

Compliance Training for Small Tobacco Product Manufacturers – Domestic Establishment Inspections

January 17, 2012

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FDA's Center for Tobacco Products

Who Will FDA Inspect?

- Federal Food, Drug, and Cosmetic Act (FDCA) directs FDA to inspect “every establishment registered with [FDA]... engaged in the manufacture, compounding, or processing of a tobacco product ...” – Section 905(g) FDCA
- FDA has the authority to inspect “any factory, warehouse, or establishment in which ... tobacco products ... are manufactured, processed, packed, or held” – Section 704(a)(1) FDCA

See FDA Letter to Tobacco Product Registered Establishments at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts_Guidance_Compliance_Regulatory_Information_Tobacco)

When Will FDA Inspect?

- FDCA requires that FDA inspections be conducted
 - at reasonable times and within reasonable limits and in a reasonable manner – Section 704(a)(1) FDCA
 - at least once every 2-years for each tobacco product establishment registered with FDA – Section 905(g) FDCA

Who Will Perform FDA Inspections?

- Office of Regulatory Affairs (ORA)
 - Investigators
- Center for Tobacco Products
 - Representatives from the Office of Compliance and Enforcement

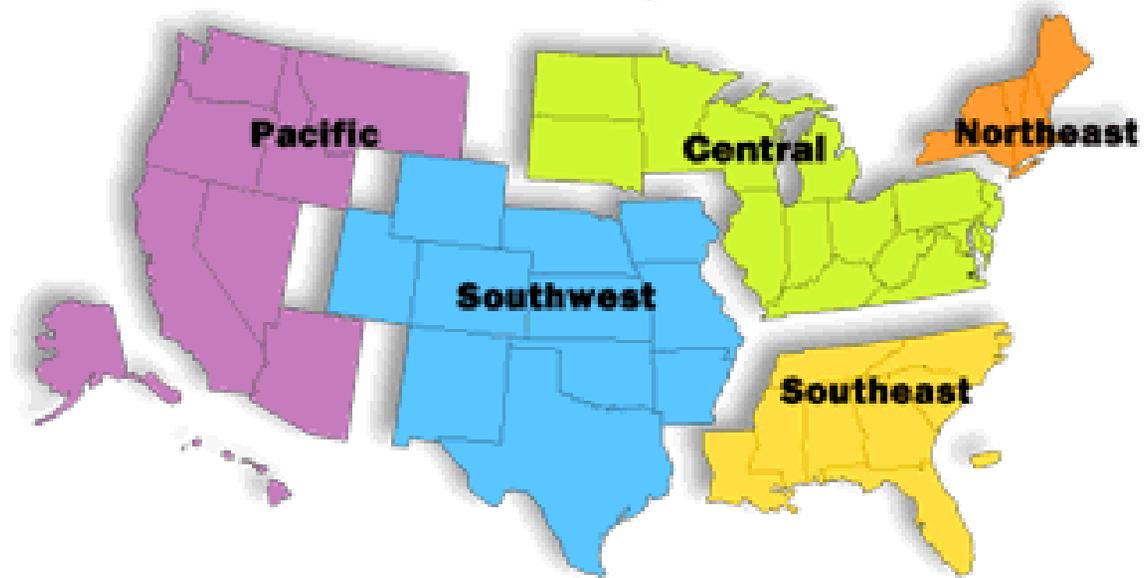


ORA Field Structure

- 5 Regions – Regional Food and Drug Directors
 - District Offices
 - Laboratories
- 20 Districts – District Directors
 - Investigations Branch
 - Compliance Branch
- 13 Field Laboratories



ORA Regions



ORA District Offices

Pacific	Southwest	Central	Southeast	Northeast
Los Angeles	Dallas	Baltimore	Atlanta	New England
San Francisco	Denver	Chicago	Florida	New York
Seattle	Kansas City	Cincinnati	New Orleans	
	SW Import District	Detroit	San Juan	
		Minneapolis		
		New Jersey		
		Philadelphia		

Visit "About FDA, About the Office of Regulatory Affairs" at <http://www.fda.gov>

FDA Inspections

Authority – Section 704(a) FDCA

- 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 – Limits of Authority Under Section 704(a)(1) FDCA

- Financial data, sales data (other than shipment data), and pricing data
- Personnel data
 - Other than qualifications of technical or professional personnel performing functions subject to the FDCA

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)
 - The IOM is the primary source of information regarding Agency policy and procedures for field investigators

Visit <http://www.fda.gov> search “IOM”



Initiating an FDA Inspection

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

Sample Form FDA 482 at <http://www.fda.gov> search "IOM"

EXHIBIT 5-1

INVESTIGATION'S OPERATIONS MANUAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO. 1431 Harbor Bay Parkway Alameda, CA 94502-7070 408-225-3332	
2. NAME AND TITLE OF INDIVIDUAL Robert K. Thompson, Plant Manager		3. DATE 08-10-08	
4. FIRM NAME Garden City Nut Shellers		5. HOUR 8:30 a.m.	
6. NUMBER AND STREET 2704 Sellers Ave		p.m.	
7. CITY AND STATE & ZIP CODE San Jose, CA 95131		8. PHONE NO. & AREA CODE 408-213-4567	
<p>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</p> <p>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</p> <p>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.</p> <p>For industry information, go to www.fda.gov/oc/industry.</p>			
9. SIGNATURE(S) (Food and Drug Administration Employee(s)) <i>Sidney H. Rogers</i>		10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s)) Sidney H. Rogers, Investigator	
<p>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:</p> <p>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 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 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</p> <p>(Continued on Reverse)</p>			
FORM FDA 482 (7/10)		PREVIOUS EDITION IS OBSOLETE	
		Page 1 of 3	
		NOTICE OF INSPECTION	

What Can Be Covered In an FDA Tobacco Product 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 <http://www.fda.gov/TobaccoProducts>, Guidance, Compliance & Regulatory Information (Tobacco)

Administrative Information

Examples:

- Firm contact information
- Most Responsible Individual
- Firm History
 - Legal status
 - Organization
 - Number of persons employed
 - Hours of operation
 - Top management officials

Administrative Information (continued)

- Interstate Commerce
 - Where regulated products are shipped
 - General promotion and distribution patterns
 - Documentation of interstate commerce
- List of regulated tobacco products manufactured, distributed, packed, labeled, promoted, or advertised
- Individual responsibility and persons interviewed
- Manufacturing and design operations

Registration & Listing – Section 905 FDCA

- Establishment registration: owners and operators of any establishment engaged in the “manufacture, preparation, compounding, or processing of a tobacco product”
 - includes repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product

See FDA Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

Registration & Listing (continued)

- All establishments
 - Initial Registration
 - Update annually
- Product listing: all regulated tobacco products for commercial distribution
 - At the time of initial registration
 - Update twice a year to reflect changes: once in June and once in December

- New Registration and Product Listing (per 905(b) and 905(i)(1))
- Update to a Registration (per 905(b)) (previously submitted to the FDA)
- Update to a Product List (per 905(i)(3)) (previously submitted to the FDA)

See FDA Tobacco Compliance Webinar: Establishment Registration & Product Listing

See FDA Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments at <http://www.fda.gov/TobaccoProducts>, Guidance, Compliance & Regulatory Information (Tobacco)

Listing of Ingredients – Sections 904(a)(1) and (c) FDCA

- Ingredient and additive information for manufactured, regulated tobacco products
- For products on the market as of June 22, 2009 – listed by December 22, 2009
- For products not on the market as of June 22, 2009 – list at least 90 days prior to delivery for introduction into interstate commerce
- Update list when an additive is changed

See FDA Guidance for Industry: Listing of Ingredients in Tobacco Products at <http://www.fda.gov/TobaccoProducts>, Guidance, Compliance & Regulatory Information (Tobacco)

Tobacco Health Documents – Section 904(a)(4) FDCA

- Documents “that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives”
- Documents created between June 23, 2009 and December 31, 2009 – submitted by April 30, 2010
- Documents created after December 31, 2009 – do not submit, but preserve

See FDA Guidance for Industry: Tobacco Health Document Submission at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information](http://www.fda.gov/TobaccoProducts_Guidance_Compliance_Regulatory_Information) (Tobacco)

Packaging, Labeling, & Advertising – Regulatory and Statutory Provisions

- **21 CFR Part 1140** - Cigarettes and Smokeless Tobacco

See Draft Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (currently accepting comments) at <http://www.fda.gov/TobaccoProducts>, Guidance, Compliance & Regulatory Information (Tobacco)

See FDA Tobacco Training Compliance Webinar: Overview of the Regulations Restricting the Sale and Distribution of Cigarettes & Smokeless Tobacco to Protect Children and Adolescents

- **Sections 907, 911, and 920 FDCA**
- **Section 204 Comprehensive Smokeless Tobacco Health Education Act (CSTHEA)**

Packaging, Labeling, & Advertising – Regulatory Provisions

- 21 CFR Part 1140 includes restrictions on, for example:
 - usage of regulated tobacco products’ brand name or other indicia on nontobacco items
 - advertising and labeling content, formats, and mediums
 - gift and incentive programs
 - sponsorship
 - distribution of free samples
 - minimum package size

See FDA Tobacco Training
Compliance Webinar:
Impersonal Modes of Sale;
Prohibition Against Breakage
of Packages of Cigarettes and
Smokeless Tobacco Products;
Minimum Cigarette Package
Size; Discussion of Free
Samples

Packaging, Labeling, & Advertising – Statutory Provisions

- Ban on cigarettes that contain certain characterizing flavors – Section 907 FDCA

See FDA Letter for Industry on Cigarettes Containing Certain Characterizing Flavors at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

See FDA Guidance to Industry & FDA Staff: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

- Modified risk tobacco products – Section 911 FDCA

See Guidance for Industry & FDA Staff: Use of “Light,” “Mild,” “Low,” or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

Packaging, Labeling, & Advertising – Statutory Provisions (continued)

Additional Provisions for Smokeless Tobacco Products

- Required Warning Statements on Smokeless Tobacco Product Packaging and Advertising – Section 204 CSTHEA

See FDA Tobacco Compliance Training Webinar: Smokeless Tobacco Product Packaging and Advertising Requirements

See Draft Guidance for Industry: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products (currently accepting comments) at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

- Required Warning Plans for Smokeless Tobacco Packaging and Advertising – Section 204 CSTHEA

See FDA Tobacco Compliance Training Webinar: Cigarettes and Smokeless Tobacco Warning Plan Requirements

See Guidance for Industry: Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

Packaging, Labeling, & Advertising – Statutory Provisions (continued)

Additional Provisions for Smokeless Tobacco Products (continued)

- Origin labeling: “...label, packaging and shipping containers of tobacco products other than cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement ‘sale only allowed in the United States’” – Section 920(a)(1) FDCA

Market Authorization

- New Tobacco Products

- Substantial Equivalence 905(j) Report

- Substantial Equivalence Exemption Request – 21 CFR 1107.1

- Pre-market Tobacco Application (PMTA)

See FDA Tobacco Compliance Webinar: Draft Guidance for Industry Applications for Premarket Review of New Tobacco Products

See Guidance for Industry & FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

See Draft Guidance for Industry & FDA Staff: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (currently accepting comments) at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

See Draft Guidance for Industry: Applications for Premarket Review of New Tobacco Products (currently accepting comments) at [http://www.fda.gov/TobaccoProducts, Guidance, Compliance & Regulatory Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

Market Authorization (continued)

- “Grandfathered”:
commercially
marketed as of
February 15, 2007

See Draft Guidance for Industry & FDA Staff:
Establishing that a Tobacco Product was
Commercially Marketed in the United States as
of February 15, 2007 (currently accepting
comments) at
[http://www.fda.gov/TobaccoProducts,
Guidance, Compliance & Regulatory
Information \(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

- Modified Risk Tobacco
Product Application
(MRTPA)

See Draft Guidance for Industry & FDA Staff:
Preliminary Timetable for the Review of
Applications for Modified Risk Tobacco Products
under the Federal Food, Drug, and Cosmetic Act
(currently accepting comments) at
[http://www.fda.gov/TobaccoProducts,
Guidance, Compliance & Regulatory Information
\(Tobacco\)](http://www.fda.gov/TobaccoProducts,Guidance,Compliance&RegulatoryInformation(Tobacco))

How an FDA inspection will conclude

- 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 at <http://www.fda.gov> search "IOM"

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	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED		FBI NUMBER 0000112233	
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		
<small>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.</small>			
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 <i>Sidney H. Rogers</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Sidney H. Rogers, Investigator	DATE ISSUED 10/7/2008
FORM FDA 483 (9/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 1 of 1 PAGES <small>PSC Media Arts (201) 642-1090 EF</small>

FDA Inspections – Final Report

- Establishment Inspection Report (EIR)
- Copy of EIR to Firm – FMD-145

<http://www.fda.gov> search “Establishment Inspection Report EIR”

Contact Information

- ORA District Office
- CTP
 - AskCTP@fda.hhs.gov
 - Office of Small Business Assistance
 - 1-877-CTP-1373
 - SmallBiz.Tobacco@fda.hhs.gov