



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

TO: The Secretary
Through: DS
COS DMO
ES _____

FROM: Commissioner of Food and Drugs

DATE: March 8, 2013

SUBJECT: Report to Congress on United States Tobacco Product Exports That Do Not Conform to Tobacco Product Standards Required by Section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act – **DECISION**

BACKGROUND

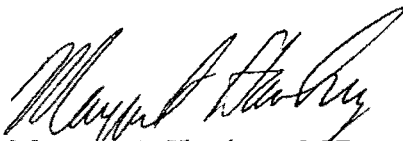
Attached for your consideration is the Food and Drug Administration's (FDA's) Report to Congress, as required by section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), regarding the export of tobacco products that do not conform to tobacco product standards established pursuant to the Act.

HIGHLIGHTS

This report summarizes our findings, and the data and information gathered that led to our conclusions. FDA concludes that there are currently no documented instances of the export of tobacco products that do not conform to current U.S. tobacco product standards.


RECOMMENDATION

I recommend that you review and approve the report and forward it to Congress.


Margaret A. Hamburg, M.D.

DECISION

Approved Disapproved Need More Information



Kathleen Sebelius
Secretary

APR 24 2013

Date

Attachments

Tab A – Transmittal Letters

Tab B – Report to Congress



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

April 24, 2013

The Honorable Tom Harkin
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for your consideration is the Food and Drug Administration's (FDA) Report to Congress on United States Tobacco Product Exports That Do Not Conform to Tobacco Product Standards, as required by section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act.

This report summarizes FDA's examination and findings as they relate to the tracking and reporting of tobacco product exports that do not conform to product standards established by FDA. FDA concludes that there are currently no documented instances of the export of tobacco products that do not conform to current U.S. tobacco product standards.

I hope you will find the report useful and informative.

Sincerely,

A handwritten signature in black ink that reads "Kathleen Sebelius". The signature is written in a cursive style with a large initial "K".

Kathleen Sebelius

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

April 24, 2013

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for your consideration is the Food and Drug Administration's (FDA) Report to Congress on United States Tobacco Product Exports That Do Not Conform to Tobacco Product Standards, as required by section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act.

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Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

April 24, 2013

The Honorable John Boehner
Speaker of the House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Enclosed for your consideration is the Food and Drug Administration's (FDA) Report to Congress on United States Tobacco Product Exports That Do Not Conform to Tobacco Product Standards, as required by section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act.

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Kathleen Sebelius

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

April 24, 2013

The Honorable Joseph R. Biden, Jr.
President
United States Senate
Washington, DC 20510

Dear Mr. President:

Enclosed for your consideration is the Food and Drug Administration's (FDA) Report to Congress on United States Tobacco Product Exports That Do Not Conform to Tobacco Product Standards, as required by section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act.

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Kathleen Sebelius

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

April 24, 2013

The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, DC 20515

Dear Representative Waxman:

Enclosed for your consideration is the Food and Drug Administration's (FDA) Report to Congress on United States Tobacco Product Exports That Do Not Conform to Tobacco Product Standards, as required by section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act.

This report summarizes FDA's examination and findings as they relate to the tracking and reporting of tobacco product exports that do not conform to product standards established by FDA. FDA concludes that there are currently no documented instances of the export of tobacco products that do not conform to current U.S. tobacco product standards.

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Kathleen Sebelius

Enclosure



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

April 24, 2013

The Honorable Lamar Alexander
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Senator Alexander:

Enclosed for your consideration is the Food and Drug Administration's (FDA) Report to Congress on United States Tobacco Product Exports That Do Not Conform to Tobacco Product Standards, as required by section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act.

This report summarizes FDA's examination and findings as they relate to the tracking and reporting of tobacco product exports that do not conform to product standards established by FDA. FDA concludes that there are currently no documented instances of the export of tobacco products that do not conform to current U.S. tobacco product standards.

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Kathleen Sebelius

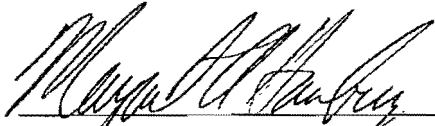
Enclosure

Report to Congress

**United States Tobacco Product Exports That Do Not Conform to
Tobacco Product Standards**

U.S. Department of Health and Human Services

Food and Drug Administration



Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Date 3/8/13

EXECUTIVE SUMMARY

In June 2009, the President signed into law 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 U.S. Food and Drug Administration (FDA) to regulate the manufacture, distribution, and sale of tobacco products. The Tobacco Control Act requires FDA to report to Congress on the export of tobacco products that do not conform to U.S. tobacco product standards. Only one product standard, the prohibition on cigarettes or their component parts containing characterizing flavors, is currently applicable. Based on the review and analyses of a number of data and information sources, FDA concludes that there are currently no documented instances of the export of tobacco products that do not conform to current U.S. tobacco product standards.

The Tobacco Control Act also requires FDA to assess the public health impact of noncompliant tobacco product exports and to provide recommendations for mitigating the negative public health impact associated with such exports. As noted above, FDA found 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, there is no evidence at this time that allows for an analysis of the nature and extent of violations of the standard, a determination as to which countries the products in violation are being shipped, or the public health implications and policy alternatives.

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INTRODUCTION

In 2009, President Obama signed 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 U.S. Food and Drug Administration (FDA) to regulate tobacco products.

This report complies with section 801(p)(1) of the FD&C Act, which states:

Not later than 36 months¹ 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—

- (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.²

TOBACCO PRODUCT STANDARDS

The FD&C Act establishes two tobacco product standard special rules and allows the Secretary to revise these standards or adopt additional standards through rulemaking.³ The first tobacco product standard states that:

Beginning 3 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.⁴

The second tobacco product standard states that:

Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown

¹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, §6, 123 Stat. 1776, 1783 (2009) explains that the deadline for this report is modified to the first day of the first fiscal quarter following the initial two consecutive fiscal quarters of fiscal year 2010 for which the Secretary of Health and Human Services has collected fees under section 919 of the Federal Food, Drug, and Cosmetic Act. Thus, the due date for this report is April 1, 2013.

² FD&C Act Sec. 801(p)(1)

³ FD&C Act Sec. 907

⁴ FD&C Act Sec. 907(a)(1)(A)

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.⁵

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 consulted with the U.S. Department of Agriculture (USDA) and the U.S. Environmental Protection Agency (EPA). According to both USDA and EPA, there are currently no established tolerance limits for pesticide chemical residues that apply to domestically grown tobacco.

The Secretary has not promulgated any additional tobacco product standards at this time. Currently, therefore, the only applicable tobacco product standard is the characterizing flavor ban mandated by Section 907(a)(1)(A) and quoted above. Consequently, the only U.S. tobacco product exports that would not conform to U.S. tobacco product standards are cigarettes or their component parts (including the tobacco, filters, or paper) that contain a prohibited characterizing flavor.

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 the Act.⁶ However, FDA found no evidence that flavored cigarettes or their component parts are being exported for consumption abroad.

Pursuant to its authority under the FD&C Act, FDA conducts biennial inspections of tobacco product manufacturers and other regulated entities. As part of these inspections, FDA requests tobacco export data from these manufacturers. As of December 1, 2012, FDA had conducted 61 inspections of registered establishments in the United States. Based on these inspections, FDA has found no evidence of the exportation of flavored cigarettes or their component parts (including the tobacco, filters, or paper).

In addition, FDA consulted with other U.S. government entities whose mission includes activities relevant to tobacco product exports. FDA found no U.S. government agency that required tobacco 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 Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau (TTB) reporting requirements and found that flavored cigarettes and their component parts are not reported separately from cigarettes in general. The TTB Director of the Regulations and

⁵ FD&C Act Sec. 907(a)(1)(B)

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."

Ruling Division confirmed this finding in a letter to the Director of the FDA Center for Tobacco Products, dated October 16, 2012. (Tab A, Appendix 2)

FDA also consulted the USDA 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.

Finally, 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.

To aid in future data collection, FDA requested a revision to the existing export codes used by Census that would allow FDA 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), which is composed of the U.S. Customs and Border Protection (CBP), the U.S. International Trade Commission (ITC), and Census. This interagency committee routinely reviews requests for changes to the statistical reporting requirements of Schedule B for exports. FDA's request was denied in November 2011. In notifying FDA of its decision, Census reported that there are no 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. The agency also 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. In addition, Census asked companies engaged in the export of tobacco products to report on the export of flavored cigarettes or cigarette papers. These companies responded that, as a result of the domestic ban on characterizing flavors, they halted their production of flavored cigarettes for export. (Tab A, Appendix 1A, 1B).

In sum, outside of the data collected by FDA as part of its biennial inspections, no other federal agency collects data on the export of flavored cigarettes or cigarette papers.

Additionally, FDA examined the Tobacco Information Service database on the website of the Tobacco Merchants Association, a non-profit trade association, and found no data on cigarettes or their component parts with characterizing flavors.

BACKGROUND ON TOBACCO PRODUCT EXPORTS

The total value of manufactured tobacco products exported from the U.S. has significantly declined over the last decade, dropping from \$3.3 billion in 1999 to \$488 million in 2011 (Table 1). 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.⁷ For example:

⁷ U.S. Government Accountability Office report, *“Illicit Tobacco: Various Schemes are Used to Avoid Taxes and Fees,”* accessed August 21, 2012, from www.gao.gov/assets/320/316372.pdf

- On May 12, 1999, RJR Nabisco Holding Company (RJR) completed the sale of its Reynolds International Tobacco business to Japan Tobacco.⁸ Consequently, all RJR brands that had been marketed abroad before May 12, 1999 are now controlled by Japan Tobacco.
- On October 27, 2003, RJR and British American Tobacco PLC (BAT) announced an agreement to combine their domestic businesses to form a new publicly traded holding company, Reynolds American Inc. (RAI).⁹ Pursuant to this agreement, Brown & Williamson Tobacco Company (B&W), an American subsidiary of BAT with domestic sales and exports, merged with RAI on July 30, 2004. RAI assumed the U.S. assets of B&W and BAT retained all non-U.S. assets.¹⁰
- On March 28, 2008, Altria Client Services spun off Philip Morris International to Altria shareholders as a separate company.¹¹

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."

⁸ SEC Form 10-Q Quarterly Report for RJR dated May 5, 1999; accessed August 14, 2012.

⁹ SEC Form 8-K filed 10/30/03 by Reynolds Tobacco Holdings Inc., Item 5. Other Events, page 2; Accessed October 17, 2012, from investing.money.msn.com/investments/sec-filings/?symbol=RAI

¹⁰ SEC Form 8-K, Exhibit 10.1, Definitions "Excluded Assets", filed August 9, 2004, accessed October 19, 2012, from investing.money.msn.com/investments/sec-filings/?symbol=RAI

¹¹ SEC Form 8-K for Altria Client Services dated March 3, 2009; accessed August 14, 2012.

Table 1. Value of U.S. Exports of Manufactured Tobacco Products

1999, 2004, and 2011^{12,13}

(thousands of US Dollars)

Product	YEAR		
	1999	2004	2011
Cigars, Cigarettes	3,250,873	1,325,473	429,000
Other Tobacco Products	625,945	240,749	59,913
Total	3,876,818	1,566,222	488,913

DESTINATION OF U.S. TOBACCO PRODUCT EXPORTS

While there is no evidence of 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 2011 indicate that tobacco products (including unmanufactured tobacco) totaling approximately \$1.6 billion are exported from the United States to 111 countries. These tobacco product exports represent approximately 0.106 percent of all U.S. exports, which are valued at \$1.497 trillion.¹⁴ Of the total amount of U.S. tobacco product exports, \$383 million (78 percent) were cigarette exports. Combined, Japan, Mexico, Jamaica, Turkey, and Macau (none of which ban the import or use of flavored tobacco products) receive 98.2 percent of U.S. cigarette exports:

Table 2. Top Five Recipients of U.S. Cigarette Exports in 2011

Trade Partner	Number of Sticks (millions)
Japan	23,231.8
Mexico	601.7
Jamaica	398.5
Turkey	112.3
Macau	68.9

¹² USDA Foreign Agricultural Service, accessed August 20, 2012, from www.fas.usda.gov/GATS/default.aspx.

¹³ “Manufactured tobacco products” consist of cigarettes, cigars, cheroots, smokeless, water pipe, roll-your-own, pipe and smoking tobaccos.

¹⁴ USDA Foreign Agricultural Service, accessed August 20, 2012, from www.fas.usda.gov/GATS/default.aspx.

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

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

Given the risks associated with tobacco use in general, exported products that do not conform to tobacco product standards could contribute to death and disease in countries that import U.S. tobacco products. However, FDA currently has no evidence that flavored cigarettes or their component parts (including the tobacco, filters, or paper) with prohibited flavors are being exported. Consequently, FDA has no evidence to suggest that tobacco products that do not conform to tobacco product standards are exported, and therefore the impact to public health of these exports cannot be assessed.

POTENTIAL PUBLIC HEALTH IMPACT OF RE-IMPORTATION

FDA has found no evidence of the re-importation of tobacco products that do not conform to tobacco product standards. A 2011 GAO report to Congress regarding illicit tobacco trade addressed the practice of “export diversion,” in which tobacco products are exported for immediate importation back into the United States. This practice involves false documentation to avoid federal excise taxes as well as some state sales taxes.¹⁵ It has been documented that tax avoidance results in lower tobacco product prices and, consequently, can be expected to lead to increased initiation (especially among youth) and increased consumption. In the mid-1990s, export diversion was recognized as a serious problem and led to the passage of so-called “grey market” laws, which erected numerous barriers to illicit trade. In the 2011 GAO report to Congress, GAO stated that “[a]ccording to experts we spoke with, export diversion may be less prevalent following the decline in cigarettes produced for export by the three largest cigarette manufacturers.”¹⁶ Again, FDA found no evidence of re-importation of tobacco products that do not conform to U.S. tobacco product standards.

POLICY ALTERNATIVES

Because there do not appear to be any 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, FDA provides no policy alternatives to reduce any negative impact on public health at this time.

¹⁵ U.S. Government Accountability Office. *Illicit Tobacco: Various Schemes Are Used to Evade Taxes and Fees* (GAO-11-313), 2011.

¹⁶ *Ibid.*

CONCLUSION

The only currently applicable tobacco product standard is the ban on cigarettes or their component parts (the tobacco, filters, or paper) with characterizing flavors other than menthol or tobacco. FDA found no evidence that these products are being exported from the U.S. Census confirmed that, from August 2010 to July 2011, companies responsible for 94.8 percent of the trade for cigarettes and 96.4 percent of the cigarette paper trade did not export flavored cigarettes or flavored cigarette paper, respectively. Therefore, there is no evidence on which to base analyses of the nature and extent of violations of the standard; designated countries to which the products in violation are being shipped; public health implications; and policy alternatives.

As directed by the Tobacco Control Act, FDA will submit an annual report to Congress on exports of tobacco products that do not conform to FDA product standards. FDA will continue to use available data sources on tobacco product exports for use in these reports.

TAB A

Appendix 1A



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850-3229

David Beck, Chairman
Committee for Statistical Annotation of Tariff Schedules
United States International Trade Commission
Washington, D.C. 20436

Dear Chairman Beck:

FDA is requesting a change to Schedule B numbers for Chapter 24: Tobacco and Manufactured Tobacco Substitutes and Chapter 48: Paper and Paperboard, Articles of Paper Pulp, of Paper or of Paperboard. The needs of our Agency are based on Section 801(p)(1) of the Food, Drug, and Cosmetics Act and are described in more detail below.

Background

No later than April 1, 2013, the FDA is required to provide a report to the Senate Committee on Health, Education, Labor and Pensions and the House Energy and Commerce committee regarding:

- (A) the nature, extent, and destination of U.S. tobacco product exports that do not conform to tobacco product standards established pursuant to the Food and Drug 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

For the first report due April 1, 2013, CTP must obtain information regarding export of flavored cigarettes, flavored tobacco, or any of its component parts (including the tobacco filter, or paper). If our changes are implemented in the Schedule B system, FDA is further requesting that the Secretary of Commerce provide data collected to us for use in assessing the public health impact of flavored cigarette and component parts exports. Please let us know if additional documentation is needed to allow this data to be shared. We are familiar with 13 U.S.C. 301(g) and are willing to meet any requirements that would allow the data to be shared.²

Census data dated from July 1, 2011 shows the United States exported \$176 million in cigarettes. Data regarding the monetary value for flavored cigarette exports is not available under the current Schedule B breakout. The number of flavored cigarette exporters is also unavailable with the current breakout. FDA requests a determination be made as to whether the value of flavored cigarette exports and number of flavored cigarette exporters warrant the Schedule B

¹ Food, Drug, and Cosmetic Act § 801(p)(1)(2), 21 U.S.C.A. §381(p)(1)(2) (Thompson-Reuters 2011).

² "Shipper's export declaration (or successor document), wherever located, shall be exempt from public disclosure unless the Secretary determines that such exemption would be contrary to public interest."

breakout. FDA intends that CBP will be able to determine a flavored cigarette by the product packaging.

Information Requested

In order to obtain information regarding flavored cigarettes, FDA requests the following additional numbers be added to Schedule B Chapter 24:

2010 Schedule B – Chapter 24

Cigars, cheroots, cigarillos and cigarettes, of tobacco or of tobacco substitutes:

- 2402200100 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco herb) ...Thsnds
- 2402200110 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco spice) ...Thsnds
- 2402200120 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco strawberry) ...Thsnds
- 2402200130 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco grape) ...Thsnds
- 2402200140 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco orange) ...Thsnds
- 2402200150 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco clove) ...Thsnds
- 2402200160 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco cinnamon) ...Thsnds
- 2402200170 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco pineapple) ...Thsnds
- 2402200180 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco vanilla) ...Thsnds
- 2402200190 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco coconut) ...Thsnds
- 2402200200 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco licorice) ...Thsnds
- 2402200210 Cigarettes containing tobacco (flavored cigarettes or flavored component parts cocoa) ...Thsnds
- 2402200220 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco chocolate) ...Thsnds
- 2402200230 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco cherry) ...Thsnds
- 2402200240 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco coffee) ...Thsnds
- 2402200250 Cigarettes containing tobacco (flavored cigarettes or flavored filter, tobacco other (except menthol)) ...Thsnds

In order to obtain information regarding flavored cigarette component parts, FDA requests the following additional numbers be added to Schedule B Chapter 48:

2010 Schedule B – Chapter 48

Paper and Paperboard, Articles of Paper Pulp. of Paper or of Paperboard

4813900100 Other (Flavored Cigarette Paper herb)
4813900110 Other (Flavored Cigarette Paper spice)
4813900120 Other (Flavored Cigarette Paper strawberry)
4813900130 Other (Flavored Cigarette Paper grape)
4813900140 Other (Flavored Cigarette Paper orange)
4813900150 Other (Flavored Cigarette Paper clove)
4813900160 Other (Flavored Cigarette Paper cinnamon)
4813900170 Other (Flavored Cigarette Paper pineapple)
4813900180 Other (Flavored Cigarette Paper vanilla)
4813900190 Other (Flavored Cigarette Paper coconut)
4813900200 Other (Flavored Cigarette Paper licorice)
4813900210 Other (Flavored Cigarette Paper cocoa)
4813900220 Other (Flavored Cigarette Paper chocolate)
4813900230 Other (Flavored Cigarette Paper cherry)
4813900240 Other (Flavored Cigarette Paper coffee)
4813900250 Other (Flavored Cigarette Paper other (except menthol))

The above breakouts are intended to provide a category by which exporters will provide information if they export flavored cigarettes, filters, tobacco, or paper. Any flavoring as evidenced by the packaging will qualify under this breakout.

Also FDA is not requesting this change for the Harmonized Tariff Schedule import numbers.

Thank you for your consideration. If FDA can provide any further information to assist in your decision please do not hesitate to contact: Paul Perdue, Supervisory Consumer Safety Officer, Enforcement and Manufacturing Group, Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration 301-796-9338 paul.perduejr@fda.hhs.gov.

Sincerely,



Joanna Weitershausen
Acting lead, Enforcement and Manufacturing Group
Office of Compliance and Enforcement
Center for Tobacco Products
Food and Drug Administration

Appendix 1B



UNITED STATES DEPARTMENT OF COMMERCE
Economics and Statistics Administration
U.S. Census Bureau
Washington, DC 20233-0001

August 23, 2012

MEMORANDUM FOR: Kate Collins, J.D.
Regulatory Counsel
Office of Compliance and Enforcement
Center for Tobacco Products
U.S. Food and Drug Administration

From: Carol Aristone
Chief, Commodity Analysis Branch
Foreign Trade Division

Subject: Conversation of procedures and methods used by FTD to determine insufficient trade of proposed breakouts for flavored cigarettes under Schedule B subheading 2402.20 and flavored cigarette paper under Schedule B subheading 4813.90

The request made by the USFDA to create specific Schedule B numbers for flavored cigarettes and flavored cigarette paper was denied November 4, 2011 based upon a determination by Census that there was not significant exports of flavored cigarettes.

To make this determination, Census reviewed export data regarding cigarette tobacco and cigarette paper from August 2010 to July 2011. Census then reviewed the export data by specific exporter. Census contacted the companies responsible for 94.8 percent of the trade for cigarettes and 96.4 percent of the paper trade. Census asked whether these companies were exporting any flavored cigarettes or flavored cigarette paper. The exporters responded that due to the domestic ban, they have stopped producing flavored cigarettes for exports.

Census also conducted internet searches for the exporting companies that stated they were no longer producing flavored cigarettes. The company websites indicated that the companies were no longer making flavored cigarettes.

Appendix 2



DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
WASHINGTON, D.C. 20220

October 16, 2012

4040000:BJF
5200:2012-000448-T

Lawrence R. Deyton, MSPH, MD
Director, Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850-3229

Dear Dr. Lawrence Deyton:

This letter regards requests for information that the Alcohol and Tobacco Tax and Trade Bureau (TTB) received from Nakki Price and Clarence (Grayson) Fowler, both of the Office of Policy at the Center for Tobacco Products (CTP). Specifically, CTP has requested any information that TTB collects on the export of U.S. manufactured cigarettes, or their component parts, that have characterizing flavors other than menthol. We understand that this information was requested in the context of a report CTP is sending to Congress on noncompliance with the provisions of the Family Smoking Prevention and Tobacco Control Act.

In a letter dated May 30, 2012, TTB responded to an email request from Ms. Price, by stating that TTB does not collect information on the export of U.S. manufactured cigarettes with characterizing flavors. On September 24, 2012, Mr. Fowler requested that TTB provide further clarification regarding information that TTB collects on the export of U.S. manufactured cigarettes *or their component parts* that have characterizing flavors other than menthol. We have responded by telephone and this letter formalizes that response.

TTB requires, for administration of the Internal Revenue Code of 1986, that certain information be reported to TTB on the manufacture and export of cigarettes, processed tobacco, and cigarette papers and tubes. However, such reporting does not include, and collection of Federal excise tax does not require, information that could be used to distinguish between different types and styles of cigarettes or information about the "component parts" (such as the tobacco, filter, or paper) of manufactured cigarettes, including information related to "characterizing flavors." In summary, TTB does not collect information relevant to CTP's request.

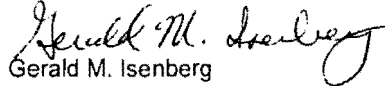
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OCT 22 2012
BY: CTP/MAILROOM

Dr. Lawrence Deyton

Please feel free to contact us if CTP has any additional questions regarding TTB authority or the information we collect. You may contact Brian Folan at (202) 453-2048 or by email at Brian.Folan@ttb.gov.

Sincerely,

A handwritten signature in cursive script that reads "Gerald M. Isenberg". The signature is written in black ink and is positioned above the printed name.

Gerald M. Isenberg
Director, Regulations and Rulings Division