RETAIL COMPLIANCE CHECK INSPECTIONS AND FDA ACTIONS: AN OVERVIEW FOR TOBACCO RETAILERS

Presented by
Michelle Jackson
Director, Division of Business Operations
Office of Compliance and Enforcement, CTP, FDA

2016

AGENDA

1. FDA Authority and Retailers
2. Compliance Check Inspections
    1. Undercover Buy
    2. Advertising & Labeling
3. Follow-up Actions
    1. Warning Letters
    2. Civil Money Penalties
    3. No-Tobacco-Sale Orders
4. Additional Resources

FDA AUTHORITY AND RETAILERS

The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA authority to regulate the manufacture, distribution, and marketing of cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco and other tobacco products that the agency, through regulation, deems to be subject to the law.

The Deeming Rule extends FDA's regulatory authority to cover additional products that meet the definition of a tobacco product under section 201(rr) of the FD&C Act, **except** accessories of those newly deemed products.

FDA REGULATED TOBACCO PRODUCTS

Examples of Tobacco Products Regulated Before Deeming Rule	Examples of Newly Regulated Tobacco Products Under Deeming Rule
• Cigarettes • Cigarette tobacco • Roll-Your-Own tobacco • Smokeless tobacco	• ENDS* (meeting the statutory definition of a tobacco product) • Pipe Tobacco • Cigars • Hookah/Waterpipe tobacco • E-liquid (meeting the statutory definition of a tobacco product)

*ENDS = Electronic Nicotine Delivery System (example: e-cigarette, e-hookah, vape pens)

FDA REGULATED TOBACCO PRODUCTS

Covered Tobacco Product means:

- Any tobacco product deemed to be subject to the FD&C Act, but excludes any component or part of a tobacco product that is not made or derived from tobacco.
- Covered Tobacco Products will be subject to certain regulatory requirements under 21 CFR 1140:
  - Minimum age of purchase and identification requirements;
  - Requirement for health warnings for product packages and advertisements; and
  - Prohibition of vending machine sales of such products, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time.
- Free samples of newly deemed tobacco products are also prohibited.

FDA AUTHORITY OVER RETAILERS

- The Tobacco Control Act gives FDA authority to inspect retail establishments.

- Violations of the Tobacco Control Act may result in the following enforcement actions:
  - Advisory Actions (e.g. Warning Letters)
  - Administrative Actions (Civil Money Penalties, or No-Tobacco-Sale Orders)
  - Judicial Actions (e.g. seizure, injunction, or criminal prosecution)

RETAILERS

A “Retailer” under the Tobacco Control Act is

- Any person, government, or entity who:
  - sells tobacco products to individuals for personal consumption, or
  - operates a facility where vending machines or self-service displays of tobacco products are permitted.

Retailers include brick and mortar stores and online tobacco retailers.

COMPLIANCE CHECK INSPECTIONS

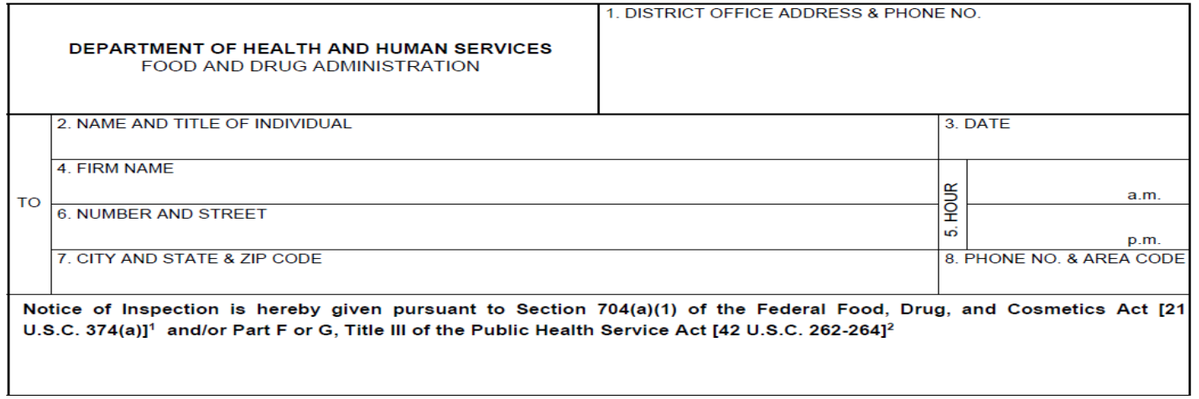
COMPLIANCE CHECK INSPECTIONS

Inspecting Retailers

- The Tobacco Control Act authorizes FDA to contract with states, territories, and tribes to inspect retail establishments within their jurisdiction, where feasible.
- FDA also uses its own employees to conduct inspections.
- In states without contracts, FDA may also use a third-party to conduct inspections.
- Inspectors are commissioned by FDA to act on behalf of the FDA.
- Inspectors conduct compliance check inspections of tobacco retailers and send evidence of potential violations to FDA for review.

COMPLIANCE CHECK INSPECTIONS

- FDA conducts two types of inspections:
  - Undercover Buy Inspections
  - Advertising and Labeling Inspections
- Compliance Check Inspections are not preannounced to the retailer.
- For certain types of inspections (i.e. sale to a minor) you will not be aware at the time that you are being inspected by FDA.
- In other circumstances, inspectors identify themselves and issue an Inspection Form FDA 482 – Official “Notice of Inspection”.



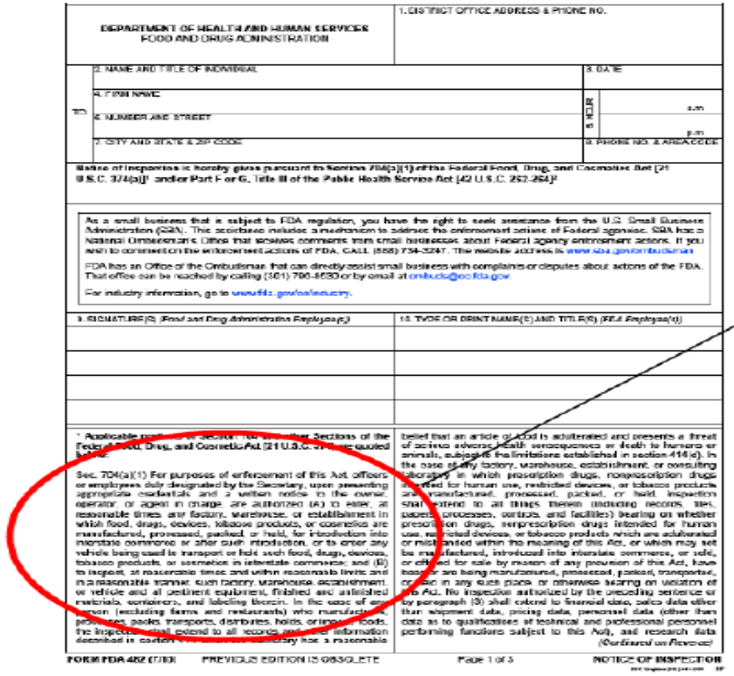
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO.	
TO	2. NAME AND TITLE OF INDIVIDUAL		3. DATE
	4. FIRM NAME	5. HOUR	a.m.
	6. NUMBER AND STREET		p.m.
	7. CITY AND STATE & ZIP CODE		8. PHONE NO. & AREA CODE

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

Form FDA 482

COMPLIANCE CHECK INSPECTIONS

The Form FDA 482 explains FDA's authority to enter and inspect a retail establishment under section 704 of the Federal Food, Drug & Cosmetic Act.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.

2. NAME AND TITLE OF INDIVIDUAL

3. DATE

TO

4. FIRM NAME

5. TYPE ESTAB.

6. NUMBER AND STREET

7. CITY AND STATE & ZIP CODE

8. PHONE NO. & AREA CODE

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)]* and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264]*

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at omb.cds@oc.fda.gov.

For industry information, go to www.fda.gov/ora/industry.

9. SIGNATURE(S) (Food and Drug Administration Employee(s))

10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s))

* Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any [illegible] (excluding farms and restaurants) who manufacture, [illegible] packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section [illegible] if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data

(Continued on Reverse)

FORM FDA 482 (7/93) PREVIOUS EDITION IS OBSOLETE Page 1 of 3 NOTICE OF INSPECTION

Sec. 704(a)(1) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, **tobacco products**, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

COMPLIANCE CHECK INSPECTIONS

Undercover Buy Inspections

- Some Compliance Check Inspections involve the use of a minor under the supervision of the inspector(s).
- A minor attempts to purchase cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, or a covered tobacco product to confirm whether:
  - You sell only to individuals who are 18 years old or older; and
  - You request the photo ID of anyone under 27 years of age who attempts to purchase to verify their date of birth.
- If an inspector reports that a minor was able to enter your establishment and made a purchase during an inspection, FDA will send a Compliance Check Inspection Notice shortly after the inspection.

COMPLIANCE CHECK INSPECTIONS

Compliance Check Inspection Notice

The Notice informs you of the following:

1. That a potentially violative inspection involving a minor occurred at the establishment;
2. Provides a photo of the establishment taken at the time of the inspection, if available;
3. The date and approximate time of the inspection; and
4. A description of the on-duty clerk (including their name, if available) who sold to the minor.

Other potential violations of federal tobacco laws may have also been reported to FDA by the inspector, but they are not addressed in this notice.

COMPLIANCE CHECK INSPECTIONS

Compliance Check Inspection Notice

- You are NOT required to contact FDA after receiving this notice.
- FDA cannot release any further details of this open investigation until a final decision is made.
- If you think that there has been an error regarding the location or address of your establishment, contact FDA at the phone number or e-mail address on the notice.
- FDA will review the evidence collected by the inspector and make a final determination whether a violation occurred.
- If FDA determines that there was a violation of federal law, FDA may issue an enforcement action.

COMPLIANCE CHECK INSPECTIONS

Advertising and Labeling Inspections

- If an inspector issues a Notice of Inspection (Form FDA 482), the Inspector will:
  - Introduce themselves by name, title, and organization, and provide credentials
  - Ask to speak with the most responsible person present
  - Ask the most responsible person present to provide:
    - His or her name
    - The establishment's name, physical address, and telephone number
    - Ownership information
  - Sign the Notice of Inspection (Form FDA 482)
  - Give a copy to the most responsible person present

COMPLIANCE CHECK INSPECTIONS

Advertising and Labeling Inspections

- An FDA inspector will check for compliance with FDA's laws and regulations such as:
  - That you DO NOT give away free samples of tobacco products, except for smokeless tobacco from a "qualified adult-only facility"
  - That you DO NOT break open cigarette or smokeless tobacco packages to sell products in smaller amounts
  - That you DO NOT sell cigarette packages containing fewer than 20 cigarettes
  - That you DO NOT sell single cigarettes (also called "loosies")
  - That you DO NOT sell flavored cigarettes or flavored cigarette tobacco
    - Exception: menthol or tobacco flavored cigarettes or cigarette tobacco are allowed
  - That required warning statements are present on all tobacco products.

COMPLIANCE CHECK INSPECTIONS

Advertising and Labeling Inspections

- That you DO NOT sell cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, or covered tobacco products using a Vending Machine (VM) in a non-age restricted facility

- That you DO NOT sell cigarettes, cigarette tobacco, smokeless tobacco, or roll-your-own tobacco using a Self Service Display (SSD) in a non-age restricted facility

Note: If Vending Machine labels and/or buttons do not match the product being sold, the products may be in violation of the misbranding provisions of the FD&C Act.

INSPECTION RESULTS

Results of Compliance Check Inspections are available on FDA's website in a searchable database.

- The database lists all completed inspections, including those where violations were observed and those where there were no observed violations.
- The database is available at: http://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm

INSPECTION RESULTS

Compliance Check Inspections of Tobacco Product Retailers Website

FOLLOW-UP ACTIONS

VIOLATIONS OF THE LAW

Potential Advisory and Enforcement Actions Include:

- Warning Letter
- Civil Money Penalty
- No-Tobacco-Sale Order

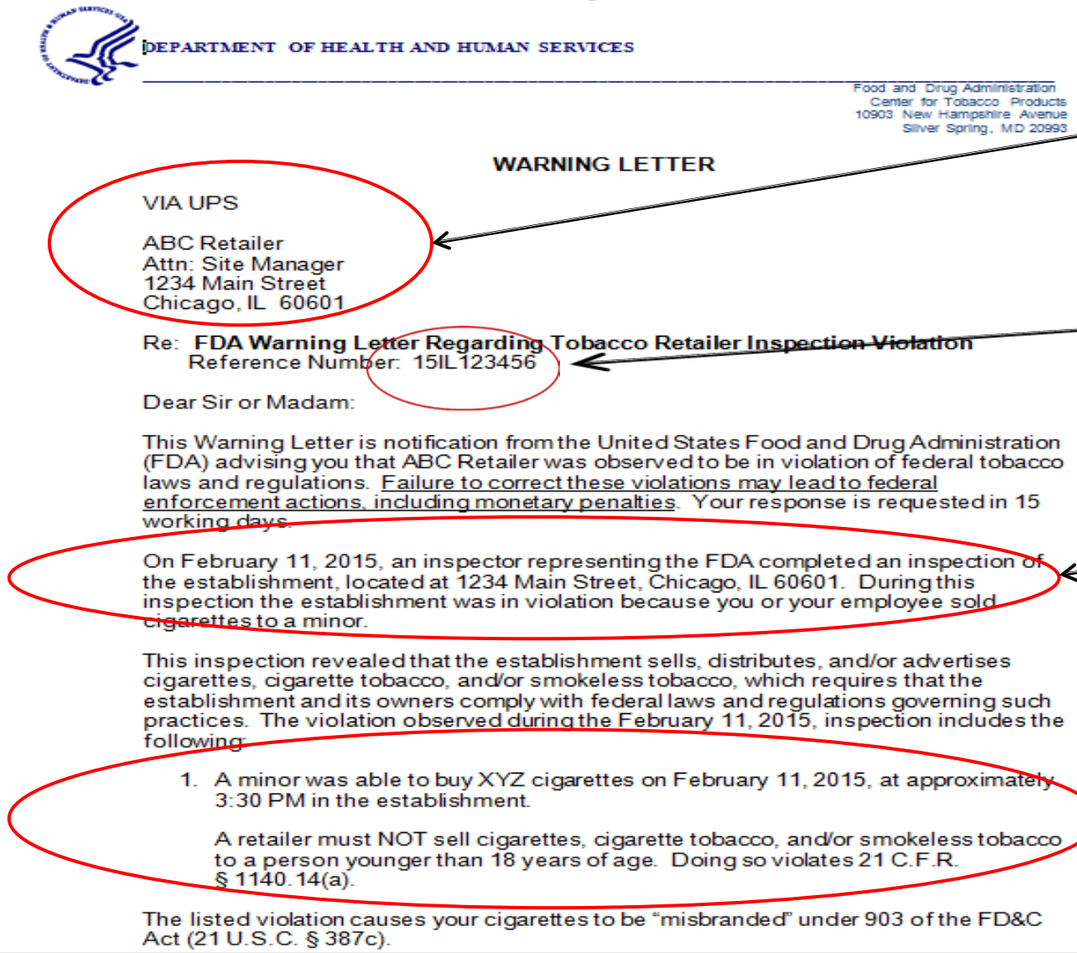
WARNING LETTER

What is a Warning Letter (WL)?

- The first time FDA finds violations during a tobacco retailer inspection, FDA generally issues a Warning Letter.
- A Warning Letter is the Agency's advisory action used to try to achieve prompt voluntary compliance with the law and establish prior notice.

WARNING LETTER

What will the Warning Letter Include?



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

VIA UPS

ABC Retailer
Attn: Site Manager
1234 Main Street
Chicago, IL 60601

Re: **FDA Warning Letter Regarding Tobacco Retailer Inspection Violation**
Reference Number: 15IL123456

Dear Sir or Madam:

This Warning Letter is notification from the United States Food and Drug Administration (FDA) advising you that ABC Retailer was observed to be in violation of federal tobacco laws and regulations. Failure to correct these violations may lead to federal enforcement actions, including monetary penalties. Your response is requested in 15 working days.

On February 11, 2015, an inspector representing the FDA completed an inspection of the establishment, located at 1234 Main Street, Chicago, IL 60601. During this inspection the establishment was in violation because you or your employee sold cigarettes to a minor.

This inspection revealed that the establishment sells, distributes, and/or advertises cigarettes, cigarette tobacco, and/or smokeless tobacco, which requires that the establishment and its owners comply with federal laws and regulations governing such practices. The violation observed during the February 11, 2015, inspection includes the following:

1. A minor was able to buy XYZ cigarettes on February 11, 2015, at approximately 3:30 PM in the establishment.

   A retailer must NOT sell cigarettes, cigarette tobacco, and/or smokeless tobacco to a person younger than 18 years of age. Doing so violates 21 C.F.R. § 1140.14(a).

The listed violation causes your cigarettes to be "misbranded" under 903 of the FD&C Act (21 U.S.C. § 387c).

Retail Establishment Address

Reference Number

Date of Inspection

List of Violation(s)

WARNING LETTER

What will the Warning Letter include?

- The date the store was inspected and approximate time of the sale
- The particular violation(s) the inspector observed and an explanation of the evidence used to support the violation(s)
- References to relevant laws and regulations
- A statement directing you to correct the violation(s)
- A statement that failure to correct the violations may result in FDA taking regulatory action without further notice
- A request to submit a written response to FDA within fifteen (15) working days of receiving the Warning Letter
- A statement that the violations listed in the Warning Letter may not be a complete list of violations at the establishment
- The establishment must comply with all applicable laws and regulations

WARNING LETTER

What Should You Do if You Receive a Warning Letter?

- Review the Warning Letter carefully to see what charges are listed.
- Respond in writing to the Warning Letter within fifteen (15) working days by mail or e-mail. Include the following in your response to the Warning Letter:
  - An explanation of the steps you will take to correct the violation(s) and prevent future violations (e.g., retrain your employees, remove the problematic items, etc.); and
  - Your current contact information, including telephone number and e-mail address.
- Promptly and adequately correct the violations listed and be sure that you comply with all applicable laws and regulations.

WARNING LETTER

- Retailers who respond to the Warning Letter will receive a reply from FDA.
- FDA will conduct a follow-up Compliance Check Inspection at the establishment without further notice.
- If violations are observed during a follow-up Compliance Check Inspection, you may be subject to Civil Money Penalties.

CIVIL MONEY PENALTY

What is a Civil Money Penalty?

- A Civil Money Penalty (CMP) is a penalty assessed for a violation of FDA's laws and regulations. FDA is authorized to seek CMPs for violation of the FD&C Act relating to tobacco products.

- The amount of the CMP sought is determined in accordance with an established schedule provided in the Tobacco Control Act.

CIVIL MONEY PENALTY

Current Schedule for Civil Money Penalties

Number of Violations of the regulations in 21 CFR 1140	Amount
1	$0 with a Warning Letter
2 within a 12-month period	$250
3 within a 24-month period	$500
4 within a 24-month period	$2000
5 within a 36-month period	$5000
6 within a 48-month period	$11,000

For more information see guidance: “Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions”.

NO-TOBACCO-SALE ORDER

- A No-Tobacco-Sale Order (NTSO) is an order prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified period of time.
- FDA may seek to impose an NTSO when a tobacco retailer is found to have committed “repeated violations” of certain restrictions on the sale and distribution of tobacco products.
- “Repeated violations” means at least 5 violations of particular requirements over a 36 month period at a particular retail outlet that constitute a repeated violation of the Tobacco Control Act.
- FDA recently published a guidance on the timeframes that FDA would seek when asking for the imposition of an NTSO.
  - 1st NTSO – 30 days
  - 2nd NTSO – 6 months
  - 3rd and subsequent NTSOs – permanent

ADDITIONAL RESOURCES

Additional Resources

- Guidances:
  - Civil Money Penalties and No-Tobacco-Sale-Orders for Tobacco Retailers
  - Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions
  - The Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order

- Additional information can be found at the FDA Center for Tobacco Products Website at: http://www.fda.gov/TobaccoProducts

- Please direct any additional questions to : AskCTP@fda.hhs.gov

THANK YOU


DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
FDA
CENTER FOR
TOBACCO
PRODUCTS