

Illegal Tobacco Task Force

Notice of Public Meeting

Meeting Date: Tuesday, June 13th, 2017

Meeting Time: 10:30 AM

Meeting Location: 100 Cambridge Street, 2nd Floor, Room A, Boston, MA

- A. Opening Remarks/Approval of Last Meeting Minutes
- B. Housekeeping Items/Member Updates
- C. Legislative and Budget Update/Discussion
- D. FDA Q&A
- E. Upcoming Meeting (7/11)
- F. Wrap Up/Closing Comments

Due to security at the Saltonstall Building, those interested in attending the meeting should allow for additional time to check-in.

If any member of the public wishing to attend this meeting seeks special accommodations in accordance with the American with Disabilities Act, please contact DOR Human Capital Development at 617-626-2355.

Date of Posting: June 9, 2017 @ 10:30am

Illegal Tobacco Task Force Minutes

Meeting Date: April 6, 2017

Meeting Time: 10:30am

Meeting Location: 100 Cambridge Street, 2nd Floor, Conference Room A

Board Members Present: Kajal Chattopadhyay (Co-Chair), Capt. Steve Fennessy (Co-Chair), Tom Bocian, Amber Villa, Patti Henley, David Solet, Michael Sweeney

Others: Molly Parks, Julie Flynn, Molly Slingerland, Scott Delaney, Mark Delaney, Paul Caron, Alex Finkel, Todd Skakal, Evan Garcia, Brenda McConville

Call to Order:

- Mr. Chattopadhyay called the meeting to order at 10:39am, and gave a quick recap of what was to be covered at the meeting.
- Task Force members were then called by Mr. Chattopadhyay to review the previous meeting minutes.
 - Mr. Solet made a motion to accept the minutes; it was seconded by Ms. Henley. The meeting minutes were approved unanimously.

Housekeeping and Updates:

- Task Force agencies were asked by Mr. Chattopadhyay to update the group on ISA spending.
 - DPH: Funds have been encumbered to spend on the Retail Data Management System (RDMS) and will be spent by the end of FY17.
 - AGO: Funds are being spent in furtherance of ongoing prosecution activities; most funds expected to be spent by end of FY17.
 - State Police: All available funds expected to be spent by end of FY17.

Legislative Update:

- Mr. Chattopadhyay gave the Task Force an update on the FY 18 budget developments.
 - Based on the Governor's proposed budget, Mr. Chattopadhyay says the Task Force is level funded at \$600K and funding will be housed at DOR instead of EOPSS.
 - Many stages in the budget process remain as House and Senate will next work on their own proposed budgets and then will go to conference committee before going to the Governor. Mr. Chattopadhyay will provide a further update at the next meeting.
- Mr. Chattopadhyay also gave an update on the Task Force's proposed legislation, which is now SB1614. A hearing on the bill is tentatively scheduled for June 20, 2017. He asks the Task Force to submit any proposed amendments for discussion at the next meeting.

SICPA Presentation – Alex Finkel:

- Mr. Finkel from SICPA presented to the Task Force regarding the prototype of SICPA & USI's OTP (specifically smokeless tobacco) stamping machine.
- Mr. Finkel says he hopes the presentation to the Task Force will begin the process of looking at the deeper questions involving pricing and logistics for operating an OTP stamping machine. He gave a brief overview of what MA is currently using with SICPA for its cigarette stamping program. He says much of the same framework can be used in the OTP context as well.
- According to Mr. Finkel, there are many challenges in stamping OTP including tax structure, stamp creation, adhering to labeling requirements and creating the correct data flow.
- During his presentation, Mr. Finkel mentioned "Non-Denominational" tax stamps, which would not represent a fixed dollar amount (unlike cigarettes). Ms. Henley asked how that will work for smokeless tobacco. Since the excise on smokeless tobacco is based on the value of the product, the system will need to be set up to calculate the proper tax amount for each product.
- He later showed the Task Force a video demonstration of the OTP stamping machine in operation. The most popular form of OTP are the familiar hockey puck shaped tins, which are fed into the machine. The machine has the capacity to stamp 80 pucks per minute.
- Questions were asked to Mr. Finkel about stamping requirements and whether there are liability issues and/or legal ramifications. In short, Mr. Finkel said there may be requirements, but they will depend on the stamping location ultimately decided upon by the Task Force.
- Mr. Bocian wants to know whether there are any federal offenses for covering a label on OTP either purposefully or by accident.
- Mr. Solet stated maybe the FDA is the proper agency to offer guidance.
- The Task Force next discussed the price of the machine and its benefits and impact on revenue collection. Total cost for the machine is roughly \$77K and has the potential to recover between \$41-61M in lost annual revenue, according to Mr. Finkel's estimates.
- Mr. Caron, who represents wholesalers and distributors in MA, shared his concerns over the new machinery and how it will affect stampers. He states that packaging is a concern for wholesalers as is the \$1.6M in machine costs. The issue is how to spread the cost fairly so that it doesn't further squeeze wholesalers and cut into their small profit margins. He cited the ownership model with Lottery equipment and machinery as a source of guidance.
- Mr. Sweeney, from Treasury, confirmed that lottery machinery is state funded, but they will be changing those machines out soon.

Other Business:

- DPH and AGO were asked by Mr. Chattopadhyay to research labeling requirements and if stamping raises concerns with labeling laws.
- Mr. Bocian asked if someone could speak to the Task Force about what labeling can or cannot be blocked with a tax stamp.
- Mr. Chattopadhyay scheduled the next meeting for May 11, 2017. Meeting adjourned at 12:02pm.

62C, §21 – Disclosure of Tax Information

[XX] Paragraph 19 of section 21 of chapter 62C, as appearing in the 2014 Official Edition, is hereby amended by striking out the phrase

"sections 33A, 34 and 35 of chapter 64C"

inserting in place thereof the following phrase:

"sections 10, 33A, 34, 35, 37, 37A, and 38 of chapter 64C"

[XX] Paragraph 28 of section 21 of chapter 62C, as inserted by section 68 of chapter 46 of the acts of 2015 is hereby amended by inserting after the phrase "chapter 64C"

the phrase:

"or to task force member agency personnel described in paragraph (ii) of subsection (b) of said section 40"

[XX] Paragraph 28 of section 21 of chapter 62C, as inserted by section 68 of chapter 46 of the acts of 2015 is hereby further amended by inserting after the phrase "federal law enforcement"

the phrase:

"or to revenue or law enforcement officials from another state"

So that the relevant portions of the section as amended shall read:

Section 21. (a) The disclosure by the commissioner, or by any deputy, assistant, clerk or assessor, or other employee of the commonwealth or of any city or town therein, to any person but the taxpayer or his representative, of any information contained in or set forth by any return or document filed with the commissioner, except in proceedings or other activities to determine or collect the tax or for the purpose of criminal prosecution under this chapter, chapters sixty A, sixty-two to sixty-five C, inclusive, section ten of chapter one hundred and twenty-one A and section twenty-one of chapter one hundred and thirty-eight, is prohibited.

(b) Nothing herein shall be construed to prevent

. . .

(19) the disclosure of such information as is reasonable and appropriate to the implementation and enforcement of sections 10, 33A, 34, 35, 37, 37A, and 38 of chapter 64C.

. . .

(28) the disclosure of information to members of the multi-agency illegal tobacco task force established in section 40 of chapter 64C [or to task force member agency personnel described in paragraph \(ii\) of subsection \(b\) of said section 40](#) or to federal law enforcement or to revenue or law enforcement officials from another state for the purpose of investigating or prosecuting criminal offenses relative to contraband tobacco distribution or conducting other enforcement actions relative to contraband tobacco distribution.

62C, §67 - Licenses and registration certificates of taxpayers under chapters 64A, 64C, 64E to 64J or 64M

[XX] Chapter 62C of the General Laws is hereby amended by striking out section 67, as appearing in the 2014 Official Edition, and inserting in place thereof the following section:

Section 67. Licenses and registration certificates of taxpayers under chapters 64A, 64C, 64E to 64J or 64M

(a) Each vendor as defined in chapter 64H or 64I and each operator as defined in chapter 64G who desires to obtain a certificate of registration as required by said chapters 64G, 64H or 64I and each person who desires to obtain a license as a distributor, unclassified importer or unclassified exporter as defined in chapter 64A, as a manufacturer, wholesaler, vending machine operator, unclassified acquirer, retailer, cigar distributor or cigar retailer as defined in chapter 64C, as a user-seller, supplier or user of special fuels as defined in chapter 64E, as a motor carrier as defined in chapter 64F, as a user-seller or supplier of aircraft fuel as defined in chapter 64J or as a direct broadcast satellite service provider as defined in chapter 64M shall file with the commissioner an application in such form as the commissioner prescribes, giving such information as the commissioner requires; provided, however, if the application is for a wholesaler's license other than a cigar distributor's license, both as defined in said chapter 64C, the commissioner shall require, in addition to such other information as may be deemed necessary, the filing of affidavits from 3 licensed manufacturers as defined in said chapter 64C, stating that the manufacturer will supply the wholesaler if the applicant is granted a license, and provided further that at least 2 of the 3 required

affidavits shall be from licensed manufacturers who are participating manufacturers, as defined in section one of chapter 94C-

(b) In the instance of an application for a license as a manufacturer, wholesaler, vending machine operator, unclassified acquirer, retailer, cigar distributor or cigar retailer, as defined in chapter 64C, the commissioner shall investigate the prior activities of the applicant; provided further that the commissioner may also, and shall in the case of applicants for a license as a wholesaler, cigar distributor, or unclassified acquirer (other than unclassified acquirer applicants that are hospitals, educational institutions or non-profit entities seeking to acquire tobacco products solely for medical research or other non-commercial purposes), investigate the prior activities of all controlling persons of applicants for any such license. For purposes of this section and section 68, "controlling person" shall mean any person who is: (1) an officer, director or partner of an applicant or licensee; or, in the case of a limited liability company, a member or a person having with respect to such limited liability company authority comparable or analogous to that of an officer or director with respect to a corporation; or (2) a shareholder, directly or indirectly owning more than ten percent of the number of shares of voting stock of such applicant or licensee, in the case of an applicant or licensee that is a corporation; or (3) a person who exercises or will exercise authority within the applicant or licensee's business comparable or analogous to that of a corporate officer or director irrespective of the form of business organization or lack of actual title. The commissioner may, as a condition of licensing, require individual applicants and controlling persons of applicants for such licenses to submit such personal and background information as the commissioner deems necessary to conduct an investigation into their prior activities, and as part of any such investigation, the commissioner is authorized to obtain criminal offender record information relative to

such applicants and controlling persons of such applicants from the department of criminal justice information services pursuant to section 172 of chapter 6. If the commissioner determines that (i) said applicant or a controlling person of said applicant has been convicted of or has admitted to sufficient facts to support a finding of guilt of any violation of this chapter, any violation of the provisions of chapter 64C, any violation of federal law where the conduct underlying the conviction or admission relates to tobacco products, or any violation of law involving dishonesty or fraud, within the five-year period preceding the date of the application in the case of a misdemeanor or within the ten-year period preceding the date of the application in the case of a felony, or (ii) the commissioner has assessed against said applicant or a controlling person of said applicant a civil penalty, which has been finally determined to be due, for the violation of any provision of chapter 64C providing for a civil penalty on three or more occasions during the five-year period preceding the date of the application, or (iii) unstamped cigarettes or untaxed other tobacco products have been seized from the applicant's business premises or the business premises of a controlling person of said applicant on three or more occasions during the five-year period preceding the date of the application, or (iv) an aggregate total of one hundred packs of unstamped cigarettes or two thousand units of untaxed tobacco products, as those terms are defined in section 1 of chapter 64C, have been seized from the applicant's business premises or the business premises of a controlling person of said applicant during the five-year period preceding the date of the application, or (v) the applicant or a controlling person of said applicant has during the five-year period preceding the date of the application refused to permit, hindered or obstructed an examination, investigation, or search authorized by section 5 or 11 of chapter 64C, or (vi) the commissioner has received notice from another state or municipal agency, board or law

enforcement official that the applicant or a controlling person of said applicant has been fined, cited or otherwise penalized by a state or municipal agency board or law enforcement official (a) for the sale of tobacco products to a person under the minimum legal sales age, or (b) for any other violation of the laws or regulations of the commonwealth regarding tobacco, on three or more occasions during the five-year period preceding the date of the application and that any administrative remedies available to the applicant or controlling person of said applicant have been exhausted or have expired, or (vii) the applicant or a controlling person of said applicant has failed to submit any required documents or information or has submitted an incomplete application or an application containing false information or has otherwise committed fraud or deceit in connection with the application, he may deny the application, and the commissioner may also deny the application for any of the reasons set forth in subsection (k) below; provided, however, that the commissioner shall grant or deny a license to said applicant within ninety days from the date of application; and provided further, that if the commissioner fails to act within such time period, the application shall be deemed denied.

(c) All licenses, except as otherwise prescribed by the commissioner, shall expire annually on a date prescribed by the commissioner. The commissioner may provide for combined forms of licenses and license applications.

(d) Registration certificates may be issued for a specified term of not less than three years, subject to renewal without the payment of any additional fee and in accordance with regulations issued by the commissioner. Whether or not such certificates are issued for a specified term, they shall be subject to suspension or revocation as provided in this section. Existing registration certificates may be made subject to

renewal or reissuance for a specified term in accordance with regulations issued by the commissioner.

(e) Registration certificates shall be issued for each place of business. Licenses for said manufacturers, wholesalers, vending machine operators, unclassified acquirers, retailers, cigar distributors and cigar retailers shall be issued for each place of business. Licenses for users of special fuels shall be issued for each vehicle propelled by special fuels. In addition to the license issued to a motor carrier, licenses shall be issued for each motor vehicle which the motor carrier desires to operate or cause to be operated upon the highways of the commonwealth which is propelled by fuel or special fuels purchased or acquired outside the commonwealth.

(f) The fee for each registration shall be determined annually by the commissioner of administration under the provision of section 3B of chapter 7.

(g) The secretary of administration and finance shall annually determine the fees for licenses and renewals thereof under section 3B of chapter 7 in the following categories: distributors; unclassified importers; unclassified exporters; manufacturers; wholesalers; vending machine operators; unclassified acquirers; retailers; cigar distributors; cigar retailers; user-sellers; suppliers; users of special fuels; and motor carriers or their vehicles; provided, however, that in case of a manufacturer, wholesaler, cigar distributor or vending machine operator who maintains more than 1 place of business, the fee for each additional place of business shall be one-half of the above determined fee. No fee or part thereof, shall be refunded by reason of relinquishment, suspension or revocation of a license.

(h) In the event that the holder of a license, or registration certificate removes his business to another location within the commonwealth, the license or registration certificate with respect to the former place of business shall, without the payment of an additional fee, be reissued for the new location for the balance of the unexpired term.

(i) Registrations and licenses shall not be assignable and shall be displayed conspicuously by the holder thereof in the manner prescribed by the commissioner.

(j) As a condition precedent to granting a license to a distributor, unclassified importer, or unclassified exporter the commissioner shall require the applicant to furnish a bond pursuant to section 66.

(k) An application for a registration or license may be denied by the commissioner for any one of the following reasons, and in addition, in the case of an application for a license as a manufacturer, wholesaler, vending machine operator, unclassified acquirer, retailer, cigar distributor or cigar retailer, as defined in chapter 64C may also be denied for any of the reasons set forth in subsection (b) above:

(1) The registration, license or permit of the applicant has been previously revoked or cancelled for cause by the commissioner;

(2) In the opinion of the commissioner, such application is filed by a person as a subterfuge for the real person in interest, including but not limited to situations in which the real person in interest is a person (i) whose registration or license has previously been revoked or cancelled for cause by the commissioner, or (ii) whose application for a registration or license could be denied by the commissioner for any of the reasons set forth in paragraphs (3) through ~~(8)~~12 below, or (iii) in the case of an application for a

license as a manufacturer, wholesaler, vending machine operator, unclassified acquirer, retailer, cigar distributor or cigar retailer, as defined in chapter 64C, whose application could be denied by the commissioner for any of the reasons set forth in subsection (b), or (iv) who is not identified;

(3) The applicant fails to pay the prescribed fee or to file such bond as the commissioner requires pursuant to section 66;

(4) Any tax payable under this chapter has been reported by the applicant to be due from the applicant or has been finally determined to be due from the applicant and has not been paid in full;

(5) Any tax payable under this chapter has been finally determined to be due from an officer, director, partner or employee of the applicant in his capacity as a person under a duty to collect and pay over a tax on behalf of the applicant or another person and has not been paid in full;

(6) The applicant has been convicted of, or has admitted to sufficient facts to support a finding of guilt of, a crime provided for in this chapter within one year from the date on which such application is filed;

(6 1/2) The applicant has otherwise willfully failed to comply with any provision of the tax laws of the commonwealth or regulations thereunder;

(7) An officer, director, partner or employee of the applicant, which officer, director, partner or employee is a person under a duty to collect and pay over a tax on behalf of the applicant has in his capacity as a person under a duty to collect and pay over a tax on behalf of the applicant or another person been convicted of, or has admitted to

sufficient facts to support a finding of guilt of, a crime provided for in this chapter within one year from the date on which such application is filed; ~~or~~

(8) A person who owns, directly or indirectly, a controlling interest in the applicant, has any tax payable under this chapter, which has been reported by the person as due or which has been finally determined to be due and has not been paid in full; or another legal entity, in which applicant owns a controlling interest, directly or indirectly, has any tax payable under this chapter, which has been reported by the entity to be due or which has been finally determined to be due and has not been paid in full; or a person, who owns, directly or indirectly, a controlling interest in the applicant, has been convicted of, or has admitted to sufficient facts to support a finding of guilt of a crime provided for in this chapter within one year from the date on which such application is filed:-

(9) The applicant has willfully failed to file any return or report required by this chapter;

(10) The applicant has willfully filed, causes to be filed, given or caused to be given a return, report, certificate or affidavit required under this chapter, or under the provisions of the applicable tax, which is false;

(11) The applicant has willfully failed to collect, truthfully account for or pay over any tax under the provisions of this chapter; or

(12) The applicant is a business organization that (i) because of dissolution is not legally authorized to conduct business either at all or beyond the winding up of business affairs, or (ii) is a foreign corporation, foreign limited liability company or foreign limited partnership that transacts or proposes to transact business in the Commonwealth or

has a usual place of business in the Commonwealth and that has either failed to comply with a legal requirement to register or file a certificate to transact business in the Commonwealth or has had its authority to transact business in the Commonwealth revoked by the secretary of state.

(l) Any person aggrieved by the refusal of the commissioner to grant a registration or license may within sixty days of the date of notice of such refusal appeal to the appellate tax board, whose decision shall be final.

62C, §68 - Suspension or revocation of license or registration; appeal; reissuance of registration

[XX] Section 68 of chapter 62C, as appearing in the 2014 Official Edition and as amended by section 69 of chapter 46 of the acts of 2015, is hereby amended by striking out paragraph(4) and inserting in place thereof the following the following paragraph:

(4) The licensee or registrant has been convicted of, or has admitted to sufficient facts to support a finding of guilt of, a crime provided for in this chapter;

[XX] Section 68 of chapter 62C, as so appearing, is hereby further amended by inserting after paragraph (4) the following paragraph:

(4 1/2) In the instance of a licensee licensed as a manufacturer, wholesaler, vending machine operator, unclassified acquirer, retailer, cigar distributor or cigar retailer, as defined in chapter 64C, (i) the licensee or a controlling person of the licensee, as defined in section 67 above, has been convicted of or has admitted to sufficient facts to support a finding of guilt of any violation of the provisions of chapter 64C, any violation of federal law where the conduct underlying the conviction or admission relates to tobacco products, or any violation of law involving dishonesty or fraud, within a five-year period in the case of a misdemeanor or within a ten-year period in the case of a felony, or (ii) the commissioner has assessed against said licensee or a controlling person of said licensee a civil penalty, which has been finally determined to be due, for the violation of any provision of chapter 64C providing for a civil penalty on three or

more occasions during a five-year period, or (iii) unstamped cigarettes have been seized from the licensee's business premises or the business premises of a controlling person of said licensee on three or more occasions during a five-year period, or (iv) an aggregate total of fifty packs of unstamped cigarettes or one thousand units of untaxed tobacco products, as those terms are defined in section 1 of chapter 64C, have been seized from the licensee's business premises or the business premises of a controlling person of said licensee during a five-year period, or (v) the licensee or a controlling person of said licensee has refused to permit, hindered or obstructed an examination, investigation, or search authorized by section 5 or section 11 of chapter 64C, or (vi) the commissioner has received notice from another state or municipal agency, board or law enforcement official that the licensee or a controlling person of said licensee has been fined, cited or otherwise penalized by a state or municipal agency board or law enforcement official (a) for the sale of tobacco products to a person under the minimum legal sales age, or (b) for any other violation of the laws or regulations of the commonwealth regarding tobacco, on three or more occasions during a five-year period and that any administrative remedies available to the licensee or controlling person of said licensee have been exhausted or have expired, or (vii) the licensee or a controlling person of said licensee has committed fraud or deceit in procuring his or its license.

[XX] Section 68 of chapter 62C, as so appearing, is hereby further amended by striking out the period at the end of paragraph (6) and inserting in its place:

": or"

[XX] Section 68 of chapter 62C, as so appearing, is hereby further amended by inserting after paragraph (6) the following paragraphs:

(7) The licensee or registrant is a business organization that (i) because of dissolution is not legally authorized to conduct business either at all or beyond the winding up of business affairs, or (ii) is a foreign corporation, foreign limited liability company or foreign limited partnership that transacts business in the Commonwealth or has a usual place of business in the Commonwealth and that has had its authority to transact business in the Commonwealth revoked by the secretary of state or is otherwise not authorized to transact business in the Commonwealth.

The commissioner may suspend or revoke the appointment of a stamper, as defined in section 1 of chapter 64C, for any of the reasons set forth in paragraphs (1) through (6) above, and for any of the reasons set forth in chapter 94F, §5(b), and for the willful use or operation of stamping equipment in any manner that violates instructions prescribed in writing by the commissioner.

[XX] Section 68 of chapter 62C, as so appearing, is hereby further amended by striking out the final paragraph, as inserted by section 69 of chapter 46 of the acts of 2015, and inserting in place thereof the following paragraph:

The commissioner shall provide notice to the director of the state lottery of a retailer or a cigar retailer, as defined in section 1 of chapter 64C, whose license, issued under section 67, has been suspended or revoked by the department for a willful violation of subsections (a), (b) or (c) of section 10 of said chapter 64C, or of sections 34, 35, 37, 37A, or 38 of said chapter 64C and who is a licensee authorized to sell lottery tickets under sections 26 and 27 of chapter 10.

So that the section as amended shall read:

Section 68. Suspension or revocation of license or registration; appeal; reissuance of registration

The commissioner may suspend or revoke any license or registration issued pursuant to section sixty-seven for any one of the following reasons: --

(1) The licensee or registrant willfully fails to file any return or report required by this chapter;

(2) The licensee or registrant willfully files, causes to be filed, gives or causes to be given a return, report, certificate or affidavit required under this chapter, or under the provisions of the applicable tax, which is false;

(3) The licensee or registrant willfully fails to collect, truthfully account for or pay over any tax under the provisions of this chapter;

(4) The licensee or registrant has been convicted of, or has admitted to sufficient facts to support a finding of guilt of, a crime provided for in this chapter;

(4 1/2) In the instance of a licensee licensed as a manufacturer, wholesaler, vending machine operator, unclassified acquirer, retailer, cigar distributor or cigar retailer, as defined in chapter 64C, (i) the licensee or a controlling person of the licensee, as defined in section 67 above, has been convicted of or has admitted to sufficient facts to support a finding of guilt of any violation of the provisions of chapter 64C, any violation of federal law where the conduct underlying the conviction or admission relates to tobacco products, or any violation of law involving dishonesty or fraud, within a five-year period in the case of a misdemeanor or within a ten-year period in the case of a felony, or (ii) the commissioner has assessed against said licensee or a controlling person of said licensee a civil penalty, which has been finally determined to be due, for the violation of any provision of chapter 64C providing for a civil penalty on three or

more occasions during a five-year period, or (iii) unstamped cigarettes have been seized from the licensee's business premises or the business premises of a controlling person of said licensee on three or more occasions during a five-year period, or (iv) an aggregate total of fifty packs of unstamped cigarettes or one thousand units of untaxed tobacco products, as those terms are defined in section 1 of chapter 64C, have been seized from the licensee's business premises or the business premises of a controlling person of said licensee during a five-year period, or (v) the licensee or a controlling person of said licensee has refused to permit, hindered or obstructed an examination, investigation, or search authorized by section 5 or section 11 of chapter 64C, or (vi) the commissioner has received notice from another state or municipal agency, board or law enforcement official that the licensee or a controlling person of said licensee has been fined, cited or otherwise penalized by a state or municipal agency board or law enforcement official (a) for the sale of tobacco products to a person under the minimum legal sales age, or (b) for any other violation of the laws or regulations of the commonwealth regarding tobacco, on three or more occasions during a five-year period and that any administrative remedies available to the licensee or controlling person of said licensee have been exhausted or have expired, or (vii) the licensee or a controlling person of said licensee has committed fraud or deceit in procuring his or its license.

(5) The licensee or registrant has otherwise willfully failed to comply with any provision of the tax laws of the commonwealth or regulations thereunder; or

(6) The licensee or registrant has ceased to act in the capacity for which the license or registration was issued-or

(7) The licensee or registrant is a business organization that (i) because of dissolution is not legally authorized to conduct business either at all or beyond the winding up of

business affairs, or (ii) is a foreign corporation, foreign limited liability company or foreign limited partnership that transacts business in the Commonwealth or has a usual place of business in the Commonwealth and that has had its authority to transact business in the Commonwealth revoked by the secretary of state or is otherwise not authorized to transact business in the Commonwealth.

The commissioner may suspend or revoke the appointment of a stamper, as defined in section 1 of chapter 64C, for any of the reasons set forth in paragraphs (1) through (6) above, and for any of the reasons set forth in chapter 94F, §5(b), and for the willful use or operation of stamping equipment in any manner that violates instructions prescribed in writing by the commissioner

Any person aggrieved by such suspension or revocation may appeal therefrom to the appellate tax board within ten days after written notice of the decision has been mailed or delivered to him. The appellant shall at the time of taking an appeal file with said board a surety company bond running to the commonwealth, with a surety company authorized to do business in the commonwealth as surety, in such sum as said board shall fix, conditioned to prosecute the appeal to effect and to comply with the orders and decrees of said board in the premises. Such appeals shall be preferred cases to be heard, unless cause appears to the contrary, in priority to other cases. During the pendency of any such appeal the decision of the commissioner so appealed from shall, unless otherwise ordered by said board, be inoperative. Said board may grant such relief as may be equitable. If the appeal shall have been taken without probable cause, the board may tax double or triple costs, as the case shall demand; and, upon all such appeals which may be denied, costs may be taxed against the appellant at the

discretion of the board; provided, that no costs shall be taxed against the commonwealth.

A person whose registration has been suspended or revoked shall pay to the commissioner a fee of twenty dollars for the reissuance of a registration. The commissioner shall not issue a new registration after the suspension or revocation of a registration unless he is satisfied that the former holder of the registration will comply with the provisions of this chapter and with all pertinent rules and regulations made thereunder.

The commissioner shall provide notice to the director of the state lottery of a retailer or a cigar retailer, as defined in section 1 of chapter 64C, whose license, issued under section 67, has been suspended or revoked by the department for a willful violation of subsections (a), (b) or (c) of section 10 of said chapter 64C, or of sections 34, 35, 37, 37A, or 38 of said chapter 64C and who is a licensee authorized to sell lottery tickets under sections 26 and 27 of chapter 10.

~~[XX] Section 73 of chapter 62C, as so appearing, is hereby further amended by striking out subsection (h), as inserted by section 22 of chapter 415 of the acts of 1978, and inserting in place thereof the following subsection:~~

~~(h) Whoever corruptly, or by force or threats of force, including any threatening letter or communication, endeavors to intimidate or impede an officer or employee of the commonwealth acting in an official capacity under this chapter, or in any other way corruptly, or by force or threats of force, including any threatening letter or communication, obstructs or impedes, or endeavors to obstruct or impede, the due administration of this chapter, shall upon conviction thereof, be fined not more than five thousand dollars, or imprisoned not more than three years, or both, except that if the~~

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offense is committed only by threats of force, and not corruptly or by actual force, the person convicted thereof shall be fined not more than three thousand dollars or imprisoned not more than one year, or both. The term "threats of force", as used in this subsection, means threats of bodily harm to the officer or employee of the commonwealth or to a member of his family. The term "corruptly", as used in this subsection, means to act with the intent to secure an unlawful advantage or benefit either for oneself or another.

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64C, §2 - Vendors' licenses; display

[XX] Section 2 of chapter 64C, as appearing in the 2014 Official Edition, is hereby amended by striking out the first sentence and inserting in place thereof the following sentence:

No person shall sell tobacco products or act as a manufacturer, wholesaler, cigar distributor, vending machine operator, unclassified acquirer, cigar retailer or retailer, in the commonwealth unless licensed to do so in accordance with section sixty-seven of chapter sixty-two C.

[XX] Section 2 of chapter 64C, as so amended, is hereby further amended in line 5 by inserting after the word "manufacturer" the phrase:

" , cigar distributor"

[XX] Section 2 of chapter 64C, as so amended, is hereby further amended in line 15 by striking out the phrase "disc or marker" and inserting in place thereof the word

"decal"

[XX] Section 2 of chapter 64C, as so amended, is hereby further amended by adding at the end the following sentences:

"Every licensed wholesaler, cigar distributor, vending machine operator, unclassified acquirer, cigar retailer and retailer shall be required to report to the commissioner, on a form prescribed by the commissioner, the complete addresses, including any unit number, of any and all premises in addition to such licensee's place or places of

business at which the licensee holds, places or stores tobacco products. Such reports shall be made at the time of licensing, and if the licensee adds additional such premises during the licensing period or ceases to use any such premises for such purpose, reports as to such changes shall be made within three business days of the date the change is made. Every applicant for a license as a wholesaler, cigar distributor, or unclassified acquirer (other than unclassified acquirer applicants that are hospitals, educational institutions or non-profit entities seeking to acquire tobacco products solely for medical research or other non-commercial purposes) shall submit with its application satisfactory proof that it will provide workers' compensation insurance for its employees. In addition, every such applicant shall submit with its application satisfactory proof that it will conduct its day-to-day businesses from a commercial space. Such proof shall consist of either a copy of a deed to, or a copy of an executed lease for a minimum period of two years for the commercial space identified on the application as the applicant's principal place of business."

So that the section as amended shall read:

Section 2. No person shall sell tobacco products or act as a manufacturer, wholesaler, cigar distributor, vending machine operator, unclassified acquirer, cigar retailer or retailer, in the commonwealth unless licensed to do so in accordance with section sixty-seven of chapter sixty-two C. If a manufacturer, cigar distributor, wholesaler, vending machine operator or unclassified acquirer acts in more than one of said capacities at any one place of business he shall procure a license for each capacity in which he acts. Every machine operated or maintained for the purpose of vending tobacco products shall for the purposes of this chapter be deemed to constitute a place of retail business, and no person shall maintain or cause to be operated such a machine without procuring

a retailer's license. Each license so issued or a duplicate copy thereof shall be prominently displayed on the premises covered by the license and in the case of vending machines there shall be attached to the same a decal to be furnished by the commissioner showing it to have been licensed. The licensing of the operation of cigarette vending machines is retained exclusively by the commonwealth and no city, town or other political subdivision of the commonwealth may license such operation. Every licensed wholesaler, cigar distributor, vending machine operator, unclassified acquirer, cigar retailer and retailer shall be required to report to the commissioner, on a form prescribed by the commissioner, the complete addresses, including any unit number, of any and all premises in addition to such licensee's place or places of business at which the licensee holds, places or stores tobacco products. Such reports shall be made at the time of licensing, and if the licensee adds additional such premises during the licensing period or ceases to use any such premises for such purpose, reports as to such changes shall be made within three business days of the date the change is made. Every applicant for a license as a wholesaler, cigar distributor, or unclassified acquirer (other than unclassified acquirer applicants that are hospitals, educational institutions or non-profit entities seeking to acquire tobacco products solely for medical research or other non-commercial purposes) shall submit with its application satisfactory proof that it will provide workers' compensation insurance for its employees. In addition, every such applicant shall submit with its application satisfactory proof that it will conduct its day-to-day business from a commercial space. Such proof shall consist of either a copy of a deed to, or a copy of an executed lease for a minimum period of two years for, the commercial space identified on the application as the applicant's principal place of business.

64C, §33 – Unstamped cigarettes or stamps; prohibition of sale, etc.; examination and replacement of unstamped or improperly stamped packages

[XX] Chapter 64C of the General Laws is hereby amended by striking out section 33, as appearing in the 2014 Official Edition, and inserting in place thereof the following section:

Section 33. Unstamped cigarettes or stamps; prohibition of sale, etc.; examination and replacement of unstamped or improperly stamped packages

Licensees and stampers shall not sell, borrow, loan or exchange unstamped cigarettes or stamps to, from or with other such licensees or stampers unless previously authorized in writing by the commissioner, and licensees and stampers proposing to engage in such a transaction involving the sale, borrowing, loan or exchange of unstamped cigarettes shall submit a written request for the commissioner's

authorization not less than thirty days before the date of the proposed transaction:

provided however that, notwithstanding the thirty-day requirement set forth above, in an emergency situation caused by the failure or malfunction of stamping equipment where that requirement would cause undue hardship, licensees and stampers may submit a written request for expedited authorization for a sale, borrowing, loan or exchange of unstamped cigarettes or stamps between stampers, and the commissioner may grant such authorization. Licensees, unless they are also appointed as stampers, shall not

accept deliveries of unstamped or improperly stamped packages of cigarettes except as previously authorized in writing by the commissioner. Every licensed retailer and licensed vending machine operator shall immediately examine all packages of cigarettes received by them and shall immediately return to their supplier any and all packages of cigarettes that are unstamped or improperly stamped. Such supplier shall replace them

with packages of cigarettes upon which stamps have been properly affixed. In addition to other remedies provided by law, the commissioner may assess a civil penalty of not more than \$5,000 for a first violation of this section or not more than \$25,000 for each subsequent violation.

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64C, §38A - Seizure, ~~and forfeiture and sale~~ of unstamped cigarettes and ~~smokeless other tobacco products on which tax has not been paid~~; warrants

[XX] Chapter 64C of the General Laws is hereby amended by striking out section 38A, as appearing in the 2014 Official Edition, and inserting in place thereof the following section:

Section 38A. Seizure, ~~and forfeiture and sale~~ of unstamped cigarettes and ~~smokeless other tobacco products on which tax has not been paid~~; warrants

(a) Whenever the commissioner discovers:

~~(b)~~(1) any unstamped cigarettes subject to tax under this chapter which are found in the possession of any person other than a stamper, a common carrier transporting such cigarettes under a proper bill of lading or freight bill which states the quantity, source and designation or destination of such cigarettes, or other person transporting unstamped cigarettes in actual possession of the documents required by section 36, or a person authorized in writing by the commissioner to possess such unstamped cigarettes; or

~~(c)~~(2) any unstamped cigarettes or other tobacco products that are being stored or appear to be stored at a location that has not been reported by any licensee, as required by section 2, as premises at which tobacco products are currently held, placed, or stored.

~~(d)~~(3) any such unstamped cigarettes or other tobacco products that are otherwise held, purchased, possessed, imported or acquired in violation of

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paragraphs (a), (b), (c), (d), (f), or (g) of section 10 or of sections 34, 35, 37, or 37A; or

~~(e)~~(4) more than ten thousand units of other tobacco products in the possession of a licensed wholesaler or licensed cigar distributor under circumstances that provide reason to believe that such licensee possesses such other tobacco products with the intent to evade any of the excises imposed by this chapter on such other tobacco products or payment thereof; provided that such circumstances shall include but not be limited to such licensee's history in two or more recent periods of failure to file returns and pay excise relative to other tobacco products of the type such licensee is found to be in possession of or of reporting sales and paying excise on sales of other tobacco products corresponding to quantities substantially below the quantities such licensee is found to be in possession of or is known to have purchased or otherwise acquired during those periods; or

~~(f)~~(5) any falsely made, fraudulently made, forged, altered or counterfeited cigarette excise stamps and any cigarette excise stamps otherwise not prescribed or authorized by the commissioner; or

~~(g)~~(6) any un-affixed genuine cigarette excise stamps found in the possession of anyone not being a stamper or a person otherwise authorized by the commissioner to possess such stamps; or

~~(h)~~(7) any machines or devices for affixing stamps not prescribed or authorized by the commissioner;

he may seize and take possession of such unstamped cigarettes, other tobacco products, stamps, and machines or devices, together with any vending machine or other receptacle in which the unstamped cigarettes or other tobacco products are

contained, and forfeiture proceedings shall be pursued in accordance with the provisions of section 38B.

(b) If the commissioner believes that any of the items described in paragraph subject to seizure under subsection (a) above as being subject to seizure of this section are being kept, stored, sold or concealed in a store, warehouse, building, vehicle, vessel or other place anywhere in the commonwealth or territorial waters thereof, the commissioner or his authorized agent or designee may make a complaint on oath to a district court justice or district court clerk or district court assistant clerk or superior court justice authorized to issue search warrants in criminal cases setting forth the basis for his belief and describing the place to he seeks to search and the items and property he seeks to search for and seize. The justice, if satisfied that there is probable cause for such belief, may issue a warrant describing the place to be searched, identifying the property to be searched for, and authorizing the search for and seizure of such property. In addition to authorizing the search for and seizure of the items described in paragraph (a), a warrant may authorize search for and seizure of documents, records or other items relevant to the origin of tobacco products seized or to be seized, the payment or non-payment of tax on such tobacco products, and the possession or control of the place to be searched. Search warrants issued pursuant to this section shall be directed to the sheriff or his deputy or to a constable or police officer, and shall otherwise be issued and executed in the manner provided in sections 2, 2A, and 2B of chapter 276, in so far as they are applicable, and return of such warrants shall be in the manner provided in section 3A of chapter 276. Nothing in this paragraph shall be construed to prevent warrantless entries and administrative inspections pursuant to sections 5 and 11, nor shall it be construed to prevent warrantless seizures of property authorized by paragraph (a) above in connection with

such inspections, nor shall it be construed to prevent warrantless entries and seizures in any other situations in which a warrant is not required by the laws or constitution of the commonwealth.

64C, §38B [new section] - Forfeiture of Property

[XX] Chapter 64C, as appearing in the 2014 Official Edition, is hereby amended by inserting after section 38A the following section:

Section 38B. Forfeiture of Property

(a) The following property shall be subject to forfeiture to the commonwealth and all property rights therein shall be in the commonwealth:

(1) Any unstamped cigarettes subject to tax under this chapter which are found in the possession of any person other than a stamper, a common carrier transporting such unstamped cigarettes under a proper bill of lading or freight bill which states the quantity, source and designation or destination of such cigarettes or other person transporting such unstamped cigarettes in actual possession of the documents required by section 36, or a person authorized in writing by the commissioner to possess such unstamped cigarettes; any such unstamped cigarettes or other tobacco products that are being stored or appear to be stored at a location that has not been reported by any licensee, as required by section 2, as premises at which tobacco products are currently held, placed, or stored; any such unstamped cigarettes and other tobacco products which are otherwise held, purchased, possessed, imported or acquired in violation of paragraphs (a), (b), (c), (d), (f), or (g) of section 10 or of sections 34, 35, 37, or 37A; any falsely made, fraudulently made, forged, altered or counterfeited cigarette excise stamps and any cigarette excise stamps otherwise not prescribed or authorized by the

commissioner; any un-affixed genuine cigarette excise stamps found in the possession of anyone not being a stamper or a person otherwise authorized by the commissioner to possess such stamps.

...

(b) Property subject to forfeiture under subparagraphs (1), (2), (4), (5), (6), and (7) of subsection (a) shall, upon motion of the attorney general or district attorney or the commissioner, be declared forfeit by any court having jurisdiction over said property or having final jurisdiction over any related criminal proceeding brought under any provision of this chapter. Unless the court for good cause shown orders otherwise, regardless of the final disposition of such related criminal proceeding, if any, Property property subject to forfeiture under subparagraph (1) of subsection (a) shall be turned over to the commissioner if not already in his possession and destroyed, ~~regardless of the final disposition of such related criminal proceeding, if any, unless the court for good cause shown orders otherwise~~ provided that the commissioner may authorize the use of such property for law enforcement purposes.

...

Massachusetts Department of Revenue



ENCRYPTED STAMP PROGRAM

JUNE 13, 2017

Encrypted Stamp Program



- Idea surfaced in December 2007.
- Initially thought of as a revenue enhancer and for administrative efficiency.
- Initially would include 12 Enforcement individuals.
- Modeled after the successful California program.

Encrypted Stamp Program



- In March of 2008, working group was established.
- Determined benefits/ drawbacks of the program that included:
 - Administering such a program.
 - MSA affects.
 - Potential revenue.
 - Stamper migration costs.
 - Added costs.
 - Fire Safe Laws.

Encrypted Stamp Program



- Administering the Program:
 - RFR (Request for Response).
 - Existing program review (California).
 - Procedural updates.
- MSA:
 - Prevents NPM's from being stamped.
 - Identifies all product stamped.
 - Strengthens MSA position.

Encrypted Stamp Program



- Potential Revenue:
 - California Comparison.
 - Counterfeit resistant which should ensure only legal product would be sold.
 - Other Tobacco Products.
- Stamper Migration Costs:
 - New Stamping machinery.
 - Compensation.

Encrypted Stamp Program



- Added Costs:
 - Increase in stamp costs.
 - Stamper compensation.
 - Processing personnel.
 - 12 Enforcement Examiners.
- Fire Safe Laws:
 - Ensures only Fire Safe product can be stamped.
 - Ability to track illegal product.

Encrypted Stamp Program



- In conjunction with the program DOR would also plan for a change in the Cigar and Tobacco Tax by:
 1. Creating a new license type “Cigar Distributor and;
 2. Transitioning the collection, filing and payment of the Excise Tax from the Retailer community to the Distributors.

Encrypted Stamp Program



- On July 1, 2008 the Cigarette Excise was increased from \$1.00 to \$2.51 per pack.
- On October 1, 2008 the collection of the Cigar Excise was transitioned from the Retailers to the new Cigar Distributors. The responsibility went from over 3,500 businesses to less than 150 businesses.

Encrypted Stamp Program



- **RFR Process:**
 - California Stamp discussions.
 - RFR preparation.
 - Two main bidders with significantly different products.
 - Selection process.

Encrypted Stamp Program



- Selection Announcement, July 10, 2009.
 - Contract finalized and signed February 2010.
- Stamper Notification, August 13, 2009.
- RFR Debriefing, August 2009
- Stamper Meeting, September 10, 2009.

Encrypted Stamp Program



- **Stamper Meeting:**
 - 47 Wholesale Stamper Representatives.
 - 6 Industry Executives (Caron).
 - 7 Members SICPA Contract Team.
 - 10 DOR / Attorney General Managers.
- **Discussion / Concerns:**
 - Program Rollout.
 - Equipment Costs.
 - Stamper Compensation.

Encrypted Stamp Program



- **Contract finalization.**
- **Equipment Rollout.**
 - **Installation (5/20/2010 – 3/14/2011)**
(Wiring, area prep, equipment delivery, installation.)
- **Stamper Compensation.**
 - **Roll Application (\$92.50 / \$600.00 / \$200.00)**
 - **One Million Dollars in Grants.**
 - Application Process (11/30/2010 Deadline).
 - LVSM Hand held applicators (\$500.00)
 - HVSM Equipment. (\$ 55,416.00) {18}

Encrypted Stamp Program



Department of Revenue:

- DMS stamp ordering / reporting.
- Scanner equipment issues/ updated version.
- Vendor (sicpa) contract / relationship.
- Investigator positions.
-

Draft Guidance for Industry

Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Written comments and suggestions may be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to <http://www.regulations.gov>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9:00 a.m. – 4:00 p.m. EDT.

Additional copies are available online at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products**

September 2011

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II. Background

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Appendix A – Example Cigarette Warning Plan

Appendix B – Example Smokeless Tobacco Warning Plan

Draft Guidance for Industry¹

Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

This guidance document is intended to assist persons submitting warning plans for cigarettes, as required by section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA), and warning plans for smokeless tobacco products, as required by Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act). This guidance document discusses, among other things:

- x The statutory requirements to submit warning plans
- x Definitions
- x Who submits a warning plan
- x The scope of a warning plan
- x When to submit a warning plan
- x What information should be submitted in a warning plan
- x Where to submit a warning plan
- x What approval of a warning plan means

¹ This guidance has been prepared by the Office of Compliance and Enforcement and the Office of Regulations in the Center for Tobacco Products at the U.S. Food and Drug Administration.

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FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means something is suggested or recommended, but not required.

II. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Section 201 of the Tobacco Control Act amended section 4 of FCLAA, 15 U.S.C. 1333, to prescribe nine health warning statements that must appear on cigarette packages and advertisements. It also modified FCLAA's requirements regarding the submission of warning plans for cigarette packages and advertisements and requires that such warning plans be submitted to FDA (as delegated by the Secretary of Health and Human Services) for review and approval, rather than to the Federal Trade Commission (FTC). However, these requirements are currently not in effect, which means that the FTC will continue to review warning plans for current cigarette warnings that will be in effect until 15 months after FDA issues regulations as directed by Section 201(b). Section 4(d) of FCLAA requires FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany those warning statements. 15 U.S.C. 1333(d). Section 201(b) of the Tobacco Control Act states that the requirements take effect 15 months after FDA issues these regulations. Under the provision, however, if a cigarette product was manufactured prior to the effective date of the final rule but its package does not contain a required warning, the product may be introduced into commerce in the United States within thirty days from such effective date. After the 30-day period, manufacturers must not introduce into domestic commerce any cigarette the package of which does not contain a required warning, irrespective of the date of manufacture. FDA issued a proposed rule regarding these requirements on November 12, 2010. 75 FR 69524. FDA issued final regulations on June 22, 2011. 76 FR 36628. Accordingly, the requirements for the warnings for cigarettes will become effective on September 22, 2012.

Similarly, section 204 of the Tobacco Control Act amended section 3 of the Smokeless Tobacco Act, 15 U.S.C. 4402, to prescribe requirements for four warning statements that must appear on smokeless tobacco product packages and advertisements, and to require the submission of warning plans for smokeless tobacco product packages and advertisements to FDA for review and approval, rather than to the FTC. These requirements are currently in effect.

A. Cigarettes

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Under 15 U.S.C. 1333, each cigarette package and advertisement must bear one of nine textual warning statements.

Packages. Once the required warnings take effect, it will be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarette unless the product package bears one of the required warnings (i.e., one of the nine textual warning statements and its accompanying color graphic) in accordance with the requirements set forth in 15 U.S.C. 1333 and applicable regulations. In certain situations described in 15 U.S.C. 1333(a)(4), retailers of cigarettes are exempt from this requirement. To fall within this exemption, the retailer must ensure that cigarette packaging: 1) contains a health warning; 2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and 3) is not altered by the retailer in a way that is material to the requirements of 15 U.S.C. 1333(a). However, a retailer is still responsible for complying with other applicable requirements relating to cigarettes, including those contained in 21 CFR Part 1140.

Advertisements. Once the required warnings take effect, it will be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears one of the required warnings in accordance with the requirements set forth in 15 U.S.C. 1333 and applicable regulations. As with packaging, retailers may be exempt from this requirement under certain circumstances, which are described in 15 U.S.C. 1333(c)(4).

Warning Plans. The requirement for submission of warning plans for cigarettes, and the specific requirements relating to the random display of required warnings on cigarette packaging and quarterly rotation of required warnings in cigarette advertising, appear at 15 U.S.C. 1333(c).

In particular, warning plans for cigarette packaging must provide that all of the required warnings:

- x Are randomly displayed in each 12-month period on each brand of the product,
- x Are randomly displayed in as equal a number of times as is possible on each brand of the product, and
- x Are randomly distributed in all areas of the United States in which the product is marketed.

15 U.S.C. 1333(c)(1). For FDA to approve it, a warning plan must provide for the required equal distribution and display of required warnings on packaging and must assure that all of the required warnings will be displayed by the manufacturer, importer, distributor, or retailer at the same time. 15 U.S.C. 1333(c)(3).

For FDA to approve it, a warning plan for cigarette advertising must provide that all of the required warnings are rotated quarterly in alternating sequence in advertisements for each brand of cigarettes. 15 U.S.C. 1333(c)(2) and (3).

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B. Smokeless Tobacco Products

Under 15 U.S.C. 4402, each smokeless tobacco product package and advertisement must bear one of four textual warning statements.

Packages. It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears one of the following required warning statements:

- x WARNING: This product can cause mouth cancer.
- x WARNING: This product can cause gum disease and tooth loss.
- x WARNING: This product is not a safe alternative to cigarettes.
- x WARNING: Smokeless tobacco is addictive.

15 U.S.C. 4402(a)(1).

In certain situations described in 15 U.S.C. 4402(a)(5), retailers of smokeless tobacco products are exempt from this requirement. To fall within this exemption, the retailer must ensure that smokeless tobacco packaging: 1) contains a health warning; 2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and 3) is not altered by the retailer in a way that is material to the requirements of 15 U.S.C. 4402(a). 15 U.S.C. 4402(a)(5). However, a retailer is still responsible for complying with other applicable requirements relating to smokeless tobacco products, including those contained in 21 CFR Part 1140.

Advertisements. It is also unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer to advertise or cause to be advertised within the United States any smokeless tobacco product unless the advertising bears one of the required warning statements. 15 U.S.C. 4402(b)(1). As with packaging, retailers may be exempt from this requirement under certain circumstances, which are described in 42 U.S.C. 4402(b)(3)(D).

In an important change from prior law, outdoor billboard advertising for smokeless tobacco products must now include the required warning statements. Prior to its amendment by the Tobacco Control Act, the Smokeless Tobacco Act exempted outdoor billboard advertising from the requirement that smokeless tobacco product advertisements bear required warning statements,² but the Tobacco Control Act amendments eliminated this exemption. 15 U.S.C. 4402(b). Thus, it is unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer to advertise or cause to be advertised a smokeless tobacco product on an outdoor billboard unless the advertisement bears one of the required warning statements.

² This exemption had been codified at 15 U.S.C. 4402(a)(2).

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Warning Plans. The requirement for submission of warning plans for smokeless tobacco products and the specific requirements relating to random display of required warning statements on smokeless tobacco product packaging and quarterly rotation of required warning statements in smokeless tobacco product advertising appear at 15 U.S.C. 4402(b)(3).

In particular, warning plans for smokeless tobacco product packaging must provide that all of the required warning statements:

- x Are randomly displayed in each 12-month period on each brand of the product,
- x Are randomly displayed in as equal a number of times as is possible on each brand of the product, and
- x Are randomly distributed in all areas of the United States in which the product is marketed.

15 U.S.C. 4402(b)(3)(A). For FDA to approve it, a warning plan must provide for the required equal distribution and display of required warning statements on packaging and must assure that all of the required warning statements will be displayed by the manufacturer, importer, distributor, or retailer at the same time. 15 U.S.C. 4402(b)(3)(C)(ii).

Warning plans for smokeless tobacco product advertising must provide that all of the required warning statements are rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product. 15 U.S.C. 4402(b)(3)(B).

Because section 9(1) of the Smokeless Tobacco Act, 15 U.S.C. 4408(1) (as amended by Section 101(c) of the Tobacco Control Act), defines "smokeless tobacco," by reference to section 900(18) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387(18)), as "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity," smokeless tobacco products intended to be placed in the nasal cavity must now comply with the warning requirements in section 3 of the Smokeless Tobacco Act. At this time, as an exercise of enforcement discretion, FDA does not intend to commence or recommend enforcement of the requirement that smokeless tobacco products marketed solely for use in the nasal cavity bear either the "WARNING: This product can cause mouth cancer." or the "WARNING: This product can cause gum disease and tooth loss." so long as a warning plan providing that packages and advertising for such products will bear the other two warnings has been submitted to FDA and implemented. FDA will give further consideration to the warnings smokeless tobacco products marketed solely for use in the nasal cavity should bear. FDA intends to provide further public notice prior to revising or rescinding this enforcement policy.

III. Discussion

A. Definitions

For purposes of this guidance, FDA intends to use the definitions in section 4 of FCLAA, in Section 3 of the Smokeless Tobacco Act, and in any implementing regulations, as well as the following definitions:

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“Required warning” means the combination of a textual warning statement and its accompanying color graphic required pursuant to section 4 of FCLAA to be on packaging and in advertising for cigarettes.

“Required warning statement” means a textual warning statement required pursuant to section 3 of the Smokeless Tobacco Act to be on packaging and in advertising for smokeless tobacco products.

“Warnings” refers to the required warnings (for cigarettes) and the required warning statements (for smokeless tobacco products).

“Original submission.” FDA considers the submission of a warning plan to be an original submission if it is the first time the submitter has provided to FDA a warning plan for cigarettes or smokeless tobacco products.

“Amendment.” FDA considers a submission to be an amendment if the submitter is submitting additional information to a warning plan that is currently under review at FDA.

“Supplement.” FDA considers a submission to be a supplement if the submitter is seeking approval of a change to an FDA-approved warning plan.

B. Who submits a warning plan?

This section describes what FDA believes are the relevant considerations in determining whether the manufacturer, importer, distributor, or retailer is best suited to submit a warning plan. These considerations will help ensure the applicable requirements are complied with as well as avoid situations where multiple persons unnecessarily submit a warning plan applicable to the same distribution chain.

Packages

As explained above, when the warning requirements are in effect, it is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarette or smokeless tobacco product unless the product package bears one of the warnings required by 15 U.S.C. 1333 and 4402, respectively. In addition, warnings on packages must be randomly displayed on each brand and randomly distributed in all areas of the United States in accordance with a warning plan submitted to, and approved by, FDA. 15 U.S.C. 1333(c) (cigarettes) and 15 U.S.C. 4402(b)(3) (smokeless tobacco products). For a particular brand, this warning plan may be submitted by the tobacco product manufacturer, importer, distributor, or retailer. While the warning plan may be submitted by someone other than you, before you “manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States” a brand of cigarettes or smokeless tobacco product, it is

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important that you make sure a warning plan has been approved covering your actions and you comply with this plan.

Based on the FTC's experience reviewing warning plans, we believe it is likely that for domestic products only one plan will be submitted for each brand and that the brand's manufacturer will submit this plan. Moreover, in most circumstances, the brand's manufacturer is the entity that is most able to ensure a warning plan would be sufficient for approval by FDA – that it would provide for equal distribution and display on packaging and assure that all of the warnings that are required will be displayed at the same time. This is because the brand's manufacturer is usually the entity responsible, either directly or through a contractor or other agent, for placing or directing the placement of the warnings on the brand's packages and for directing distribution of the packages. Placing the warning on the packages and directing distribution of the packages are the key elements of a warning plan. If a product is manufactured under contract, such as for a private label brand, it is likely that the contracting entity, typically the private label brand's distributor, specifies or otherwise directs the placement of the warnings on the product package. In such situations, FDA believes the private label brand distributor would be best suited to submit the warning plan. If a retailer is responsible for or directs the placement of warnings on packaging, the retailer would be best suited to submit the warning plan.

For finished cigarettes and smokeless tobacco products that are imported, distribution is usually handled by the product's importer or importers. Because importers typically either direct the foreign manufacturer's placement of the warnings on the product package or direct the packaging and placement of the warnings in the United States, we recommend that the importer or importers of a brand of cigarettes or smokeless tobacco product submit the plan. Compared with the manufacturer or other entities, importers are in a position to create a warning plan that best meets the legal requirements, particularly the requirement that the warnings will be randomly distributed in all areas of the United States in which the product is marketed.

Advertisements.

When the required warnings are in effect, it is unlawful for any tobacco product manufacturer, importer, distributor, or retailer to advertise or cause to be advertised within the United State any cigarette or smokeless tobacco product unless its advertising bears one of the required warnings in accordance with the requirements of 15 U.S.C. 1333 and 4402, respectively. One requirement is that the warnings in advertisements be rotated quarterly for each brand in accordance with a warning plan submitted to, and approved by, FDA. 15 U.S.C. 1333(c) (cigarettes) and 15 U.S.C. 4402(b)(3) (smokeless tobacco products). For a particular brand, this warning plan may be submitted by the tobacco product manufacturer, importer, distributor, or retailer. While the warning plan may be submitted by someone other than you, before you advertise a brand of cigarettes or smokeless tobacco product, it is important that you make sure a warning plan has been approved covering your actions, and your actions in rotating warnings in advertising comply with this plan.

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In most circumstances, the person who creates advertising, causes advertising to be created, or is otherwise responsible for inclusion of the warning on advertising for a brand of cigarettes or smokeless tobacco products is most able to ensure a warning plan would be sufficient for approval by FDA – that it would provide for quarterly rotation of warnings in advertising for the brand. FDA recommends that each manufacturer, importer, distributor, and retailer who creates advertising, causes advertising to be created, or is otherwise responsible for inclusion of the warning on advertising for a brand of cigarettes or smokeless tobacco products submit a warning plan that covers all of the brands it advertises. A retailer typically would not submit a warning plan for advertising supplied by the manufacturer of a tobacco product if the advertising is already covered by a plan submitted by the manufacturer. The retailer would need to comply with the plan, such as by following the manufacturer's instructions for displaying advertising.

C. What is the scope of a warning plan?

If you are submitting warning plans for both cigarettes and smokeless tobacco products, you must submit one warning plan for cigarettes and one warning plan for smokeless tobacco products - because the requirements for submission of these warning plans rest on separate, albeit similar, statutory authority and the text and number of the applicable warnings is different for cigarettes and smokeless tobacco products - but you may submit these plans as a single document or together in the same envelope. For the efficiency of review, FDA asks that each warning plan cover both packaging and advertising to the extent applicable.

D. When should a warning plan be submitted?

Warnings must be equally distributed and displayed on packages, and rotated quarterly in advertisements, for cigarettes and smokeless tobacco products *in accordance with an approved warning plan*. 15 U.S.C. 1333(c)(1), (2) and 15 U.S.C. 4402(b)(3)(A), (B) (emphasis added). As discussed in the Background section, the required warnings for cigarettes will become effective on September 22, 2012. In order to afford FDA sufficient time to review and approve proposed warning plans for cigarettes before the effective date, FDA strongly recommends that the warning plans for cigarettes be submitted to the agency as soon as possible. Given the volume of submissions FDA currently believes it will receive and that all of these will be initial submissions under the requirements, our best estimate is that it will take at least six months for the agency to review a submission. If the volume is greater than anticipated, or the quality of the submissions is poor, then it will likely take FDA longer to review them. You should keep these factors in mind in deciding when to submit your warning plan.

Under section 204 of the Tobacco Control Act, the requirement for an FDA approved warning plan for smokeless tobacco products became effective June 22, 2010. On June 8, 2010, FDA announced by guidance its intent not to enforce the requirement that a brand of smokeless tobacco product must have an FDA-approved warning plan so long as

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a warning plan for the brand was submitted to FDA by July 22, 2010, and implemented. (See 75 FR 32481). FDA expects to begin enforcing the requirement under section 204 that there be an approved warning plan 6 months after the publication of the notice of availability of a final guidance on the "Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products" or 6 months after the publication of a final regulation regarding the submission of warning plans, whichever comes first.

Because warnings must be equally distributed and displayed on packages, and rotated quarterly in advertisements, for cigarettes and smokeless tobacco products in accordance with an approved warning plan, a new warning plan or supplement to an approved warning plan must be submitted and approved before making changes to the distribution or display of warnings on packages or rotation of warnings in advertisements. Likewise, a new plan or a supplement to an approved warning plan must be submitted and approved before distributing or displaying packages and advertisements for a new brand. In order to afford FDA sufficient time to review a supplement to an approved warning plan, FDA strongly recommends that you allow at least three months for FDA to review and approve a supplement. The amount of time it will take FDA to review a supplement, however, will depend upon the volume and quality of the submissions.

FDA may request an amendment to a warning plan or to a supplement to a warning plan if FDA needs clarification of information in the warning plan or minor additional information to determine whether it can approve the warning plan or supplement. Any such amendments will likely increase the overall review time.

E. What information should be submitted as part of a warning plan?

The following information should be submitted to FDA. Appendix A provides an example of what FDA considers to be an acceptable warning plan for cigarettes. Appendix B provides an example of what FDA considers to be an acceptable warning plan for smokeless tobacco products.

1. Cover letter

In order to facilitate FDA's review of warning plans, FDA requests that your warning plan be accompanied by a cover letter that includes:

- x Date of the submission;
- x One of the following subject lines:
 - o "RE: WARNING PLAN FOR CIGARETTES ("Original," "Amendment," or "Supplement"), or
 - o "RE: WARNING PLAN FOR SMOKELESS TOBACCO PRODUCTS ('Original,' 'Amendment,' or 'Supplement');
- x A statement as to whether the warning plan covers packages, advertising, or both packages and advertising;
- x The name, address, and phone number of the person making the submission, the name of the most responsible individual if the submitter is a company,

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- identification of the person as the manufacturer, distributor, retailer, or importer of the tobacco products covered by the warning plan; and the Data Universal Numbering System (D-U-N-S®) Number of the person making the submission;
- x The name, address, phone number, fax number, and email address of the person authorized to act as the FDA contact point for the warning plan;
 - x A list of any submissions made to FDA relating to the warning plan, identified by CTP-assigned reference number and the date of submission;
 - x A list of all cigarettes or smokeless tobacco products covered by the plan, preferably identified using the unique name and identifying number (e.g., SKU, catalog number, UPC) that was provided when the product was listed under section 905 of the Federal Food, Drug, and Cosmetic Act; and
 - x A certification by an authorized official of the company making the submission that all information submitted has been reviewed prior to filing.

2. Information to include in the warning plan for packaging

For each cigarette or smokeless tobacco product brand, your plan should state the specific applicable statutory or regulatory warning plan requirements and provide a detailed description of how:

- x Each of the warnings will be randomly displayed during each 12-month period on each brand;
- x Each of the warnings will be displayed in as equal a number of times as possible on each brand of the product;
- x Product packages will be randomly distributed in all areas of the United States in which the product is marketed; and
- x Each of the warnings will be displayed at the same time.

The plan for packaging should include a discussion of how the requirements are to be implemented based on the specific manufacturing processes and distribution procedures. FTC previously defined as “equal number of times as possible” as permitting deviations of 4 percent or less in a 12-month period and FDA considers that to be a good rule-of-thumb (see 16 CFR 307.11, which as part of 16 CFR Part 307 was rescinded by FTC on September 28, 2010 (75 FR 59609) because of the transfer of jurisdiction to FDA).

For the reasons discussed in section II above, warning plans for smokeless tobacco products marketed solely for use in the nasal cavity should provide for the equal distribution and display of two warnings: “WARNING: This product is not a safe alternative to cigarettes.” and “WARNING: Smokeless tobacco is addictive.”

FDA expects that a plan for equal distribution and display of warnings on packages will ordinarily be based on the date of manufacture or shipment of the product. FDA does not consider a plan that merely re-states the statutory requirements for equal distribution and display of warnings on packages to be sufficiently detailed to enable FDA to determine whether it can approve a warning plan.

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Appendices A and B provide an example of a warning plan for cigarettes and an example of a warning plan for smokeless tobacco products, respectively, that FDA believes would meet the applicable requirements for approval.

3. Information to include in the warning plan for advertising

Your plan should state the specific applicable warning plan requirements. Then, for each cigarette or smokeless tobacco brand, your plan must provide a sufficiently detailed description of how the warnings will be rotated quarterly in advertisements, including outdoor billboard advertisements.

For the reasons discussed in section II above, warning plans for smokeless tobacco products marketed solely for use in the nasal cavity should provide for the quarterly rotation of two warnings: "WARNING: This product is not a safe alternative to cigarettes." and "WARNING: Smokeless tobacco is addictive."

Among other things, your plan should specify the date on which quarterly rotation is based and, if the date varies for different types/forms of advertising, specify both the dates and their associated types/forms of advertising, and describe the schedule for rotating warnings for each brand. A warning plan may take into account practical constraints on the production and distribution of advertising. FDA does not consider a warning plan that merely re-states the statutory requirement for quarterly rotation of warnings on advertising to be sufficiently detailed to enable FDA to determine whether it can approve a warning plan.

4. Representative packaging and advertising

FDA requests that your warning plan include representative samples of packages and advertisements with each of the warnings. Such samples will place the warning plan in context and, therefore, facilitate FDA's review. By representative samples, we mean different types of cigarette or smokeless tobacco product packaging and a range of package sizes for each type of product. Samples of advertising could include actual examples of different types of advertising materials for various brands, prototypes of actual advertising materials, the warning as it would appear in different sizes of advertisements, or acetates or other facsimiles for the warning as it would appear in different sizes of advertisements.

G. Where should a warning plan be submitted?

Written warning plans, including the cover letter addressed to the Office of Compliance and Enforcement, should be directed to:

Food and Drug Administration
Center for Tobacco Products
Office of Compliance and Enforcement
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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H. What does it mean to get FDA approval of a warning plan?

FDA's review of a warning plan is only for the purpose of determining compliance with the statutory criteria for approval of a warning plan, as set forth in 15 U.S.C. 1333(c)(3) and 4402(b)(3)(C). Approval of a warning plan does *not* represent a determination by FDA that any specific package or advertisement complies with any of the other requirements set forth in FCLAA or the Smokeless Tobacco Act, including the requirements set forth in 15 U.S.C. 1333(a)(2), and (b)(2), 4402(a)(2) and (b)(2), and applicable regulations regarding the placement, type, size, and color of the warnings.

Appendix A – Example Cigarette Warning Plan

Note: This document is intended to serve as an example of a plan that FDA believes would meet the applicable requirements for approval and provide information that would help facilitate FDA's review; however, alternative approaches may also satisfy the applicable requirements.

I. Cover Letter (Cigarette Sample)

Date

Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: WARNING PLAN FOR CIGARETTES
([INSERT "Original," "Amendment," or "Supplement"])

To Whom It May Concern:

Pursuant to Section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA), as amended by section 201 of the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), [INSERT: company name] submits this proposed warning plan covering [INSERT: packaging and advertising or packaging or advertising] for cigarettes. See attached.

This plan is being submitted by:

Company Name:
Name of most responsible individual:
Company Role (manufacturer, distributor, importer, or retailer):
Street Address:
City, State, and Zip Code:
Phone Number:
DUNS Number:

Contact information

Name of contact for the warning plan:
Street Address (if different):
City, State, and Zip Code (if different):
Phone Number:
Fax Number:
Email Address:

Transmitter information (if different from the submitter)

Name of person transmitting the warning plan on behalf of the submitter:
Company Name:
Street Address:
City, State, and Zip Code:
Phone Number:
Fax Number:
Email Address:

Previous Related Warning Plan Number(s) (if applicable):

Appendix A – Example Cigarette Warning Plan

This plan covers the following cigarette products:

Brand Name	Product (Subbrand)	Unique Identifier	Type of Unique Identifier (SKU, Catalog #, UPC)
1. <i>Brand x</i>	<i>Blues 100 Hard Pack</i>	<i>12345</i>	<i>Catalog #</i>
2.			

If you have any questions regarding the attached warning plan, please contact *[INSERT: name of company contact listed above]*.

Sincerely,

Name, Title

CERTIFICATION

This certifies that all of the information submitted in the attached Warning Plan dated *[INSERT: date]* which covers cigarettes *[SELECT: packaging and/or advertising]* was reviewed by me *[IF APPLICABLE: and [INSERT: name of person transmitting warning plan]* has the authority to transmit it on my behalf].

Printed Name of official of company who is authorized to submit plan

Signature of official of company who is authorized to submit plan

Appendix A – Example Cigarette Warning Plan

II. Warning Plan for Cigarette Packaging

In accordance with Section 4 of the FCLAA, each cigarette package must bear one of nine warning statements and its accompanying graphic on the front and rear panels of the package. Additionally, the warning statement must appear in black text if on a white background, or white text if on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package.

This plan provides the manner by which the required warnings on packages will be:

- x randomly displayed in each 12-month period on each brand of the product;
- x randomly displayed in as equal a number of times as is possible on each brand of the product;
- x randomly distributed in all areas of the United States in which the product is marketed; and
- x displayed on product packages at the same time.

To ensure display of required warnings in as equal a number of times as is possible on packaging for each brand, we will:

1. Produce a total of 9,000 packages for each print run.
2. Print each of the nine required warnings on packages in sequential order (1, 2, 3, 4, 5, 7, 8, 9 and 1, 2, 3, 4, 5, 7, 8, 9 and 1, 2, 3, 4, 5, 7, 8, 9, etc.), for a total of 9,000 (1,000 each).

OR

2. Print 1,000 of each of the nine required warnings on batches of packages simultaneously (1,000 of warning 1, 1,000 of warning 2, etc.).

This should result in an equal display of each of the nine different required warnings for each brand of product, subject to minor variations due to normal commercial printing and manufacturing practices.

To ensure that the required warnings are randomly displayed in as equal a number of times as is possible on each brand during a 12-month period, that all nine required warnings are displayed at the same time, and that the required warnings are randomly distributed in all areas of the United States in which the product is marketed, we will:

Upon cigarettes being manufactured, store products in shipping containers. Each container will include all required warnings in as equal numbers as possible. When an order is placed, we will distribute such container(s).

OR

Separate cigarette packages by required warning at the time of manufacture. When an order is placed, we will fill the order with as equal a number of packages as is possible from each separate inventory of these warnings.

Appendix A – Example Cigarette Warning Plan

III. Warning Plan for Cigarette Advertising

In accordance with Section 4 of FCLAA, each cigarette advertisement must bear one of the nine required warnings. Additionally, the warning statement must appear in black text if on a white background or white text if on a black background.

This plan provides the manner by which the required warnings on cigarette advertising will be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes.

Our advertisements will rotate the nine required warnings according to the following schedule for each brand of product:

	Jan 1 – March 31	April 1 – June 30	July 1 – Sept 30	Oct 1 – Dec 31	Jan 1 – March 31	April 1 – June 30	July 1 – Sept 30	Oct 1 – Dec 31	Jan 1 – March 31
<i>Brand A</i>	1	2	3	4	5	6	7	8	9
<i>Brand B</i>	9	1	2	3	4	5	6	7	8
<i>Brand C</i>	8	9	1	2	3	4	5	6	7

1=WARNING: Cigarettes are addictive.

2=WARNING: Tobacco smoke can harm your children.

3=WARNING: Cigarettes cause fatal lung disease.

4=WARNING: Cigarettes cause cancer.

5=WARNING: Cigarettes cause strokes and heart disease.

6=WARNING: Smoking during pregnancy can harm your baby.

7=WARNING: Smoking can kill you.

8=WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

9=WARNING: Quitting smoking now greatly reduces serious risks to your health.

Cigarette brands will be advertised using the following media and the rotation of the nine required warnings will be based on the date indicated in the table below:

Type of Advertising	Start of Quarterly Rotation
<i>Advertising in periodicals (newspapers, magazines)</i>	<i>[Cover date] or [closing date of publication]</i>
<i>Posters and placards</i>	<i>[Date of scheduled appearance of the advertisement.]</i>
<i>Other Advertisements</i>	<i>[Order date] or [date of material dissemination]</i>

Appendix B – Example Smokeless Tobacco Warning Plan

Note: This document is intended to serve as an example of a plan that FDA believes would meet the applicable requirements for approval and provide information that would help facilitate FDA's review; however, alternative approaches may also satisfy those requirements.

I. Cover Letter (Smokeless Sample)

Date

Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: WARNING PLAN FOR SMOKELESS TOBACCO PRODUCTS
(*[INSERT: "Original," "Amendment," or "Supplement"]*)

To Whom It May Concern:

Pursuant to Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act), as amended by section 204 of the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), *[INSERT: company name]* submits the attached proposed warning plan covering *[INSERT: packaging and advertising or packaging or advertising]* for smokeless tobacco products. See attached.

This plan is being submitted by:

Company Name:
Name of most responsible individual:
Company Role (manufacturer, distributor, importer, or retailer):
Street Address:
City, State, and Zip Code:
Phone Number:
DUNS Number:

Contact information

Name of contact for the warning plan:
Street Address (if different):
City, State, and Zip Code (if different):
Phone Number:
Fax Number:
Email Address:

Transmitter information (if different from the submitter)

Name of person transmitting the warning plan on behalf of the submitter:
Company Name:
Street Address:
City, State, and Zip Code:
Phone Number:
Fax Number:
Email Address:

Previous Related Warning Plan Number(s) (if applicable):

Appendix B – Example Smokeless Tobacco Warning Plan

This plan covers the following smokeless tobacco products:

Brand Name	Product (Subbrand)	Type of Smokeless Tobacco	Unique Identifier	Type of Unique Identifier (SKU, Catalog #, UPC)
1. <i>Brand x</i>	<i>Long Cut Mint</i>	<i>Chew</i>	<i>12345</i>	<i>Catalog #</i>
2.				

If you have any questions regarding the attached warning plan, please contact [*INSERT: name of company contact listed above*].

Sincerely,

Name, Title

CERTIFICATION

This certifies that all of the information submitted in the attached Warning Plan dated [*INSERT: date*] which covers *smokeless tobacco products* [*SELECT: packaging and/or advertising*] was reviewed by me [*IF APPLICABLE: and [INSERT: name of person transmitting warning plan]*] has the authority to transmit it on my behalf].

Printed Name of official of company who is authorized to submit plan

Signature of official of company who is authorized to submit plan

Appendix B – Example Smokeless Tobacco Warning Plan

II. Warning Plan for Smokeless Tobacco Product Packaging

In accordance with Section 3 of the Smokeless Tobacco Act, each smokeless tobacco product package must bear one of four required warning statements on its two principal display panels. Additionally, the warning statement must appear in black text if on a white background, or white text if on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package.

This plan provides the manner by which the required warning statements on packages will be:

- x randomly displayed in each 12-month period on each brand of the product;
- x randomly displayed in as equal a number of times as is possible on each brand of the product;
- x randomly distributed in all areas of the United States in which the product is marketed; and
- x displayed on product packages at the same time.

To ensure display of the four required warning statements in as equal a number of times as is possible on packaging for each brand, we will:

1. Produce a total of 4,000 packages for each print run.
2. Print each of the four required warning statements on packages in sequential order (1, 2, 3, 4, and 1, 2, 3, 4, and 1, 2, 3, 4, etc.), for a total of 4,000 (1,000 each).

OR

2. Print 1,000 of each of the four required warning statements on batches of packages simultaneously (1,000 of warning 1, 1,000 of warning 2, etc.).

This should result in an equal display of the four different required warning statements for each brand of product, subject to minor variations due to normal commercial printing and manufacturing practices.

To ensure that the required warning statements are randomly displayed and in as equal a number of times as is possible on each brand during a 12-month period, that all four required warning statements are displayed at the same time, and that the required warning statements are randomly distributed in all areas of the United States in which the product is marketed, we will:

Upon smokeless tobacco product being manufactured, store products in shipping containers. Each container will include all required warning statements in as equal a number as possible. When an order is placed, we will ship such container(s).

OR

Separate smokeless tobacco product packages by required warning statement at the time of manufacture. When an order is placed, we will fill the order with as equal a number of packages as is possible from each separate inventory of these warning statements.

Appendix B – Example Smokeless Tobacco Warning Plan

III. Warning Plan for Smokeless Tobacco Product Advertising

In accordance with Section 3 of the Smokeless Tobacco Act, each smokeless tobacco advertisement must bear one of the four required warning statements. Additionally, the warning statement must appear in black text if on a white background or white text if on a black background.

This plan provides the manner by which the required warning statements on smokeless tobacco product advertising will be rotated quarterly in an alternating sequence in advertisements for each brand of smokeless tobacco product.

Our advertisements will rotate the four required warning statements according to the following schedule for each brand of product:

	Jan 1 – March 31	April 1 – June 30	July 1 – Sept 30	Oct 1 – Dec 31
<i>Brand A</i>	1	2	3	4
<i>Brand B</i>	2	3	4	1
<i>Brand C</i>	3	4	1	2

1 = WARNING: This product can cause mouth cancer.

2 = WARNING: This product can cause gum disease and tooth loss.

3 = WARNING: This product is not a safe alternative to cigarettes.

4 = WARNING: Smokeless tobacco is addictive.

Smokeless tobacco brands will be advertised using the following media and the rotation of the four required warning statements will be based on the date indicated in the table below.

Type of Advertising	Start of Quarterly Rotation
Advertising in periodicals (newspapers, magazines)	[Cover date] or [closing date of publication]
Posters and placards	[Date of scheduled appearance of the advertisement.]
Other Advertisements	[Order date] or [date of material dissemination]