U.S. FOOD & DRUG ADMINISTRATION

COMPLIANCE TRAINING FOR SMALL TOBACCO PRODUCT MANUFACTURERS – DOMESTIC ESTABLISHMENT INSPECTIONS

Presented by
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OCE, CTP, FDA

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Tobacco Operations Staff
OMPTO, ORA, FDA

November 2017

CENTER FOR TOBACCO PRODUCTS

WHO WILL PERFORM FDA INSPECTIONS?

Office of Regulatory Affairs (ORA)

- Tobacco Operations Staff
  - Consumer Safety Officers/Investigators

Center for Tobacco Products (CTP)

- Representatives from the Office of Compliance & Enforcement (OCE)
  - Subject Matter Experts (SMEs)

WHO CAN FDA INSPECT?

Section 905(g) FD&C Act

- Federal Food, Drug, and Cosmetic Act (FDCA) directs the Food and Drug Administration (FDA) to inspect “every establishment registered with [FDA]… engaged in the manufacture, compounding, or processing of a tobacco product”

Section 704(a)(1) FD&C Act

- FDA has the authority to inspect “any factory, warehouse, or establishment in which … tobacco products … are manufactured, processed, packed, or held”

See FDA Letter to Tobacco Product Registered Establishments at:
http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm268086.htm

WHEN WILL FDA INSPECT?

Food Drug & Cosmetic Act requires FDA inspections be conducted:

- At reasonable times and within reasonable limits and in a reasonable manner – Section 704(a)(1) FD&C Act
- At least once every 2 years for each tobacco product establishment registered with FDA – Section 905(g) FD&C Act
- As part of FDA's premarket tobacco application review process, ORA may be asked to conduct an inspection of the manufacturing facilities where the new tobacco product is being produced.

PREVIOUS ORA REGIONS & DISTRICTS

- Pacific
- Southwest
- Central
- Southeast
- Northeast

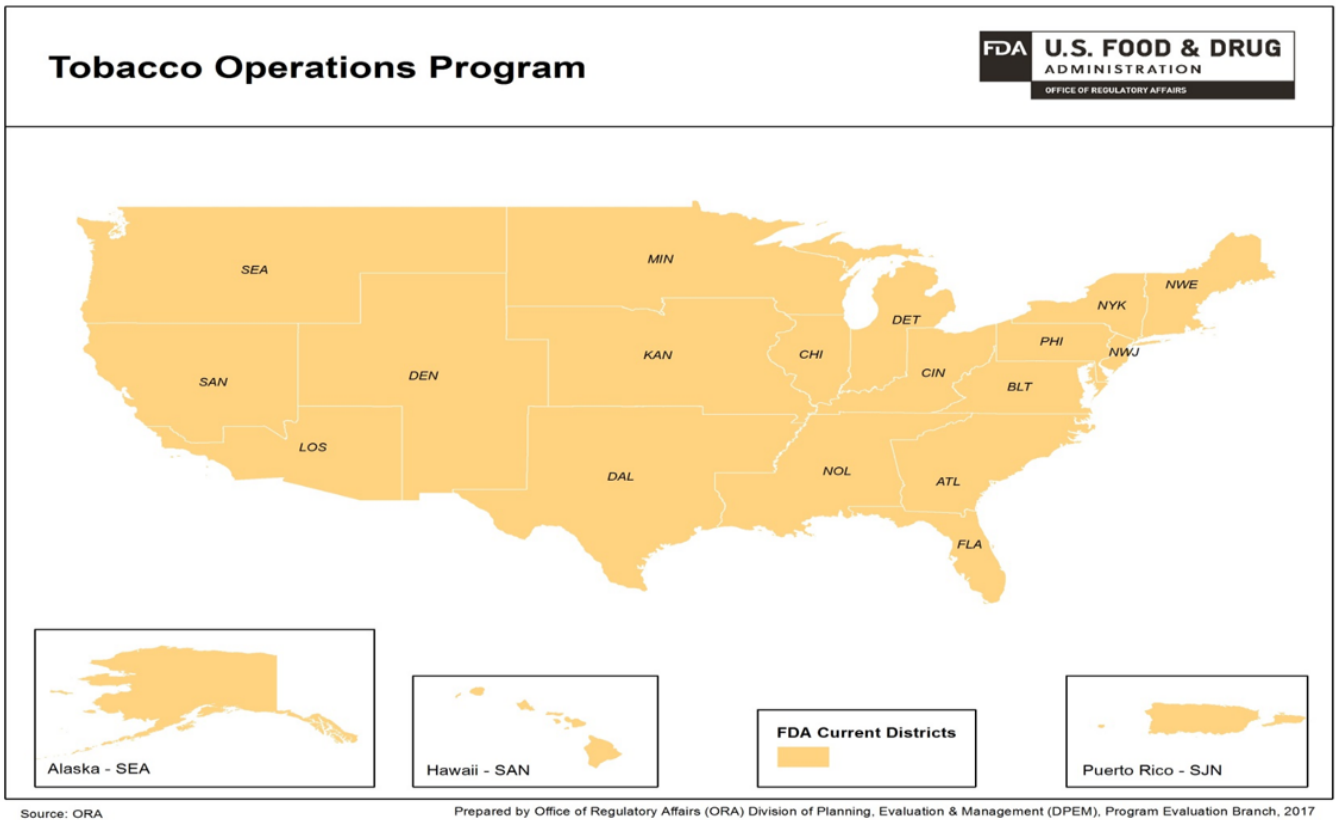
- Program Alignment – modernize and strengthen public health role and keep pace with scientific innovation.

ORA'S NEW FIELD STRUCTURE

Program Alignment – Office of Medical Products and Tobacco Operations – Tobacco Operations Staff

- Tobacco Operations is responsible for the following activities, which support the Center for Tobacco Products (CTP) and for activities conducted under the Tobacco Control Act including:
  - Conducting tobacco inspections of manufacturing and clinical trial facilities in all states and territories.
  - Conducting investigations at events to ensure tobacco product manufacturers do not distribute prohibited free samples.

ORA'S NEW FIELD STRUCTURE



FDA INSPECTIONS AUTHORITY

Section 704(a) FD&C Act

- Factories, warehouses, establishments, vehicles
- All pertinent equipment, finished and unfinished materials, containers, and labeling
- “all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether … tobacco products … 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 … or otherwise bearing on a violation of this Act.”

FDA INSPECTIONS – AUTHORITY LIMITS

Section 704(a)(1) FD&C Act does not extend to

- Financial data, sales data, pricing data
  - Other than shipment data
- Personnel data
  - Other than qualifications of technical or professional personnel performing functions subject to the FD&C Act

FDA INSPECTIONS – OBJECTIVES

- Review processes and procedures
- Observe and evaluate operations
- Document and collect information
- Identify violations
- Communicate potential violations to firm management
- Document any proposed corrective action plans

FDA INSPECTIONS – PROCEDURES

Investigations Operations Manual (IOM)

- Primary source of information regarding Agency policy & procedures for field investigators
- Updated annually

For access to the latest IOM visit: https://www.fda.gov/iceci/inspections/iom/default.htm

INVESTIGATIONS OPERATIONS MANUAL

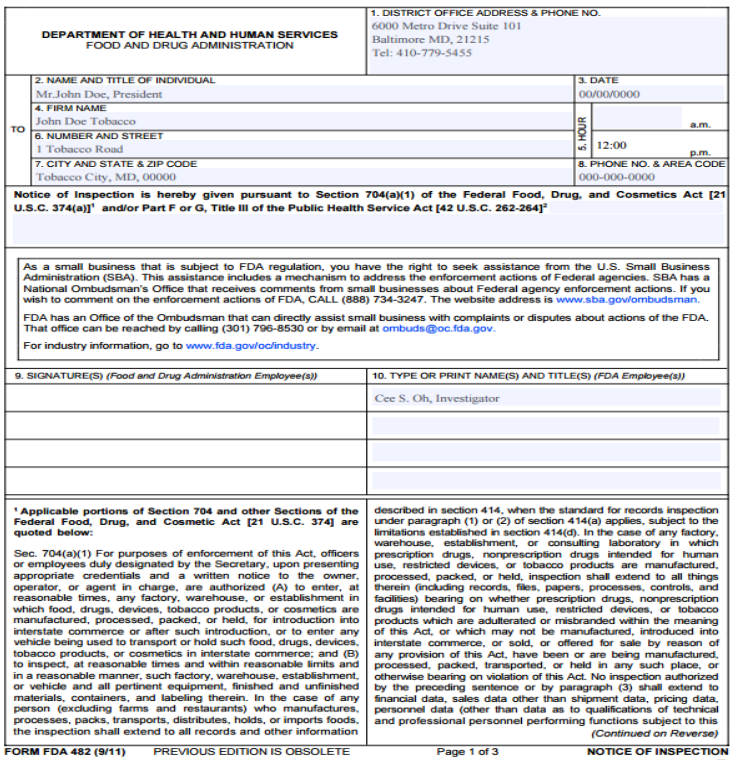
- Forward / Vision / Mission / Values (PDF - 223KB)
- Table of Contents (PDF - 37KB)
- Chapter 1 - Administration (PDF - 570KB)
- Chapter 2 - Regulatory (PDF - 2MB)
- Chapter 3 - Federal and State Cooperation (PDF - 335KB)
- Chapter 4 - Sampling (PDF - 2.3MB)
- Chapter 5 - Establishment Inspections (PDF - 5.9MB)
- Chapter 6 - Imports (PDF - 1.6MB)
- Chapter 7 - Recall Activities (PDF - 837KB)
- Chapter 8 - Investigations (PDF - 2.5MB)
- Appendix (PDF - 368KB)
- Index (PDF - 345KB)
- ORA Directory (PDF - 387KB)
- Exhibits
- Sample Schedules
- Full 2017 Investigations Operations Manual (PDF - 16.6MB)

INITIATING AN FDA INSPECTION

What happens:

- Meet with most responsible person onsite at firm
- Present credentials
- Issue Form FDA 482, Notice of Inspection

Sample Form FDA 482



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
6000 Metro Drive Suite 101
Baltimore MD, 21215
Tel: 410-779-5455

TO
2. NAME AND TITLE OF INDIVIDUAL: Mr.John Doe, President
3. DATE: 00/00/0000
4. FIRM NAME: John Doe Tobacco
5. HOUR: 12:00 a.m. / p.m.
6. NUMBER AND STREET: 1 Tobacco Road
7. CITY AND STATE & ZIP CODE: Tobacco City, MD, 00000
8. PHONE NO. & AREA CODE: 000-000-0000

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]

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 ombuds@oc.fda.gov.

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

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
	Cee S. Oh, Investigator

[1] 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 person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, 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

(Continued on Reverse)

FORM FDA 482 (9/11) PREVIOUS EDITION IS OBSOLETE Page 1 of 3 **NOTICE OF INSPECTION**

WHAT'S COVERED IN THE INSPECTION?

- Administrative information
- Establishment registration & product listing
- Listing of ingredients
- Tobacco health documents
- Packaging, labeling, & advertising requirements
- Marketing Authorization New Tobacco Products
- Modified Risk tobacco products

See FDA letter to Tobacco Product Registered Establishments at:
https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM499743.pdf

ADMINISTRATIVE INFORMATION

- Firm contact information
- Most Responsible Individual
- Firm History
  - Legal status
  - Organization
  - Number of persons employed
  - Hours of operation
  - Top management officials
- List of regulated tobacco products manufactured, distributed, packed, labeled, promoted, or advertised
- Interstate Commerce
  - Where regulated products are shipped
  - General promotion and distribution patterns
  - Documentation of interstate commerce
- Individual responsibility and persons interviewed
- Manufacturing and design operations

WHAT TOBACCO PRODUCTS CAN FDA COVER DURING AN INSPECTION?

From June 2009

- Cigarettes
- Cigarette Tobacco
- Roll-Your-Own Tobacco
- Smokeless Tobacco

From August 2016

- All products from June 2009
- E-Cigarettes
- Dissolvables
- Pipe Tobacco
- Hookah
- Cigars
- Including components and parts of the above

PROVISIONS AND REFERENCES

Provision(s)	Resources and References
Registration of establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product. **(§ 905(b), (c), and (d) of the FD&C Act)**	Section 905 of the FD&C Act FDA Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments. FDA Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule FDA Tobacco Compliance Webinar: Establishment Registration & Product Listing
Product listing for establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product. **(§§ 905(i)(1) and i(3) of the FD&C Act)**	Section 905 of the FD&C Act FDA Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments. See FDA Tobacco Compliance Webinar: Establishment Registration & Product Listing FDA Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule
Listing of ingredients in tobacco products submitted for each tobacco product by brand and quantity in each brand and subbrand. **(§§ 904(a)(1) & 904(c) of the FD&C Act)**	Section 904 of the FD&C Act FDA Guidance for Industry: Listing of Ingredients in Tobacco Products FDA Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule

PROVISIONS AND REFERENCES

Provision(s)	Resources and References
Submission of tobacco health documents relating to health, toxicological, behavioral, or physiological effects of tobacco products, their constituents (including smoke constituents), ingredients, components, and additives. **(§ 904(a)(4) of the FD&C Act)**	Section 904 of the FD&C Act FDA Guidance for Industry: Health Document Submission Requirements for Tobacco Products FDA Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule
Reporting quantities of harmful and potentially harmful constituents (HPHCs) for tobacco products by brand and subbrand. **(§ 904(a)(3) of the FD&C Act)**	Section 904 of the FD&C Act FDA Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act FDA Guidance for Industry: Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act FDA Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule
User fees. **(§ 919 of the FD&C Act)**	Section 919 of the FD&C Act FDA Guidance for Industry: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

PROVISIONS AND REFERENCES

Provision(s)	Resources and References
Premarket tobacco product authorization required for tobacco products unless: • **FDA has issued a substantial equivalence order for the tobacco product** • **FDA has granted a substantial equivalence exemption request** • **The product was on the market as of February 15, 2007 and has remained unchanged since then (Grandfathered).** **(§§ 910 and 905(j) of the FD&C Act)**	Section 905 of the FD&C Act Section 910 of the FD&C Act FDA Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions FDA Draft Guidance for Industry: Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product FDA Draft Guidance for Industry: Applications for Premarket Review of New Tobacco Products FDA Draft Guidance for Industry: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS) FDA Guidance for Industry: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products FDA Guidance for Industry: Establishing that a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 FDA Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule See FDA Tobacco Compliance Webinar: Premarket Tobacco Product Applications (PMTA) for Electronic Nicotine Delivery Systems (ENDS) – Draft Guidance

PROVISIONS AND REFERENCES

Provision(s)	Resources and References
Smokeless tobacco product packaging and advertisements must bear one of four required warning statements, and must meet certain font, text, size, placement and formatting requirements in accordance with an approved warning plan. **(15 U.S.C. § 4402)**	Section 204 of the Tobacco Control Act FDA Draft Guidance for Industry: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products See FDA Tobacco Compliance Webinar: Cigarettes and Smokeless Tobacco Warning Plan Requirements
Cigar packaging and advertisements must bear one of six required warning statements, and must meet certain font, text, size, placement and formatting requirements in accordance with an approved warning plan **(21 C.F.R. § 1143.5)**	Title 21 C.F.R. § 1143.5 FDA Guidance for Industry: Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements See FDA Tobacco Compliance Webinar: Required Warning Statements for Cigars FDA Draft Guidance for Industry: Compliance Policy for Required Warning Statements on Small-Packaged Cigars FDA Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule FDA Guidance for Industry: Submission of Warning Plans for Cigars See FDA Tobacco Compliance Webinar: Cigar Warnings and Warning Plan Requirements FDA Letter to Industry: Cigar Warning Plan Requirements

PROVISIONS AND REFERENCES

Provision(s)	Resources and References
Cigarette tobacco, roll-your-own tobacco, and covered tobacco product packages and advertisements must bear the required nicotine addictiveness warning. **(21 C.F.R. § 1143.3)**	Title 21 C.F.R. § 1143.3 FDA Guidance for Industry: Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements FDA Tobacco Compliance Webinar: New Regulatory Requirements for Tobacco Manufacturers and Importers
Product packages and ads of covered tobacco products that do not contain nicotine may bear an alternative warning statement. **(21 C.F.R. § 1143.3(c))**	Title 21 C.F.R. § 1143.3 FDA Guidance for Industry: Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements FDA Tobacco Compliance Webinar: New Regulatory Requirements for Tobacco Manufacturers and Importers
Prohibition on the introduction into interstate commerce of products that contain "light," "low," "mild," or other similar descriptors in the label, labeling, or advertising of such products without a modified risk tobacco product order in effect. **(§ 911 of the FD&C Act)**	Section 911 of the FD&C Act FDA Guidance for Industry: Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products FDA Tobacco Compliance Webinar: New Regulatory Requirements for Tobacco Manufacturers and Importers

PROVISIONS AND REFERENCES

Provision(s)	Resources and References
Prohibition on the introduction into interstate commerce of modified risk tobacco products (MRTPs) (other than those listed above) without a modified risk tobacco product order in effect. **(§ 911 of the FD&C Act).**	Section 911 of the FD&C Act FDA Draft Guidance for Industry: Modified Risk Tobacco Product Applications FDA Tobacco Compliance Webinar: New Regulatory Requirements for Tobacco Manufacturers and Importers
Package labels must bear the following label statements: • **The name and place of business of the tobacco product manufacturer, packer, or distributor** • **The quantity of the contents in terms of weight, measure, or numerical count** • **The statement "Sale only allowed in the United States".** **(§§903(a)(2) and 920 of the FD&C Act)**	Section 903 of the FD&C Act Section 920 of the FD&C Act FDA Tobacco Compliance Webinar: New Regulatory Requirements for Tobacco Manufacturers and Importers FDA Draft Guidance for Industry: Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops

PROVISIONS AND REFERENCES

Provision(s)	Resources and References
Cigarette flavor ban. **(§ 907(a)(1)(A) of the FD&C Act)**	Section 907 of the FD&C Act FDA Guidance for Industry: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2) FDA Letter to Industry: Cigarettes Containing Certain Characterizing Flavors
Minimum cigarette package size. **(21 C.F.R. § 1140.16(b))**	Title 21 C.F.R. § 1140.16 FDA Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents FDA Tobacco Compliance Webinar: Compliance Training for Retailers and Small Businesses – Guidance for Industry on Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents
Prohibition on the distribution of free samples of tobacco products. **(21 C.F.R. § 1140.16(d))**	Title 21 C.F.R. § 1140.16 FDA Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents FDA Draft Guidance for Industry: Prohibition of Distributing Free Samples of Tobacco Products FDA Tobacco Compliance Webinar: Compliance Training for Retailers and Small Businesses – Guidance for Industry on Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

PROVISIONS AND REFERENCES

Provision(s)	Resources and References
Restriction on product names for cigarettes and smokeless tobacco. **(21 C.F.R. § 1140.16(a))**	Title 21 C.F.R. § 1140.16(a) FDA Guidance for Industry: Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco
Restriction on text color and background for labeling or advertising. **(21 C.F.R. § 1140.32(a))**	Title 21 C.F.R. § 1140.32(a) FDA Guidance for Industry: Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco
Restriction on sponsorship for cigarettes and smokeless tobacco. **(21 C.F.R. § 1140.34(c))**	Title 21 C.F.R. § 1140.34 FDA Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

HOW AN FDA INSPECTION WILL CONCLUDE

What happens:

- Close-Out Discussion
- Discuss observations with management
- Issue Form FDA 483, Inspectional Observations, if necessary
- Solicit firm's responses to observations

Sample Form FDA 483

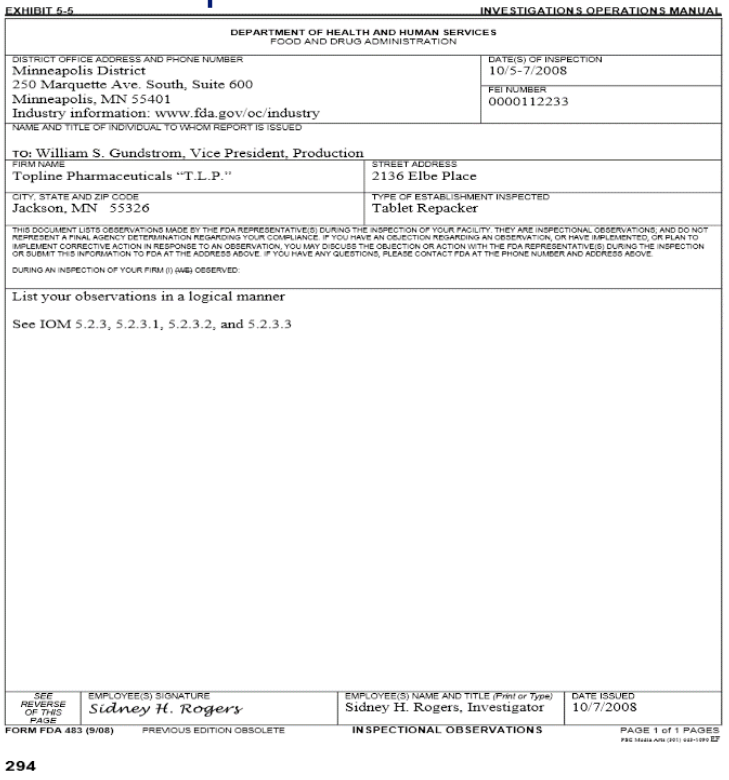


EXHIBIT 5-5 INVESTIGATIONS OPERATIONS MANUAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
Minneapolis District
250 Marquette Ave. South, Suite 600
Minneapolis, MN 55401
Industry information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION
10/5-7/2008

FEI NUMBER
0000112233

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William S. Gundstrom, Vice President, Production

FIRM NAME
Topline Pharmaceuticals "T.L.P."

STREET ADDRESS
2136 Elbe Place

CITY, STATE AND ZIP CODE
Jackson, MN 55326

TYPE OF ESTABLISHMENT INSPECTED
Tablet Repacker

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

List your observations in a logical manner

See IOM 5.2.3, 5.2.3.1, 5.2.3.2, and 5.2.3.3

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sidney H. Rogers

EMPLOYEE(S) NAME AND TITLE (Print or Type)
Sidney H. Rogers, Investigator

DATE ISSUED
10/7/2008

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FDA INSPECTIONS – FINAL REPORT

- Establishment Inspection Report (EIR) will describe the information discussed and collected during the inspection
- Field Management Directive 145 – Copy of EIR to Firm
  - Sent to most responsible individual identified during the inspection

RESOURCES AND CONTACT INFORMATION

CTP Website available at:

- http://www.fda.gov/TobaccoProducts/default.htm

For General Inquiries contact via email or phone:

- AskCTP@fda.hhs.gov
- 1-877-CTP-1373

Inquiries from small businesses

- Smallbiz.tobacco@fda.hhs.gov

Sign up for updates available at:

- http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm176164.htm