DEPARTMENT OF HEALTH AND HUMAN SERVICES
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

Docket No. FDA-2012-N-0920

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

Economics Staff
Office of Planning
Office of Policy, Planning and Legislation
Office of the Commissioner
July 2014

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 (Public Law 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). The Agency believes that this final rule is not 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 $141 million, using the most current (2012) 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.

II. Final Regulatory Impact Analysis

A. Public Comments Concerning the Regulatory Impact Analysis

FDA received comments covering topics such as compliance with the Regulatory Flexibility Act, the effect of this rule on small businesses, and the implications of the Federal Food, Drug, and Cosmetic Act (FD&C Act) methodology for calculating user fees.

(Comment 1) One comment restated our obligation under the Regulatory Flexibility Act to consider the impact of any proposed rule on small entities and analyze regulatory options that would minimize any significant impact of a rule on small entities. The comment correctly stated that FDA acknowledged uncertainty in the impact on small entities and could not rule out the possibility of a significant impact on a substantial number of small entities. The comment asserted that the proposed rule "may subject small manufacturers to significant economic consequences that FDA has not been able to adequately calculate or determine, and user fees could possibly amount to a 'substantial portion of profits' for certain low-volume manufacturers." The discussion on this topic was concluded by stating concern about the "disproportionate impact" that the proposed rule may have on the smallest entities and urging FDA to give more careful consideration to the "unreasonable financial burden" being placed on small manufacturers and recognize differences in the scale and resources of regulated entities.

(Response) This comment reflects a misunderstanding of our statement about the effect of the annual private sector compliance cost and erroneously attributes it to user fees. User fees are already collected under the FD&C Act, and this rule does not change the method with which they are calculated. Therefore, this rule has no incremental effect on user fees, and user fees are not the subject of FDA's analysis of the potential impact on small entities.

This rule requires tobacco manufacturers and importers who may be subject to user fees to submit to FDA the information necessary for calculating user fees. Using our primary

baseline, the burden on any entity includes the one-time cost of transitioning to submitting this information to FDA rather than the U.S. Department of Agriculture (USDA) and the recurring time cost for submitting the necessary forms on a monthly basis.[1] We disagree with the characterization that there are "significant economic consequences that FDA has not been able to adequately calculate or determine" or that the rule imposes an "unreasonable financial burden." In estimating the impact of the proposed rule, we showed that the one-time transition cost was estimated to be 3 hours and the annual time cost was 48 hours per manufacturer or importer, with time valued at $50.54 per hour. We did not restate the per-entity costs in the initial regulatory flexibility analysis, which may have caused confusion; we have added this information for clarity.

The main uncertainty is not the absolute size of the burden, but rather the size of the burden relative to the profits of the very smallest entities. This uncertainty arises because the most recent data providing adequate breakdown of tobacco manufacturers by size is from 2002, we lack data on profits of small manufacturers and can only look at cost relative to average value of shipments, and we cannot determine how many tobacco manufacturers within each size category are affected by the rule. Precisely because a burden that does not vary by entity size can have a disproportionate effect on the smallest entities, we have given this the most thorough and careful consideration possible with available data; no commenter submitted additional data regarding revenues or profits of small entities, or even the number of smaller entities affected. The FD&C Act requires FDA to ensure that we are able to determine class allocations and manufacturer and importer shares for user fees beginning not later than fiscal year 2015. In

[1] We have clarified that the private sector burden analyzed in the small entity analysis is calculated with respect to the primary baseline, which yields the largest burden.

section III.C of this analysis, we have expanded our discussion of alternatives that would reduce costs for small entities.

(Comment 2) A comment suggests that FDA needs to consider the differences in taxation of cigars compared to other taxable classes of tobacco products and assess the rule's "potentially inequitable impact on cigar manufacturers and importers." The comment asserts that the different excise tax rates applied within the cigar class would have the "unintended consequence" of causing manufacturers and importers of similar products to pay dramatically different amounts in user fees.

The comment further states that large cigars have different first wholesale prices, and that some of these pricing differences are due to economies of scale or other efficiency factors. Companies with significant economies of scale would benefit by paying lower user fees due to their products being produced at lower cost, while small manufacturers and importers would be disadvantaged.

In conclusion, the comment states that FDA should consider these differences in determining the impact of deeming and user fee regulations on small entities and must "carefully assess the impact that user fees will have on small cigar manufacturers before it implements a structure that economically disadvantages these companies."

(Response) This final rule does not finalize the portions of the proposed rule relating to the yearly allocation to the cigar class and does not respond to comments about the assessment of fees on individual cigar manufacturers and importers. Accordingly, we are not addressing comments related to cigars in this final regulatory impact analysis.

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 4 years.

In order to bill user fees, FDA must have data on the domestic manufacturers and importers required to pay. Currently, the necessary information is provided by USDA through a Memorandum of Understanding (Ref. 1). Section 919(b)(7)(B) of the FD&C Act (21 U.S.C. 387s(b)(7)(B)) requires the Secretary, starting no later than fiscal year 2015, to ensure that FDA is able to determine the yearly class allocations and the shares of each domestic manufacturer and importer within each class. This final rule provides a mechanism for obtaining the information necessary for these user fee calculations. Without this final rule, the Agency would have to gather the information in some other way. Our forecast of the method by which FDA would obtain this information in the absence of rulemaking provides the baseline for this final rule. While it is difficult to determine exactly how this would be done without a regulation establishing the process, section 919(b)(7)(B) of the FD&C Act would be implemented in some way and FDA would continue to collect user fees.

Methods for FDA to ensure that it can obtain the information needed to calculate or collect user fees starting in fiscal year 2015 could include obtaining the information from a Federal Agency (or Agencies) other than USDA or forming an agreement under which USDA continues to collect this information as they currently do, even though USDA will not need the information after fiscal year 2014. Either of these options might require new legislation to implement. Another possibility is for Congress to pass legislation explicitly requiring firms to submit the requisite information but without the need for an implementing regulation. We assume that in the absence of regulation, FDA would most likely obtain the information from

Federal Agencies other than USDA, and we use this as our primary baseline. This provides the greatest contrast to the final rule from the perspective of regulated industry. We also discuss how the final rule would compare to the other possible baseline scenarios.

Under our primary baseline, starting in fiscal year 2015, FDA would obtain the information necessary for collecting user fees directly from Federal Agencies (other than USDA) 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 currently used by USDA requests 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 TTB and CBP 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 legislation, 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

This final rule applies to all entities that manufacture or import any tobacco product that belongs to one of the classes of tobacco products listed in section 919 of the FD&C Act that is currently regulated under chapter IX of the FD&C Act. Currently, manufacturers and importers of cigarettes, snuff, chewing tobacco, and roll-your-own tobacco fit these criteria. Based on

discussions with another Federal Agency, FDA estimates that 200 such entities would be affected by this final rule.

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 primary baseline they would not have to submit any information to FDA. Although FDA is proposing an information collection very similar to that currently conducted by USDA, there would be some private sector costs associated with the transition from USDA to FDA collection. 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 new form and update the address for submission.[2] FDA estimates that this transition would take 3 hours per manufacturer or importer. Valuing time at the average tobacco manufacturing industry wage of $26.60[3] per hour, doubled to $53.20 per hour to account for benefits and overhead, this transition cost would be $159.60 per manufacturer or importer. Table 1 shows that the total transition cost would be approximately $32,000.

Table 1: Private Sector Transition Cost

No. of entities	200
No. of hours	3
Cost ($)	31,920

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[4] in the prior month, and excise taxes paid for such introduction into domestic commerce, by tobacco product class. This form is estimated to take 3 hours to complete. In addition, each entity would be required on a monthly basis to submit certified

[2] The FDA form is very similar to the USDA form.
[3] May 2012 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200--Tobacco Manufacturing. http://www.bls.gov/oes/
[4] The technical term for this is "removal," which is defined in footnote 2 of the preamble to the final rule.

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 per manufacturer or importer, valued at $2,553.60. 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 tobacco manufacturers and importers to government) 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 costs of complying with this final rule, compared with the primary baseline, would be approximately $511,000.

Table 2--Annual Private Sector Compliance Cost

FDA form	
No. of entities	200
Annual submissions	12
Hours per submission	3
Cost ($)	383,040
Copies of other forms	
No. of entities	200
Annual submissions	12
Hours per submission	1
Cost ($)	127,680
Total Cost ($)	510,720

Under the primary baseline, government workers (at FDA or another Agency) would do the work of compiling the information contained in various TTB and CBP forms that is needed to calculate and bill user fees. 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 be in control of 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 Federal Agencies other than USDA), taking enforcement action or even billing for user fees could be more challenging without additional legislation. In addition, because FDA will not have to rely on cooperation from another Agency, this final rule will likely result in greater efficiency. Under the primary 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 same question it faces today as to how to ensure that it can obtain the relevant data. Therefore, compared with the primary baseline, this final rule can be expected to eliminate the potential need for additional legislation and allow the collection of user fees after 2014 to proceed more smoothly than it would without legislation.

E. Alternative Baselines

The primary baseline assumes that starting in fiscal year 2015, FDA would obtain the information necessary for collecting user fees directly from another Federal Agency (or Agencies) other than USDA. However, there are other ways that FDA might obtain the necessary data.

Under one alternative baseline, USDA would continue to collect the information and perform market share calculations as it does today. Because industry would be responsible for compiling and submitting the necessary information under either this baseline or the final rule, there would be no ongoing incremental cost to industry or to society as a whole. Under this baseline scenario, the only industry cost of this final rule would be the cost of the transition. This would be a social cost (there would be no offsetting cost reduction) because if USDA were to continue to collect the information as it does today, there would be no learning or transition cost for government or industry. However, because USDA's program sunsets after fiscal year 2014, it is not clear that they could continue to collect this information without new legislation. Therefore, the final rule will eliminate the potential need for new legislation or the possibility FDA could not obtain market share information without new legislation. Finally, if the information is collected for FDA's sole use, it would arguably be more efficient over the long run for FDA to collect the information itself. Combining the information collection and use in one Agency would yield some societal benefit in the form of cost savings.

Under another possible baseline, Congress could pass legislation explicitly requiring firms to submit the information we propose to collect in this rule without the need for issuing an implementing regulation. In terms of the mechanics of the process (the transition of the information collection to FDA and the ongoing need for industry to compile and submit the

data), the final rule will have no effect under this scenario. However, issuance of this rule will make such legislation unnecessary.

III. Final Regulatory Flexibility Analysis

A. Numbers Affected

Under the primary baseline, this final rule imposes costs on domestic tobacco product manufacturers and importers. U.S. Census data provide some insight into the proportion of such entities that may be small. All cigarette manufacturers would be affected by this rule, while an unknown proportion of other tobacco product manufacturers would be affected. Importers are not identified in the Census, but instead 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. Table 3 shows the Small Business Administration (SBA) size thresholds for small businesses in each of these categories, as well as the most comparable size categories available from the U.S. Census (Refs. 2, 3, and 4).[5] 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.

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)
Tobacco Product Manufacturers				

[5] 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.

	312221	Cigarette Manufacturing		500
	312229	Other Tobacco Product Manufacturing		500
	312230	Tobacco Manufacturing	1,000	
Potential Tobacco Product Importers				
Wholesalers				
	424940	Tobacco and Tobacco Product Merchant Wholesalers	100	100
Retailers				
	453991	Tobacco Stores	$7.0	$5.00
	454111	Electronic Shopping	$30.0	$25.00
	454113	Mail-Order Houses	$35.5	$25.00

Table 4 shows the number of businesses with employees in each of the categories described previously, the number qualifying as small according to the Census size standard, and the percent qualifying as small. Statistics of U.S. Businesses data from 2010 indicate 87 percent of cigarette manufacturing and 89 percent of other tobacco product manufacturing businesses with employees are small (Ref. 3). 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. 4). 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 180 (0.9×200) 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 (%)
312221	Cigarette Manufacturing	30	26	87%

312229	Other Tobacco Product Manufacturing	55	49	89%
424940	Tobacco and Tobacco Product Merchant Wholesalers	1,064	973	91%
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. We estimate in section II.D of this analysis that the one-time private sector transition cost is $159.60 per manufacturer or importer and the annual compliance cost is $2,553.60, compared to the primary baseline.[6] (These costs are not expected to vary significantly by entity size.) Compliance costs are compared to average value of shipments, determined for establishments based on 2002 Census data (Ref. 5). We assume that most small manufacturers operate a single establishment. We use 2002 data rather than 2007 data because 2007 data suppress most 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 the same today as estimated in table 5.

With this caveat in mind, we see in table 5 that the annual compliance cost rounds to 0 percent of the average value of shipments for cigarette manufacturing establishments; we do not

[6] Comparison to the primary baseline yields the highest private sector compliance costs. Under the alternate baseline in which USDA continues to collect the necessary information on behalf of FDA, only the private sector transition cost would be attributable to the final rule. Under the alternate baseline in which Congress passes a law explicitly requiring manufacturers and importers to submit the necessary information to FDA, there is no burden attributable to the final rule.

have data to evaluate how this varies by cigarette manufacturer size. The annual compliance cost is 0.01 percent of the average value of shipments for all other tobacco product manufacturing establishments; for other tobacco product manufacturing establishments with 1 to 4 employees, the annual compliance cost is 0.74 percent of average value of shipments, which could be a substantial portion of profits. There were 38 such other tobacco product manufacturing establishments in 2002, but we do not have enough information to determine how many manufactured snuff, chewing tobacco, or roll-your-own tobacco and would therefore 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.

Table 5--Potential Impact on Tobacco Product Manufacturers (by Size)

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
Cigarette (All)	2,304	0.00%	0.00%
Other Tobacco Product (All)	44	0.01%	0.00%
1 to 4 employees	0.3	0.74%	0.05%
5 to 9 employees	2	0.17%	0.01%
10 to 19 employees	4	0.07%	0.00%
20 to 49 employees	12	0.02%	0.00%
50 to 99 employees	17	0.01%	0.00%
100 to 249 employees	64	0.00%	0.00%
250 to 499 employees	273	0.00%	0.00%

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 or copies of forms submitted to other agencies. While this would reduce costs, it would potentially cause implementation or enforcement problems. (To implement its Tobacco Transition Payment Program, USDA currently requires submission of both a USDA form and copies of forms submitted to other agencies.) 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 primary 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 be in control of the data needed for calculating and billing user fees and resolves impediments that may otherwise exist to FDA's ability to use the data for its intended purpose. Compared with other possible baseline scenarios, this final rule can be expected to eliminate the potential need for additional legislation and allow the collection of user fees after 2014 to proceed more smoothly than it could without legislation.

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.

2. U.S. Small Business Administration, 2013, Table of Size Standards. http://www.sba.gov/content/table-small-business-size-standards, accessed October 2013.

3. U.S. Census Bureau, Statistics of U.S. Businesses (SUSB), Latest SUSB Annual Data, U.S., All Industries, 2010, http://www.census.gov/econ/susb/ accessed November 2013.

4. U.S. Census Bureau, American FactFinder, Establishment and Firm Size: Summary Statistics by Sales Size of Firms for the United States: 2007, 2007 Economic Census, Retail Trade, Subject Series, http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_44SSSZ4&prodType=table.

5. U.S. Census Bureau, American FactFinder, "2002 Economic Census, Manufacturing: Industry Series: Industry Statistics by Employment Size: 2002," http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2002_US_31I4&prodType=table.