Existing and Deeming Burden Combined)**	6	6	10	**60**
Totals				**16,922**

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.