REPORT TO CONGRESS

UNITED STATES TOBACCO PRODUCT EXPORTS THAT DO NOT CONFORM TO TOBACCO PRODUCT STANDARDS

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Submitted Pursuant to

Section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act

U.S. Food and Drug Administration

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EXECUTIVE SUMMARY

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and granted authority to the Food and Drug Administration (FDA or the Agency) to regulate tobacco products, was enacted in 2009. One of the provisions of the Tobacco Control Act requires FDA to report to Congress annually on the export of U.S. tobacco products that do not conform to U.S. tobacco product standards. In addition, the provision requires the Agency to assess the public health impact of these exports and to provide recommendations for mitigating any negative public health impact of such exports.

This is the fifth report submitted to Congress by FDA. The report outlines the Agency's effort to capture data as it relates to the export of tobacco products that do not conform to tobacco product standards. FDA's conclusions in this report are the same as those issued in the 2016 report. Currently, there is only one tobacco product standard applicable: the prohibition on cigarettes or their component parts containing characterizing flavors other than tobacco or menthol. The Agency has no evidence of U.S. exports of tobacco products that do not conform to tobacco product standards established under the FD&C Act, specifically cigarettes or their component parts with prohibited characterizing flavors. Consequently, as FDA concluded in its 2016 report, there is no evidence on which to base analyses of the nature, extent, and destination of tobacco product exports that do not conform to tobacco product standards, public health implications of such exports, and policy alternatives to reduce any negative public health impact of them. A number of sources were used to develop this report and confirm that there are no documented instances of the export of tobacco products that do not conform to currently applicable tobacco product standards.

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INTRODUCTION

The Tobacco Control Act, which amended the FD&C Act and granted authority to FDA to regulate tobacco products, was enacted in 2009.

This report is in response to section 801(p)(1) of the FD&C Act, which states:

> *Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—*
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> *(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;*
> *(B) the public health implications of such exports, including any evidence of a negative public health impact; and*
> (C) *recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.*[1]

TOBACCO PRODUCT STANDARDS

The FD&C Act establishes two tobacco product standard special rules and allows the Secretary of Health and Human Services to revise these standards or adopt additional standards through rulemaking.[2] The first tobacco product standard states that:

> *Beginning three months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.*[3]

The second tobacco product standard states that:

> *Beginning two years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not*

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[1] FD&C Act Sec. 801(p)(1)
[2] FD&C Act Sec. 907
[3] FD&C Act Sec. 907(a)(1)(A)

use tobacco, including foreign grown tobacco that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal Law to domestically grown tobacco.[4]

The FD&C Act does not establish any tolerance limits for pesticide chemical residues that apply to domestically grown tobacco. To determine whether there are pesticide residue tolerance levels applicable to domestic tobacco, FDA previously consulted with the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). According to USDA and EPA, there are currently no established tolerance limits for pesticide chemical residues that apply to domestically grown tobacco.

The Secretary has not finalized any additional tobacco product standards, although, in 2016, FDA finalized a rule to bring additional categories of tobacco products under its authority.[5] At this time, the only applicable tobacco product standard is the characterizing flavor ban described in section 907(a)(1)(A) of the FD&C Act, which applies only to cigarettes and their component parts.

NATURE AND EXTENT OF U. S. TOBACCO PRODUCT EXPORTS THAT DO NOT CONFORM TO TOBACCO PRODUCT STANDARDS

Section 801(e)(1) of the FD&C Act permits the export of products that do not conform with established tobacco product standards if those exports comply with requirements set forth in that section.[6] FDA has not found evidence that flavored cigarettes or their component parts are being exported for consumption abroad. The only U.S. tobacco product exports that would not conform to U.S. tobacco product standards would be cigarettes or their component parts (including the tobacco, filters, or paper) that contain a characterizing flavor (other than tobacco or menthol).

Pursuant to its authority under the FD&C Act, FDA began conducting biennial inspections of registered tobacco product manufacturers in October 2011. As part of this inspection process, FDA requests information from manufacturers on tobacco products being exported and includes the information in its inspection report. FDA currently inspects 50 percent of registered establishments each fiscal year to meet the biennial requirement. As of June 30, 2017, the Agency has conducted 296 inspections of registered establishments. Based on those establishment inspection reports that have been finalized, FDA has found no evidence, through its inspections, of the exportation of non-conforming flavored cigarettes or their component parts (including the tobacco, filters, or paper).

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[4] FD&C Act Sec. 907(a)(1)(B)

[5] 81 FR 28973

[6] FD&C Act Sec. 801(e)(1) states that "[a] food, drug, device, tobacco product, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act, and a tobacco product intended for export shall not be deemed to be in violation of section 906(e), 907, 911, or 920(a), if it—(A) accords to the specifications of the foreign purchaser, (B) is not in conflict with the laws of the country to which it is intended for export, (C) is labeled on the outside of the shipping package that it is intended for export, and (D) is not sold or offered for sale in domestic commerce."

In addition, FDA queried other government entities to help document the extent of tobacco product exports that do not conform to tobacco product standards. However, FDA was unable to identify any U.S. government agency that required exporters to keep or report records of their shipments in a manner that would identify a flavored tobacco product of any type.

FDA reviewed the Alcohol and Tobacco Tax and Trade Bureau's (TTB) reporting requirements and found that flavored cigarettes and their component parts are not reported separately from cigarettes in general. As it did for the previous reports, FDA contacted TTB, and TTB again confirmed this finding. .

FDA again consulted the USDA's Foreign Agricultural Service (FAS) website database, which reports the amount of U.S. tobacco product exports, and found that the database does not indicate whether any of the tobacco product exports contain characterizing flavors.

The Agency also examined the Tobacco Information Service database on the website of the Tobacco Merchants Association, a non-governmental agency, and found no data on cigarettes or their component parts with characterizing flavors. Additionally, FDA reviewed the data collected by the U.S. Census Bureau (Census) under Schedule B, a numbering system administered by Census that classifies all exported products, and found that, while exports of cigarettes are reported under Schedule B, cigarettes and their component parts with characterizing flavors are not reported separately. FDA has confirmed that this remains the case.

As stated in the previous reports that were submitted to Congress, FDA requested a change to the exporting codes used by Census that would allow the Agency to identify exports of flavored cigarettes or their component parts. The request was sent to the Committee for Statistical Annotation of the Tariff Schedules (484(f) Committee), comprised of the U.S. Customs and Border Protection, the U.S. International Trade Commission, and Census. This is an interagency committee that reviews requests for changes to the statistical reporting requirements of Schedule B for exports. FDA's request was denied in November 2011 because Census determined that there were not significant exports of flavored cigarettes or cigarette paper. Census made this determination based on its review of export data regarding cigarette tobacco and cigarette paper from August 2010 to July 2011. Census reviewed export data by specific exporter, surveying companies responsible for 94.8 percent of the cigarette trade and 96.4 percent of the cigarette paper trade. Census asked whether the companies were exporting any flavored cigarettes or cigarette papers. The companies responded that, as a result of the domestic ban on characterizing flavors, they halted their production of flavored cigarettes for export. Consequently, Census has not attempted to obtain information beyond that obtained in their 2011 survey.

BACKGROUND ON TOBACCO PRODUCT EXPORTS

The volume of manufactured tobacco products exported from the United States[7] has declined significantly over the last decade. The total value of exported manufactured tobacco products

[7] This definition of manufactured tobacco products is captured from USDA FAS data, which only captures agricultural products. Electronic cigarettes and other non-agricultural tobacco products and their component parts are not included, and a source has yet to be identified to track exports of these products.

declined from $3.8 billion in 1999 to $176 million in 2015 (Table 1). As noted in FDA's previous report to Congress, this decline was primarily a result of large U.S. manufacturers selling off their international businesses or forming subsidiaries located in foreign countries. Prior to these divestitures, U.S. companies had already expanded overseas production to accommodate international markets.[8] Since 1999, many U.S. tobacco companies have merged or sold portions of their companies to other tobacco manufacturers. Some recent examples include:

- In the spring of 2015, Japan Tobacco, Inc. (JTI) acquired Logic Technology Development, LLC, which was the largest independently owned electronic-cigarette company in the United States. The acquisition was announced in a July 28, 2015, press release from JTI.[9]

- On June 12, 2015, Reynolds American, Inc. (RAI) acquired Lorillard, Inc. for $27.4 billion, and several RAI and Lorillard brands were sold to Imperial Tobacco for $7.1 billion. [10] In the divestiture transactions, subsidiaries of RAI sold the KOOL, Salem, Winston, Maverick and blu eCigs brands, and other assets and liabilities, to ITG Brands, LLC, a subsidiary of Imperial Tobacco Group, PLC, for total consideration of approximately $7.1 billion in cash. [11]

- In May 6, 2016, Xcaliber International acquired Tantus Tobacco, LLC.[12]

In 2011, the U.S. Government Accountability Office (GAO) completed a report to Congress on illicit trade that noted "the leading U.S. cigarette manufacturers have split or sold their international businesses and now sell almost exclusively in the U.S. market. … Reynolds American is the one exception among the leading tobacco companies, and manufactures its Natural American Spirit brand cigarettes for export to Asian markets."[13] This brand, however, does not include any cigarettes marketed with characterizing flavors.[14]

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[8] U.S. Gov't Accountability Off.,GAO-11-313, Illicit Tobacco: Various Schemes are Used to Avoid Taxes and Fees 5, 8 (2011) available at http://www.gao.gov/assets/320/316372.pdf.

[9] JT Completes Acquisition of leading e-cigarette Company Logic – Press Release. http://www.jti.com/files/5014/3806/5554/JT_Logic_closing_release_July_2015.pdf

[10] Chris Isidore, *Reynolds, Lorillard in Tobacco Merger*, CNN Money (July 15, 2014: 10:22 AM), http://money.cnn.com/2014/07/15/news/companies/tobacco-merger/index.html.

[11] Reynolds American Incorporated, accessed August 23, 2107, from http://www.reynoldsamerican.com/About-Us/Press-Releases/Press-Release-Details-/2015/Reynolds-American-completes-acquisition-of-Lorillard-and-related-divestitures/default.aspx.

[12] Vonder Harr, M. (2016). Xcaliber International Acquires Tantus Tobacco. http://www.cspdailynews.com/category-news/tobacco/articles/xcaliber-international-acquires-tantus-tobacco

[13] U.S. Gov't Accountability Off., GAO-11-313, Illicit Tobacco: Various Schemes are Used to Evade Taxes and Fees 8 (2011). The GAO report named only RAI as a U.S. manufacturer that currently exports cigarettes. FDA was unable to locate any export data about other manufacturers' brands.

[14] Santa Fe Natural Tobacco Company, accessed April 11, 2016, from https://www.sfntc.com/site/ourProduct/overview/

Table 1. Value of U.S. Exports of Manufactured Tobacco Products in 1999, 2009, and 2015[15, 16]
(in Thousands of U.S. Dollars)

Product	1999	2009	2015
Cigars, Cigarettes	3,250,873	454,456	124,418
Other Tobacco Products	625,945	35,024	51,538
Total	3,876,818	489,480	175,956

DESTINATION OF U.S. TOBACCO PRODUCT EXPORTS

While there is no evidence of regulated exports of U.S. tobacco products that do not conform to tobacco product standards, there are data documenting the destination of U.S. tobacco product exports in general. USDA FAS data for 2015 indicate that tobacco products (including unmanufactured tobacco) totaling approximately $423 million are exported from the United States to over 100 countries. These tobacco product exports represent .003 percent of all U.S. agricultural exports, which are valued at $133 billion.[17] Of the total amount of U.S.-manufactured tobacco product exports in 2015, $256.2 million were cigarette exports. As shown in Table 2, Japan, Mexico, the United Arab Emirates, the Netherlands, and Hong Kong —none of which ban the import or use of flavored tobacco products—receive 96.35 percent of U.S. cigarette exports combined.

Table 2. Top Five Recipients of U.S. Cigarette Exports in 2015[18]

Trade Partner	Number of Sticks (Millions)	Percentage
Japan	16,383.4	92.9
Mexico	239.8	1.36
United Arab Emirates	160.7	0.91
Netherlands	135.8	0.77
Hong Kong	72.8	0.41
Other	641.4	3.64
Total	17,633.9	99.99*

*Total does not equal 100 percent due to rounding.

As previously noted, FDA has no evidence that any of these exported cigarettes had characterizing flavors (other than tobacco or menthol).

[15] USDA FAS, accessed July 28, 2016, from www.fas.usda.gov/GATS/default.aspx.
[16] *Manufactured tobacco products* consist of cigarettes, cigars, cheroots, smokeless, water pipe, roll-your-own, pipe and smoking tobaccos, and homogenized tobacco products.
[17] USDA FAS accessed July 28, 2016, from http://apps.fas.usda.gov/gats/default.aspx.
[18] Ibid.

PUBLIC HEALTH IMPACT OF EXPORTS THAT DO NOT CONFORM TO TOBACCO PRODUCT STANDARDS

FDA continues to have no evidence that flavored cigarettes or their component parts (including the tobacco, filters, or paper) are being exported from the United States. Therefore, the impact on public health of such exports cannot be assessed.

POLICY ALTERNATIVES

As noted above, FDA currently has no evidence that flavored cigarettes or their component parts (including the tobacco, filters, or paper) are being exported. Consequently, FDA cannot assess the impact on public health of such exports or provide policy alternatives to reduce any negative impact on public health at this time.

CONCLUSION

The only currently applicable tobacco product standard is the ban on cigarettes or their component parts (the tobacco, filters, or paper) that contain a characterizing flavor (other than tobacco or menthol). FDA has no evidence that these products are being exported from the United States.