DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

Docket No. FDA-2012-N-0920

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has determined that this final rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The potential impact on small entities is uncertain, and FDA is unable to rule out the possibility that this final rule may have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

Until 2014, USDA collected information from each domestic manufacturer and importer of tobacco products on the volume of taxable removals and the resulting excise taxes paid for

those removals (7 CFR 1463.6).[1] USDA collected this information using a form that is similar to the form now being required by FDA in this rule.

II. Final Regulatory Impact Analysis

A. Public Comments Concerning the Regulatory Impact Analysis

FDA received comments regarding the implications of the proposed rule and the Federal Food, Drug, and Cosmetic Act (FD&C Act) methodology for calculating user fees on cigars and pipe tobacco. Some of these comments were addressed in the regulatory impact analysis of the user fee final rule, which was published in the Federal Register of July 10, 2014 (79 FR 39302 - 39311). We did not address comments related to cigars or pipe tobacco in that document because they were outside of FDA's jurisdiction at the time. Now that the Deeming Rule expanded FDA's authority to cover these products, those comments are addressed in the body of the final rule.

B. Baseline

Section 919 of the FD&C Act establishes a system of collecting user fees, starting from the enactment of the Tobacco Control Act on June 22, 2009. This general system for collecting user fees has already been implemented and has been operational for more than 5 years.

In order to assess user fees on domestic manufacturers and importers of cigar and pipe tobacco, FDA must collect data on these entities. Currently, FDA only collects data from domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, and roll-your-own

[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."

tobacco. Information on cigar and pipe tobacco entities was previously collected by the USDA through a Memorandum of Understanding (Ref. 1). However, USDA ceased collecting this information at the end of fiscal year 2014. This final rule provides a mechanism for obtaining information similar to what was previously submitted to USDA and is necessary for cigar and pipe tobacco user fee calculations.

Without this final rule, the Agency would have to gather the information in some other way. For this analysis, we assume that the most likely course of action would be for the FDA to obtain the information from other Federal Agencies, which may require additional policy actions. Another possibility is the creation of other policy mechanisms explicitly requiring firms to submit the requisite information. We assume that in the absence of this final rule FDA would likely obtain the information from other Federal Agencies, and we use this scenario as our baseline. Depending on the baseline scenario, the incremental impact of this final rule may differ.

Under the assumed baseline, starting in fiscal year 2015, FDA would obtain the information necessary for assessing user fees on domestic manufacturers and importers of cigar and pipe tobacco directly from Federal Agencies that collect such information. FDA could obtain raw data with which to calculate user fees, or another Agency could compile the information, perform the calculations, and possibly even issue user fee bills on behalf of FDA; in either case, government Agencies would compile the information from existing sources. The form previously used by USDA requested information from forms submitted to the Alcohol and Tobacco Tax and Trade Bureau (TTB) and U.S. Customs and Border Protection (CBP). Therefore, agreements with multiple agencies would likely have to be put into place because it is unlikely that either TTB or CBP has all of the necessary information. The government (whether

FDA or another Agency) would bear the costs of compiling all of the information from the various forms. The difficulty of this task depends on the current format of the information and the amount of work that would be required to put it into a format that can be used by FDA. Because of statutes governing TTB and CBP, without additional policy actions, this system could limit FDA's ability to disclose information supplied by one of these agencies when taking enforcement action or even when sending bills.

C. Number of Affected Entities

The Deeming Rule subjects all domestic manufacturers and importers of cigar and pipe tobacco to user fee requirements. Manufacturers and importers of cigarettes, snuff, chewing tobacco, and roll-your-own tobacco are already required to submit information necessary for the calculation of user fees under a previous rulemaking (79 FR 39302 - 39311). Based on 2013 summary data from the Alcohol and Tobacco Tax and Trade Bureau (TTB) regarding the number of permitted manufacturers and importers, 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, 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, but 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.

D. Impact of the Final Rule

Under the final rule, manufacturers and importers would have to submit information to FDA on a monthly basis, whereas under the baseline they would not have to submit any information to FDA. There are private sector costs associated with the initial change from no reporting to information submission. Manufacturers and importers would need to read the regulation or any notification potentially sent to them to explain the transition. They would need to adapt to using the submission form. FDA estimates that this transition would take 3 hours per manufacturer or importer. Valuing time at the average tobacco manufacturing industry wage of $26.56 per hour, doubled to $53.12 per hour to account for benefits and overhead, this transition cost would be $159.36 per manufacturer or importer.[2] Table 1 shows that the total transition cost would be approximately $53,000.

Given the large amount of poly-manufacturing and poly-importing implied by the estimated number of affected entities discussed previously, many manufacturers are likely submitting these forms to FDA for other tobacco products and will not need additional time to become familiar with the requirements. However, it is difficult to estimate the amount of poly-manufacturing and poly-importing in the cigar and pipe tobacco categories themselves and thus we cannot account for this overlap in the costs estimates below.

Table 1: Initial Private Sector Transition Cost

Number of entities	335
Number of hours	3
Cost ($)	**53,386**

[2] May 2014 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200-Tobacco Manufacturing: http://www.bls.gov/oes/current/naics4_312200.htm

In addition to the initial transition costs, there are annual compliance costs associated with this final rule. All of the entities affected by this final rule will be required on a monthly basis to submit the FDA form containing certain identifying information, the number of units introduced into domestic commerce in the prior month, and excise taxes paid for such introduction into domestic commerce.[3] This form is estimated to take 3 hours to complete. In addition, each entity would be required on a monthly basis to submit certified copies of the returns and forms that relate to the introduction of tobacco products into domestic commerce and the payment of Federal excise taxes imposed. Submitting copies of these forms is estimated to take 1 hour each month. These submissions are required even if the quantity introduced into domestic commerce during the month in question is 0. The total burden is 48 hours annually per manufacturer or importer, valued at $2,549.76. We do not consider any time cost associated with remitting payment for user fees (or the distributional effect of the aggregate amount of the user fees shifted from manufacturers and importers of currently regulated products to cigars and pipes as considered in the Deeming rule) because user fees will be assessed and paid regardless of how section 919(b)(7)(B) of the FD&C Act is implemented. Similarly, we do not consider the time cost of disputing or appealing user fee assessments because similar mechanisms would be in place regardless of how section 919(b)(7)(B) is implemented.

Table 2 shows the annual private sector compliance costs of this final rule, relative to the baseline, would be approximately $855,000.

[3] The technical term for introducing units of product into domestic commerce is "removal" as defined in footnote 1.

Table 2: Annual Private Sector Compliance Cost	
FDA form	
Number of entities	335
Annual submissions	12
Hours per submission	3
Cost ($)	**640,627**
Copies of other forms	
Number of entities	335
Annual submissions	12
Hours per submission	1
Cost ($)	**213,542**
Total Cost ($)	**854,170**

Under the baseline, government workers (at FDA or another Agency) would do the work of compiling the information contained in forms from various Federal Agencies. Therefore, government costs would decrease with this final rule in an amount that would approximately offset the private sector costs discussed previously. Government setup costs for learning how to compile the necessary data from the various relevant forms would be reduced or eliminated, partly offsetting the private sector transition cost. In addition, government costs for actually compiling this information on an ongoing basis would be eliminated. If the government is not able to perform these functions as efficiently as manufacturers and importers, the reduction in government costs would exceed the increase in private compliance costs, resulting in a net benefit to society. If government is able to perform these functions more efficiently, the increase in private costs would exceed the reduction in government costs, resulting in a net cost to society. Therefore, requiring industry to compile this information and submit it to FDA could result in either a net societal cost or benefit, the size of which is expected to be very small.

This final rule will have other impacts. It will allow FDA to have full access to the information used for calculating and billing user fees. This will be beneficial for resolving

disputes and taking enforcement action if a firm fails to pay. By contrast, under the baseline (in which FDA obtains information from other Federal Agencies), taking enforcement action or even billing for user fees would be more challenging without additional policy mechanisms. In addition, because FDA will not have to rely on cooperation from other Agencies, this final rule will likely result in greater efficiency. Under the baseline, the possibility would exist that at some time in the future the other Agencies would no longer be willing or able to provide the necessary data. FDA would then face the question of how to ensure that it can obtain the relevant information. Therefore, compared with the baseline, this final rule can be expected to eliminate the potential need for additional policy mechanisms and allow the collection of user fees to proceed more smoothly than it would without such mechanisms.

III. Small Entity Effects

FDA has examined the economic implications of this final rule for small entities as required by the Regulatory Flexibility Act. If a final rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA is unable to rule out the possibility that this final rule may have a significant economic impact on a substantial number of small entities. Consequently, this analysis, together with other relevant sections of this analysis and the final rule, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Numbers Affected

Under the baseline, this final rule imposes costs on domestic manufacturers and importers of cigar and pipe tobacco. In order to evaluate the potential impact on small entities, we first present Small Business Administration (SBA) size thresholds for small business classification and the most comparable U.S. Census size thresholds in Table 3 (Refs. 2, 3, 4, and 5).[4] This table is organized by North American Industry Classification System Category (NAICS). Cigar and pipe tobacco entities do not have their own NAICS classification. Rather, these entities belong to broader NAICS groups. Table 3 indicates two sets of NAICS categories for tobacco product manufacturing. An unknown number of these manufacturers would be affected by this rule, since not all of these entities produce cigar or pipe tobacco products. Importers may be designated as wholesalers or retailers. Most tobacco product-importing wholesalers would be classified as "tobacco and tobacco product merchant wholesalers." Although many different categories of retailers (such as grocery and convenience stores) may sell tobacco products, those most likely to import them are specialty tobacco shops and non-store retailers operating electronically or through delivery services. For tobacco manufacturers and tobacco product retailers, the proportion found to be small will be underestimated because the Census size category is lower than the SBA threshold.

[4] Tobacco product manufacturers (and importers) are considered small under the FD&C Act if they employ fewer than 350 people. This definition is used in determining the deadline for compliance with certain requirements under the FD&C Act. However, the SBA's definition of small is applicable to the small entity analysis required under the Regulatory Flexibility Act.

Table 3 - SBA Size Standards and Census Size Categories for Tobacco Product Manufacturers and Importers

	NAICS	Description of NAICS Category	SBA Size Standard (employees or $million)	Census Size Category (employees or $million)
Potential Tobacco Product Manufacturers				
	312229	Other Tobacco Product Manufacturing		500
	312230	Tobacco Manufacturing	1,000	500
Potential Tobacco Product Importers				
Wholesalers				
	424940	Tobacco and Tobacco Product Merchant Wholesalers	100	100
Retailers				
	453991	Tobacco Stores	$7.5	$5.0
	454111	Electronic Shopping	$32.5	$25.0
	454113	Mail-Order Houses	$38.5	$25.0

We use additional sources of data in order to estimate the proportion of cigar and pipe tobacco entities that are small. Table 4 shows the number of businesses with employees in each of the categories described above, the number qualifying as small according to the census size standard, and the percent qualifying as small. Statistics of U.S. Businesses data from 2011 indicate 90 percent of "other tobacco product manufacturing" businesses with employees are small (Ref. 3). Statistics of U.S. Businesses data from 2012 indicate that 89 percent of "tobacco manufacturing" businesses with employees are small (Ref. 4). Note that the "tobacco manufacturing" category in NAICS 2012 includes cigarette manufacturing. These data also show that 91 percent of "tobacco and tobacco product merchant wholesalers" qualify as small. Data from the 2007 Economic Census show that 94 percent of tobacco shops with payroll are

small, while 98 percent of "electronic shopping" and 94 percent of "mail-order" retailers are small (Ref. 5).

We do not know what proportion of affected entities would fall into each of these categories, but based on the percentages found in Table 4, it is likely that about 90 percent of the affected entities would be small. This implies that approximately 302 (0.9×335) small entities would be affected.

Table 4 - Estimated Percentage of Small Firms Among Firms with Employees

NAICS	Description of NAICS Category	Number of Firms	Number of Firms Below Census Size Standard	Percentage of Small Firms (%)
312229	Other Tobacco Product Manufacturing	61	55	90%
312230	Tobacco Manufacturing	93	83	89%
424940	Tobacco and Tobacco Product Merchant Wholesalers	1,158	1,068	92%
453991	Tobacco Stores	4,025	3,793	94%
454111	Electronic Shopping	11,646	11,374	98%
454113	Mail-Order Houses	5,645	5,281	94%

B. Costs for Small Entities

Table 5 shows the potential effect of this rule on small tobacco product manufacturers. In section II.D of this analysis we estimate that the one-time private sector transition cost is $159.36 per manufacturer or importer and the annual compliance cost is $2,549.76, compared with the baseline. These costs are not expected to vary significantly by entity size. Compliance costs are compared with average value of shipments, determined for establishments based on 2002 Census data (Ref. 6). With this data, we assume that most small manufacturers operate a single establishment. We use 2002 data because more recent Census data suppress information about value of shipments by tobacco product establishment size in order to safeguard confidentiality.

The distribution of small tobacco product manufacturing establishments by employment size and the average value of shipments by employment size may have changed since 2002. Therefore, we are uncertain whether the effect of this final rule will be as estimated in Table 5.

Table 5 - Potential Impact on Tobacco Product Manufacturers

Type of Manufacturing Establishment	Average Value of Shipments (million $)	Annual Compliance Cost as a % of Avg. Value of Shipments	Transition Cost as a % of Avg. Value of Shipments
Other Tobacco Product (All)	$43.7	0.01%	0.00%
1 to 4 employees	$0.3	0.74%	0.05%
5 to 9 employees	$1.5	0.17%	0.01%
10 to 19 employees	$3.8	0.07%	0.00%
20 to 49 employees	$11.5	0.02%	0.00%
50 to 99 employees	$17.2	0.01%	0.00%
100 to 249 employees	$64.3	0.00%	0.00%
250 to 499 employees	$273.4	0.00%	0.00%

With this caveat in mind, Table 5 shows that the annual compliance cost rounds to 0.01 percent of the average value of shipments for other tobacco manufacturing establishments. For establishments with 1 to 4 employees, the annual compliance cost is 0.74 percent of the average value of shipments, which represents an unknown portion of profits. There were 38 manufacturing establishments with 1 to 4 employees in 2002, but we do not have enough information to determine how many manufacturers of cigar or pipe tobacco would be affected by the final rule. Therefore, we are unable to rule out the possibility that this final rule may have a significant economic impact on a substantial number of small entities.

C. Regulatory Relief

One alternative that might reduce costs for small entities would be to exempt firms from reporting in a particular month if they did not introduce any units of any tobacco products for which user fees are assessed into domestic commerce. This would reduce costs for entities that

would otherwise have to report zero units. A drawback to this approach is that FDA would have difficulties distinguishing a firm that failed to report from a firm that introduced zero units into domestic commerce in a particular month.

Another alternative would be to require submission of either the FDA form and not copies of forms submitted to other agencies, or vice versa. While submission of only one set of reporting information to FDA would reduce costs, it would potentially cause implementation or enforcement problems. Without receiving copies of forms submitted to other Federal Agencies, FDA may have trouble verifying information submitted on an FDA form. Forms submitted to other agencies were designed for other purposes; it is doubtful that FDA could calculate user fees as efficiently using copies of other agencies' forms.

IV. Conclusion

Compared with the baseline, this final rule will impose private costs on industry to submit data to FDA on a monthly basis, with an approximately offsetting reduction in government information collection costs. The net effect of this may be a small social cost or benefit. This final rule also allows FDA to have full access to the data needed for calculating and billing user fees and resolves impediments that may otherwise exist over FDA's ability to use the data for its intended purpose. This final rule can be expected to eliminate the potential need for additional regulatory mechanisms to collect information and allow user fee assessment to proceed more smoothly than it could otherwise.

V. References

1. Memorandum of Understanding on the Sharing of Tobacco Market Share Information Between the Food and Drug Administration, U.S. Department of Health and Human Services and the Commodity Credit Corporation and Farm Service Agency, U.S. Department of Agriculture, August 2009.

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