Report to the House Committee on Appropriations

TOBACCO PRODUCT USER FEES

Report in Response to

FY 2019 Consolidated Appropriations Act

U.S. Food and Drug Administration

/Norman E. Sharpless/ Date 09/18/2019

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Executive Summary

On February 15, 2019, the Consolidated Appropriations Act, 2019 (P.L. 116-6), was enacted into law, which provided appropriations under the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill for the fiscal year (FY) ending September 30, 2019. The accompanying House Report 115-706 directed the Food and Drug Administration (FDA or the Agency) to submit planned expenditures and obligations and a status of tobacco product applications.

This report responds to the request by providing FY18 planned expenditures, FY18 actual obligations, and FY19 planned expenditures. The report details activities, contracts, and objectives to include a description of program areas. The report also includes the status of received, pending (open), and closed tobacco product applications by product class for FY16, FY17, FY18, and the first quarter of FY19.

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I. Introduction

On Feb. 15, 2019, the Consolidated Appropriations Act, 2019 (P.L. 116-6), was enacted into law, which provided appropriations under the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill for the fiscal year (FY) ending September 30, 2019. The accompanying House Report 115-706 directed the Food and Drug Administration (FDA or the Agency) to report on tobacco product user fees:

> "*Tobacco Product User Fees.—The Committee directs the FDA to submit a report to the Committees and made publicly available online on the planned expenditure and obligation of user fees for the current fiscal year within 60 days of enactment of this Act. The report shall include the amount of carryover and unobligated balances from the prior fiscal year and planned obligations and expenditures for the current fiscal year based upon the total of the new and existing amounts available. The report shall identify the type and amount of activities, contracts, and objectives to be implemented, including but not limited to public education campaigns, scientific research, communications, and product application processing and review for the current and prior fiscal year. The report shall also include a status of submitted, pending, and approved tobacco product applications per each regulatory pathway and class as defined by the Tobacco Control Act, and subsequent regulations, for the past three fiscal years and planned for the current fiscal year."*

In response to this directive, FDA prepared the following report.

II. FY 2018 Obligations/FY 2019 Expenditures

FY 2018 obligations and planned FY 2019 expenditures listed by program area are included in the chart below. Please note that product application processing and review is not tracked as a separate program area, primarily because this activity is driven by portions of various staff salaries. Additional information about product application processing is below.

	FY 2018 Planned (dollars in millions)		**FY 2018 Actual Obligations** (dollars in millions)		**FY 2019 Planned** (dollars in millions)	
Program Area	**Acquisitions**	**Personnel/ Operating**	**Acquisitions**	**Personnel/ Operating**	**Acquisitions**	**Personnel/ Operating**
Scientific Research and Research Infrastructure	$ 183.3	$ 59.3	$ 181.0	$ 55.9	$ 204.6	$ 57.0
Compliance and Enforcement	$ 93.0	$ 35.1	$ 83.6	$ 35.9	$ 92.1	$ 36.2
Public Education Campaigns	$ 144.7	$ 5.4	$ 152.2	$ 6.0	$ 139.2	$ 6.9
Communications	$ 10.3	$ 5.4	$ 10.2	$ 6.0	$ 6.5	$ 6.9
Leadership, Management Oversight, and Administrative	$ 3.9	$ 23.6	$ 5.3	$ 24.8	$ 4.4	$ 26.0
Overhead[1]	$ 114.0	$ 26.3	$ 98.3	$ 26.4	$ 106.8	$ 28.1
Total	**$ 549.1**	**$ 155.1**	**$ 530.6**	**$ 155.0**	**$ 553.6**	**$ 161.1**
	Total Planned: $704.2		**Total Obligations: $685.6**		**Total Planned: $714.7**	
Carryover balance from FY 2018 (dollars in millions): $239[2]						

The Center for Tobacco Products is fully funded by tobacco user fees, and such fees are authorized to remain available until expended.

Planned expenditures in FY18 was $704M with actual obligations of $685M. Compliance and Enforcement costs were lower than planned due to changes in contract requirements and cost for several IT, product surveillance, and retail inspections contract awards. Overhead costs came in lower than planned mostly due to a project for a new FDA/CTP facility coming in under budget, as well as lower rent costs due to a delayed move-in date at the new facility. Public Education

[1] Significant investments have been made in information technology that directly supports the product application review process.

[2] Carryover can vary from year to year based on when user fee payments are received from industry. Carryover exists due to tobacco industry user fees being collected at the end of each quarter, so most of the fourth quarter collections are not available for obligation until the first quarter of the following fiscal year. Therefore, there will always be a carryover balance equal to at least the fourth quarter projected collections.

Campaigns costs were higher than planned due to reallocated resources to further enhance youth prevention and adult cessation efforts and, in particular, new initiatives to combat the epidemic of youth e-cigarette use.

FY19 planned expenditures is $714.7M. The fluctuating acquisitions research budget is a result of collecting data for the Population Assessment of Tobacco and Health (PATH) Study and the National Youth Tobacco Survey (NYTS) every other year. The Public Education Campaigns budget also fluctuates due to differences in contract structure and campaign strategies.

Description of Program Areas

Scientific Research and Research Infrastructure: Informs FDA's efforts to achieve our goals of tobacco prevention and cessation, and reducing tobacco harms.

Compliance and Enforcement: Enforcement of the Federal Food, Drug, and Cosmetic Act as amended by the Tobacco Control Act and implementing regulations, including Regulations for Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents. Includes the FDA Office of Regulatory Affairs (ORA).

Public Education Campaigns: Public education campaigns in concert with regulatory action to reduce tobacco use and improve public health.

Communications: Campaign-specific websites where target audiences can seek additional information about the harms of tobacco product use and connections to resources for quitting.

Leadership, Management Oversight, and Administrative Services: Leadership and management oversight of all tobacco program operations and activities to support the programmatic mission of the Center.

Overhead: Includes IT infrastructure, centralized expenses, General Services Administration rent, other rent and rent-related services, and FDA Headquarters.

III. Product Application Processing Resources

The review of product applications is done by staff in the Center for Tobacco Products' (CTP) Office of Science (OS) and Office of Compliance and Enforcement (OCE) and is therefore primarily driven by salary expenses. OS staff have primary responsibility for product review, which includes premarket review of new tobacco products and modified risk tobacco products (MRTPs). OS also performs assessment of potentially false/misleading product claims and monitors adverse events and industry reports. Approximately 83 percent of OS staff spends some time on product review. Of that, CTP estimates that 68 percent of the staff spends at least 50 percent of their time on product review. OCE staff also assists with product review by monitoring compliance with registration and listing requirements and review of labeling and advertising contained in product applications. Approximately 18 percent of OCE staff spends some time on product review. Of that, CTP estimates that 15 percent of the staff spends at least 50 percent of their time on product review activities. Because many of the same staff conduct Scientific Research (including research to inform product review) and Compliance and Enforcement efforts, separate cost figures are not available. Additional support is provided by the Agency's Office of Chief Counsel (OCC) for application review and appeals, and CTP's Office of the Center Director (OCD) for appeals. Approximately 34 percent of OCC staff working on tobacco regularly spends a portion of their time on application review and appeals, and 3 percent of OCD staff regularly spends a portion of their time on appeals.

IV. Status of Product Applications

Review of product applications is a critical component of FDA's comprehensive tobacco product regulation. In reviewing tobacco product applications, FDA evaluates both new products and MRTPs and determines whether such products can be marketed. This is one of FDA's most important consumer protection responsibilities.

The Agency has taken many steps to set clear expectations for industry and to improve timeframes for product review, including increasing scientific staffing, establishing performance measures that set timeframes for reviewing for substantial equivalence (SE) reports, providing feedback to industry, holding meetings with industry, developing resources to help companies provide complete submissions, and sending letters and other communications to clarify expectations for industry. The Agency has also issued multiple guidance documents related to premarket review and hosted training webinars, including:

- Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends
- Meetings with Industry and Investigators on the Research and Development of Tobacco Products: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-industry-and-investigators-research-and-development-tobacco-products
- Tobacco Product Master Files: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files
- Small Entity Compliance Guide: National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/national-environmental-policy-act-environmental-assessments-tobacco-products-categorical-exclusions
- Modified Risk Tobacco Product Applications (Draft Guidance): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modified-risk-tobacco-product-applications
- Applications for Premarket Review of New Tobacco Products (Draft Guidance): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applications-premarket-review-new-tobacco-products
- Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/demonstrating-substantial-equivalence-new-tobacco-product-responses-frequently-asked-questions
- Webinars:
    - PMTA for ENDS: https://www.youtube.com/watch?v=oZ6273lanZ4&feature=youtu.be
    - Meeting with Office of Science: https://www.youtube.com/watch?v=B1yEoQoUgvk&feature=youtu.be

- Environmental Considerations for Tobacco Product Applications Submitted to CTP: http://fda.yorkcast.com/webcast/Play/1eb98c2084e8418b91703db8b23f20511d
- Timing and Tips – Newly Deemed Tobacco Product Applications: https://www.youtube.com/watch?v=0vGaTepE3c4&feature=youtu.be

FDA recognizes that continuous work to improve the product review process is imperative. This includes issuing additional foundational rules. A proposed rule that would establish requirements for the content and format of reports manufacturers must send to the Agency to demonstrate the SE of a new tobacco product published in the *Federal Register* on April 2, 2019 (https://www.federalregister.gov/documents/2019/04/02/2019-05787/content-and-format-of-substantial-equivalence-reports-food-and-drug-administration-actions-on). The proposed rule would also establish the general procedures the Agency intends to follow when evaluating these submissions. In addition, the proposed regulation would further clarify the "rules of the road" for what information the FDA needs in order to review and potentially allow new tobacco products to come to market.

FDA also recently posted six appendices on our website to assist manufacturers preparing SE Reports (https://www.fda.gov/tobacco-products/substantial-equivalence/common-issues-found-substantial-equivalence-reports-0). These appendices, which are broken down by product type, highlight common deficiencies that may result in an unfavorable SE decision.

In addition, FDA is actively working on proposed rules regarding Premarket Tobacco Product Applications (PMTA) and Modified Risk Tobacco Product Applications (MRTPA), which will provide further detail on the information that should be included in these applications.

FDA is taking a number of actions to provide more information to industry while continuing to work on these proposed rules. In October 2018, FDA held a 2-day public meeting to address common issues in applications, including PMTAs and MRTPAs, and responded to questions from industry (https://www.fda.gov/tobacco-products/ctp-newsroom/tobacco-product-application-review-public-meeting). FDA has also made its application review decision letters public, except for information that is trade secret or otherwise confidential commercial information. Additionally, FDA often grants requests by prospective MRTPA and PMTA applicants for pre-submission meetings to help resolve questions about product application content and organization.

The status of tobacco product applications received through each of the past 3 fiscal years, and through part of the current fiscal year, is included in the tables below.

Provisional Substantial Equivalence (SE) Reports[3,4]

Application Status	Product Class	Cumulative through FY16	Cumulative through FY17	Cumulative through FY18	Cumulative through 6/30/2019
Received	Cigarettes	2,351	2,351	2,351	2,362
	RYO	642	642	642	646
	Smokeless	588	588	588	589
	Other	18	18	18	18
	Total	**3,599**	**3,599**	**3,599**	**3,615**
Open	Cigarettes	1920	1755	781	539
	RYO	420	375	73	26
	Smokeless	480	470	204	118
	Other	0	0	0	0
	Total	**2,820**	**2,600**	**1,058**	**683**
Closed*	Cigarettes	431	596	1,570	1,823
	RYO	222	267	569	620
	Smokeless	108	118	384	471
	Other	18	18	18	18
	Total	**779**	**999**	**2,541**	**2,932**

*Closed includes refuse-to-accept, refuse-to-file, issuance of an order, special advice/information request, removed-from-review, withdrawn, or closure due to administrative issues. Please note that 1,390 reports were removed from review as of June 30, 2019.

[3] SE reports received before March 23, 2011, for products first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States between February 15, 2007, and March 22, 2011, are considered "provisional," and the products covered by those reports can remain on the market unless FDA issues an order finding the product "not substantially equivalent."

[4] The number of applications received during an FY may change slightly over time due to a number of factors, including identification of additional new products within a single submission and reclassifying a SE report from "provisional" to "regular."

Regular Substantial Equivalence Reports[5,6]

Application Status	Product Class	Cumulative through FY16	Cumulative through FY17	Cumulative through FY18	Cumulative through 6/30/2019
Received	Cigarettes	1,086	1,131	1,169	1,278
	RYO	919	943	974	985
	Smokeless	257	300	332	401
	Deemed	247	270	273	305
	Total	**2,509**	**2,644**	**2,748**	**2,969**
Open	Cigarettes	551	115	29	77
	RYO	244	74	23	8
	Smokeless	121	89	39	37
	Deemed	1	22	3	22
	Total	**917**	**300**	**94**	**144**
Closed*	Cigarettes	535	1016	1140	1,201
	RYO	675	869	951	977
	Smokeless	136	211	293	364
	Deemed	246	248	270	283
	Total	**1,592**	**2,344**	**2,654**	**2,825**

*Closed includes refuse-to-accept, refuse-to-file, issuance of an order, special advice/information request, withdrawn, or closure due to administrative issues.

[5] SE Reports that are received after March 22, 2011, and/or concern new tobacco products not first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States between February 15, 2007, and March 22, 2011, are "regular" reports. Products covered by those reports cannot be legally marketed unless FDA first issues a finding of substantial equivalence.

[6] The number of applications received during an FY may change slightly over time due to a number of factors, including identification of additional new products within a single submission and reclassifying a SE report from "provisional" to "regular."

Exemption Requests[7,8]

Application Status	Product Class	Cumulative through FY16	Cumulative through FY17	Cumulative through FY18	Cumulative through 6/30/2019
Received	Cigarettes	37	77	143	403
	RYO	7	7	7	10
	Smokeless	50	50	51	54
	Deemed	0	0	1	21
	Total	**94**	**134**	**202**	**488**
Open	Cigarettes	1	4	9	102
	RYO	0	0	0	2
	Smokeless	15	0	1	6
	Deemed	0	0	0	0
	Total	**16**	**4**	**10**	**110**
Closed*	Cigarettes	36	73	134	301
	RYO	7	7	7	8
	Smokeless	35	50	50	48
	Deemed	0	0	1	21
	Total	**78**	**130**	**192**	**378**

*Closed includes refuse-to-accept, refuse-to-file, issuance of an order, special advice/information request, withdrawn, or closure due to administrative issues.

[7] Requests for exemption from SE is an alternative to SE in which the only change to a legally marketed product is to an additive, the modification to the product is minor, a full substantial equivalence report is not necessary to ensure that permitting the tobacco products to be marketed is appropriate for the protection of public health, and an exemption from SE is otherwise appropriate.

[8] The number of applications received during an FY may change slightly over time due to a number of factors, including identification of additional new products within a single submission.

Premarket Tobacco Applications (PMTA)[9]

Application Status	Product Class	Cumulative through FY16	Cumulative through FY17	Cumulative through FY18	Cumulative through 6/30/2019
Received	Cigarettes	0	6	7	11
	RYO	3	3	3	3
	Smokeless	8	14	14	14
	Deemed	364	369	373	373
	Total	**375**	**392**	**397**	**401**
Open	Cigarettes	0	3	4	2
	RYO	0	0	0	0
	Smokeless	0	6	6	6
	Deemed	0	0	4	4
	Total	**0**	**9**	**14**	**12**
Closed*	Cigarettes	0	3	3	9
	RYO	3	3	3	3
	Smokeless	8	8	8	8
	Deemed	364	369	369	369
	Total	**375**	**383**	**383**	**389**

*Closed includes refuse-to-accept, refuse-to-file, issuance of an order, special advice/information request, withdrawn, or closure due to administrative issues.

[9] The number of applications received during an FY may change slightly over time due to a number of factors, including identification of additional new products within a single submission.

Modified Risk Tobacco Applications (MRTPA)[10,11]

Application Status	Product Class	Cumulative through FY16	Cumulative through FY17	Cumulative through FY18	Cumulative through 6/30/2019
Received	Cigarettes	7	10	10	14
	RYO	0	0	0	0
	Smokeless	12	18	19	19
	Deemed	8	8	8	9
	Total	**27**	**36**	**37**	**42**
Open	Cigarettes	2	3	3	6
	RYO	0	0	0	0
	Smokeless	8	6	7	15
	Deemed	8	0	0	0
	Total	**18**	**9**	**10**	**21**
Closed*	Cigarettes	5	7	7	8
	RYO	0	0	0	0
	Smokeless	4	12	12	4
	Deemed	0	8	8	9
	Total	**9**	**27**	**27**	**21**

*Closed includes refuse-to-accept, refuse-to-file, issuance of an order, special advice/information request, response, withdrawn, or closure due to administrative issues.

[10] Before an MRTP may be introduced or delivered for introduction into interstate commerce, there must be an order in effect issued under 21 U.S.C. § 387k(g) with respect to that product.

[11] The number of applications received during an FY may change slightly over time due to a number of factors, including identification of additional new products within a single submission.