Report to the House Committee on Appropriations

TOBACCO PRODUCT USER FEES

Report in Response to

FY 2018 Consolidated Appropriations Act

U.S. Food and Drug Administration

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I. Introduction

On March 23, 2018, the Consolidated Appropriations Act, 2018 (P.L.115-141), was enacted. It provided appropriations under the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2018, for the fiscal year ending September 30, 2018. The accompanying House Report 115-232 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 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.*
>
> *Tobacco Product User Fees.—The agreement directs the FDA to make the report on Tobacco Product User Fees described in H. Rpt. 115-232 publicly available on its website within 60 days of enactment of the Act."*

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

II. FY 2017 Obligations/FY 2018 Expenditures

FY 2017 obligations and planned FY 2018 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 2017 Actual Obligations (dollars in millions)		**FY 2018 Planned** (dollars in millions)	
Program Area	**Acquisitions**	**Personnel and Operating**	**Acquisitions**	**Personnel and Operating**
Scientific Research and Research Infrastructure[1]	$ 239.3	$ 49.5	$ 183.3	$ 59.3
Compliance and Enforcement	$ 76.1	$ 33.1	$ 93.0	$ 35.1
Public Education Campaigns	$ 228.1	$ 5.0	$ 144.7	$ 5.4
Communications	$ 8.2	$ 5.0	$ 10.3	$ 5.4
Leadership, Management Oversight, and Administrative	$ 2.2	$ 24.6	$ 3.9	$ 23.6
Overhead[2]	$ 102.9	$ 15.5	$ 114.0	$ 26.3
Total	**$ 656.8**	**$ 132.7**	**$ 549.1**	**$ 155.1**
	Total Obligations: $789.5		**Total Planned: $704.2**	
Carryover balance from FY 2017 (dollars in millions): $223[3]				

[1]The fluctuating acquisitions research budget is a result of collecting the data for the Population Assessment of Tobacco and Health Study and the National Youth Tobacco Survey every other year.

[2]Significant investments have been made in Information Technology that directly supports the product application review process.

[3]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.

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 Office of Regulatory Affairs.

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 Adminisration 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 82 percent of OS staff spends some time on product review. Of that, we estimate that 70 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 21 percent of OCE staff spends some time on product review. Of that, we estimate that 12 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.

FDA announced on April 5, 2018, that we are removing about 1,500 provisional SE applications from review. The Agency did so after concluding that these products are less likely to raise different questions of public health. Therefore, the products will not undergo any further review and can continue to be legally marketed so long as they do not undergo further changes or do not fall under a few other exceptions that would pull the products back into the review queue.

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[4]

Application Status	Product Class	Cumulative through FY15	Cumulative through FY16	Cumulative through FY17	Cumulative through 4/30/2018
Received	Cigarettes	2,350	2,350	2,350	2,350
	RYO	645	645	645	645
	Smokeless	588	588	588	588
	Other	18	18	18	18
	Total	**3,601**	**3,601**	**3,601**	**3,601**
Pending	Cigarettes	2,105	1,919	1,754	1,144
	RYO	470	423	378	123
	Smokeless	495	480	470	268
	Other	0	0	0	0
	Total	**3,070**	**2,822**	**2,602**	**1,535**
Closed*	Cigarettes	245	431	596	1,206
	RYO	175	222	267	522
	Smokeless	93	108	118	320
	Other	18	18	18	18
	Total	**531**	**779**	**999**	**2,066**

*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 929 reports were removed from review as of April 30, but we estimate 1,500 provisional products will ultimately be removed from review, depending on information provided by the applicant.

[4] SE reports received before March 23, 2011, for statutorily-regulated new products introduced into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to March 22, 2011, are considered "provisional," and the products covered by those reports can remain on the market unless FDA finds that they are "not substantially equivalent."

Regular Substantial Equivalence (SE) Reports[5]

Application Status	Product Class	Cumulative through FY15	Cumulative through FY16	Cumulative through FY17	Cumulative through 4/30/2018
Received	Cigarettes	956	1,084	1,126	1,142
	RYO	805	915	939	964
	Smokeless	230	257	300	326
	Deemed	0	247	270	272
	Total	**1,991**	**2,503**	**2,635**	**2,704**
Pending	Cigarettes	517	549	128	67
	RYO	211	388	72	37
	Smokeless	92	121	114	81
	Deemed	0	1	22	3
	Total	**820**	**1,059**	**336**	**188**
Closed*	Cigarettes	439	535	998	1,075
	RYO	594	527	867	927
	Smokeless	138	136	186	245
	Deemed	0	246	248	269
	Total	**1,171**	**1,444**	**2,299**	**2,516**

*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 received on or after March 23, 2011. Products covered by "regular" reports cannot be legally marketed in the United States unless FDA authorizes the marketing of the product through one of the three pathways.

Exemption Requests[6]

Application Status	Product Class	Cumulative through FY15	Cumulative through FY16	Cumulative through FY17	Cumulative through 4/30/2018
Received	Cigarettes	37	37	77	98
	RYO	7	7	7	7
	Smokeless	31	50	50	50
	Deemed	0	0	0	0
	Total	**75**	**94**	**134**	**155**
Pending	Cigarettes	4	1	4	8
	RYO	0	0	0	0
	Smokeless	12	15	9	9
	Deemed	0	0	0	0
	Total	**16**	**16**	**13**	**17**
Closed*	Cigarettes	33	36	73	90
	RYO	7	7	7	7
	Smokeless	19	35	41	41
	Deemed	0	0	0	0
	Total	**59**	**78**	**121**	**138**

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

[6] 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, and 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.

Premarket Tobacco Applications

Application Status	Product Class	Cumulative through FY15	Cumulative through FY16	Cumulative through FY17	Cumulative through 4/30/2018
Received	Cigarettes	0	0	6	6
	RYO	3	3	3	3
	Smokeless	8	8	14	14
	Deemed	1	364	369	369
	Total	**12**	**375**	**392**	**392**
Pending	Cigarettes	0	0	3	3
	RYO	0	0	0	0
	Smokeless	8	0	6	6
	Deemed	0	0	0	0
	Total	**8**	**0**	**9**	**9**
Closed*	Cigarettes	0	0	3	3
	RYO	3	3	3	3
	Smokeless	0	8	8	8
	Deemed	1	364	369	369
	Total	**4**	**375**	**383**	**383**

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

Modified Risk Tobacco Applications[7]

Application Status	Product Class	Cumulative through FY15	Cumulative through FY16	Cumulative through FY17	Cumulative through 4/30/2018
Received	Cigarettes	5	7	10	10
	RYO	0	0	0	0
	Smokeless	12	12	18	19
	Deemed	0	8	8	8
	Total	**17**	**27**	**36**	**37**
Pending	Cigarettes	0	2	3	3
	RYO	0	0	0	0
	Smokeless	10	8	6	7
	Deemed	0	8	0	0
	Total	**10**	**18**	**9**	**10**
Closed*	Cigarettes	5	5	7	7
	RYO	0	0	0	0
	Smokeless	2	4	12	12
	Deemed	0	0	8	8
	Total	**7**	**9**	**27**	**27**

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

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