

All about the Form FDA 483 and the ORA Electronic Reading Room

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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Office of Medical Device & Radiological Health Operations

U.S. Food and Drug Administration



Learning Objectives

- Introduce the Office of Regulatory Affairs
- Discuss the Form FDA 483 (FDA 483)
- Introduce the ORA Freedom of Information Act (FOIA) Electronic Reading Room

Office of Regulatory Affairs

About ORA

FDA's Office of Regulatory Affairs (ORA)

- Lead office for all field activities
- Conduct inspections
- Perform enforcement actions



About ORA

Inspections at firms can be:

- Routine - periodic
- Directed
- Follow up
- Risk based



FORM FDA 483

Result of inspection

- Possible FDA 483 issued
- General discussion with management
- Establishment Inspection Report (EIR)

EXHIBIT 5-5		INVESTIGATIONS OPERATIONS MANUAL 2017	
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
SUBJECT OFFICE ADDRESS AND PHONE NUMBER Minneapolis District 250 Marquette Ave. South, Suite 600 Minneapolis, MN 55401 Industry information: www.fda.gov/oc/industry		DATE OF INSPECTION 10-5-7/2008 PRECEDENCE 0000112233	
NAME AND TITLE OF PERSONAL TO WHOM REPORT IS ISSUED To: William S. Gundstrom, Vice President, Production			
FROM/TO Topline Pharmaceuticals "T.L.P.," Jackson, MN 55326		STREET ADDRESS 2136 Elbe Place TYPE OF PRODUCT/DRUG SUPPLY Tablet Repacker	
<small>THIS REPORT IS TO BE USED ONLY BY THE FDA OFFICE OF INSPECTION. THE REPORT IS FOR THE USE OF THE FDA OFFICE OF INSPECTION AND IS NOT TO BE RELEASED TO ANY OTHER AGENCY OR TO THE PUBLIC. IF YOU HAVE ANY OBJECTION TO THE REPORT, YOU MUST CONTACT THE FDA OFFICE OF INSPECTION IMMEDIATELY. IF YOU HAVE ANY OBJECTION TO THE REPORT, YOU MUST CONTACT THE FDA OFFICE OF INSPECTION IMMEDIATELY. IF YOU HAVE ANY OBJECTION TO THE REPORT, YOU MUST CONTACT THE FDA OFFICE OF INSPECTION IMMEDIATELY.</small>			
LIST your significant observations ranked in order of significance. See IOM 5.2.3, 5.2.3.1, 5.2.3.2, and 5.2.3.3			
DATE 10/7/2008 REVIEWED BY (Signature)	EMPLOYEE'S SIGNATURE Sidney H. Rogers	EMPLOYEE'S NAME AND TITLE (Print or Type) Sidney H. Rogers, Investigator	DATE REVIEWED 10/7/2008
FORM FDA 483 (10/01)		PREVIOUS EDITION OBSOLETE	

The Form FDA 483

- Notifies the company's management of objectionable conditions
- Presented and discussed with the company's senior management

The Form FDA 483

Form FDA 483 is issued:

- At the conclusion of an inspection
- When an investigator(s) has observed any conditions that may constitute violations of the Federal Food, Drug and Cosmetic (FD&C) Act and related Acts
- The firm has the option to annotate the observation

The Form FDA 483

Implications of the Form FDA 483

- Not the final Agency determination

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

The Form FDA 483

Implications of the Form FDA 483

- Part of a package with Establishment Inspection Report, all evidence or documentation collected, and any responses made by the company
- Information considered to determine further enforcement action, if any, is appropriate

The Form FDA 483

Submitting a Response to the FDA 483

- E-mail your response to the division email address provided by your investigator
- Include your company's FEI number in the subject of the email, and on the cover letter or documentation
- Hard copy responses, use the address provided by your investigator
- Must be submitted within 15 business days in order to be reviewed for enforcement action consideration

The Form FDA 483

Information contained in the response to FDA 483

- Address each observation and all parts
- Include corrections completed
- Include plans for future corrective actions
- Timelines for completion
- Include plans for consideration of preventative action

Number of 483's issued in FY 2022

Number of 483 issued from the System*


Inspections ending between 10/1/2021 and 9/30/2022

Cite Program Area Name	483s Issued
Biologics	61
Bioresearch Monitoring	126
Devices	538
Drugs	466
Foods	2399
Human Tissue for Transplantation	81
Parts 1240 and 1250	23
Radiologic Health	9
Veterinary Medicine	184
Sum Product Area 483s from System*	3887
Actual Total in System 483s**	3838

In FY 2022, ORA conducted 956 device inspections.

datadashboard.fda.gov/ora/index.htm

FDA Data Dashboard



**U.S. FOOD & DRUG
ADMINISTRATION**

DATA DASHBOARD

[Data Dashboard Home](#)
[Compliance Dashboards](#)
[FSMA Data Search](#)
[Resources](#)

FDA Data Dashboard

Compliance Dashboards

- [Inspections](#)
- [Compliance Actions](#)
- [Recalls](#)
- [Imports Summary](#)
- [Import Refusals](#)
- [Imports Entry](#)

FSMA Data Search

Find firm compliance and enforcement information.

Search Firm Information

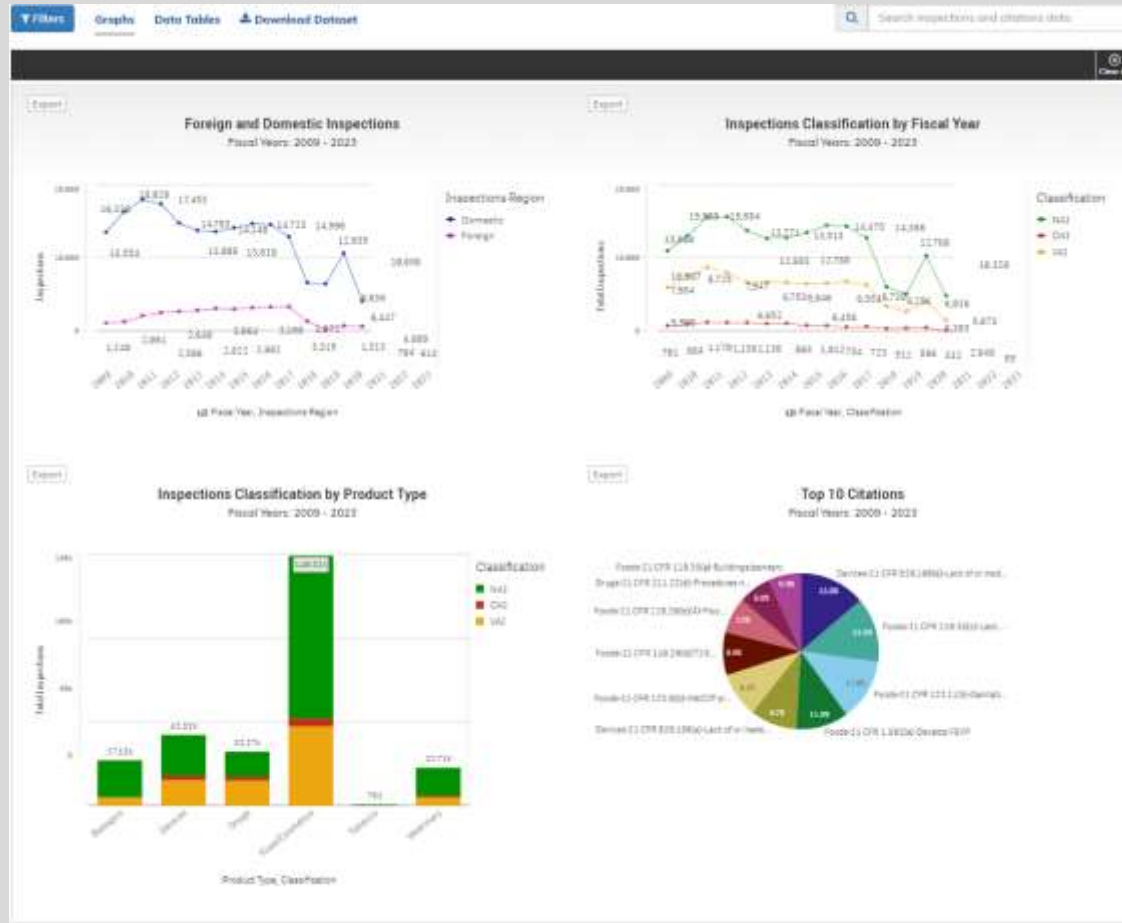
- [LAAF Participants](#)
- [TPP Participants](#)
- [Approved VQIP Importers](#)

NEW!

- A new [LAAF Dashboard](#) has been added to serve as the online public registry listing for information on participants in the Laboratory Accreditation for Analyses of Foods (LAAF) Program.
- [Sign up](#) to receive notifications about FDA Data Dashboard updates and information.
- Compliance Actions data is now available through [RESTful APIs](#) on the FDA Data Dashboard.



FDA Data Dashboard





Product Type
Devices

Clear All

Inspections Details [Help](#)

Record Count: 42,318

[Download Inspections Dataset](#)

Select Inspection ID(s) to view corresponding Inspections Citations.

FBI Number	Legal Name	City	State	Zip	Country/Area	Fiscal Year	Inspection ID	Posted Citations	Inspection End Date	Classification	Project Area	Product Type	Additional Details
2012017310	Inters Oncology, Inc.	Wellesley	Massachu...	02481	United States	2013	1201000	No	04/05/2013	No Action Indicated (NAI)	Compliance: Devices	Devices	-
2012017310	Inters Oncology, Inc.	Wellesley	Massachu...	02481	United States	2013	1201000	No	04/05/2013	No Action Indicated (NAI)	Postmarket: Assurance: Devices	Devices	-
2013400710	Toaster Labs, Inc.	Seattle	Washington	98109	United States	2013	1201733	Yes	04/04/2013	Voluntary Action Indicated (VAI)	Compliance: Devices	Devices	-
2013400710	Toaster Labs, Inc.	Seattle	Washington	98109	United States	2013	1201733	Yes	04/04/2013	Voluntary Action Indicated (VAI)	Postmarket: Assurance: Devices	Devices	-
2011796723	Republic Spine, LLC	Boca Raton	Florida	33431	United States	2013	1201991	No	04/03/2013	No Action Indicated (NAI)	Compliance: Devices	Devices	-
2011796723	Republic Spine, LLC	Boca Raton	Florida	33431	United States	2013	1201991	No	04/03/2013	No Action Indicated (NAI)	Postmarket: Assurance: Devices	Devices	-

Inspections Citations Details

Record Count: 46,438

[CFR Reference](#) | [FDCA Reference](#)

[Download Citations Dataset](#)

Citations data include Form FDA 483 citations and may not necessarily represent citations on final classification letters.

Inspection ID	FBI Number	Legal Name	Inspection End Date	Program Area	Act/CFR Number	Short Description	Long Description
1201733	2013200710	Toaster Labs, Inc.	04/04/2013	Devices	21 CFR 803.17(a)(1)	Lack of System for Event Evaluations	The written MDR Procedure does not include an internal system which provides for timely and effective evaluation of events that may be subject to medical device reporting requirements.
1201733	2013200710	Toaster Labs, Inc.	04/04/2013	Devices	21 CFR 820.50	Purchasing controls. Lack of or inadequate procedures	Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.
1201733	2013200710	Toaster Labs, Inc.	04/04/2013	Devices	21 CFR 820.100(a)	Lack of or inadequate procedures	Procedures for corrective and preventive action have not been adequately established.
1201920	2000120910	Precision Optics Corporation, Inc.	03/31/2013	Devices	21 CFR 820.90(b)(2)	Product review procedures. Lack of or inadequate procedures	Procedures for review of nonconforming product have not been adequately established.
1201920	2000120910	Precision Optics Corporation, Inc.	03/31/2013	Devices	21 CFR 820.100(a)	Lack of or inadequate procedures	Procedures for corrective and preventive action have not been adequately established.
1201500	2000120910	Precision Optics Corporation, Inc.	03/31/2013	Devices	21 CFR 820.190(a)	Lack of or inadequate procedures	Procedures for receiving, reviewing, and evaluating complaints by a

Top Five Device Observations in FY 2022



Reference Number	Short Description	Long Description	Frequency
21 CFR 820.100(a)	Lack of or inadequate procedures	Procedures for corrective and preventive action have not been [adequately] established. Specifically, ***	193
21 CFR 820.198(a)	Lack of or inadequate complaint procedures	Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been [adequately] established. Specifically, ***	138
21 CFR 820.75(a)	Lack of or inadequate process validation	A process whose results cannot be fully verified by subsequent inspection and test has not been [adequately] validated according to established procedures. Specifically, ***	86
21 CFR 820.50	Purchasing controls, Lack of or inadequate procedures	Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been [adequately] established. Specifically, ***	79
21 CFR 820.90(a)	Nonconforming product, Lack of or inadequate procedures	Procedures have not been [adequately] established to control product that does not conform to specified requirements. Specifically, ***	69

Corrective and Preventative Action

- CAPA procedure established
- Appropriate sources for quality issues and are monitored or trended
- Appropriate statistical analysis on trends
- Determine if CAPAs are investigated

Corrective and Preventative Action

- Determine if corrective actions are appropriate
 - Re-training might not be enough
- Corrective action is effective and verified to be effective
- Corrective action is documented and disseminated

Complaint Handling

- Establish Procedures
- Uniform and timely processing
- Evaluate for MDR reportability
- Evaluate for investigation and rationale for no investigation

ORA FOIA Electronic Reading Room

Where can I find copies of FDA 483s or EIRs?

- ORA records can become public through the Freedom of Information Act (FOIA)
- ORA hosts a website called the ORA FOIA Reading Room

ORA FOIA Electronic Reading Room

- Displays copies of domestic inspection and related records (Redacted as appropriate)
- Some records already publicly available either
 - proactively at our discretion
 - they are "frequently requested"

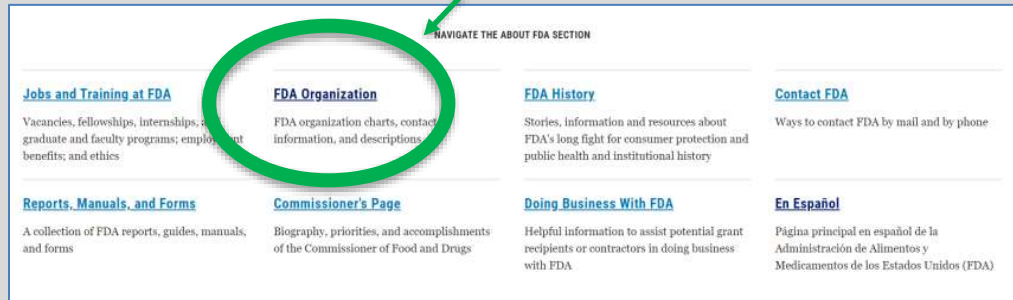
Access ORA FOIA Reading Room

- www.fda.gov
- Select “About FDA”



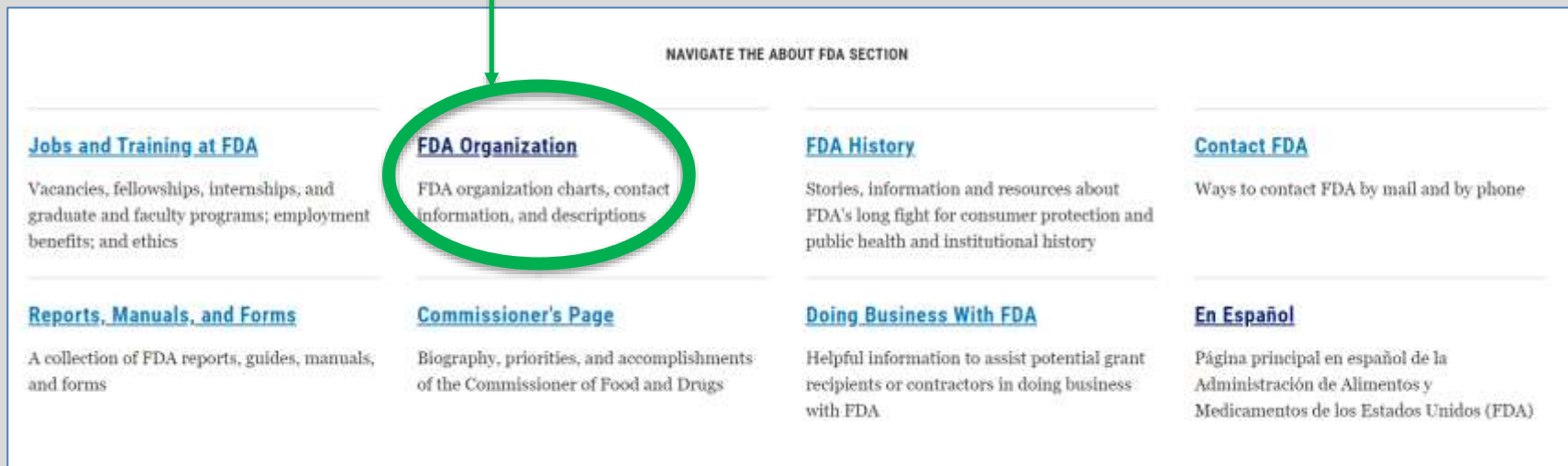
Access ORA FOIA Reading Room

- Select “FDA Organization”



Access ORA FOIA Reading Room

- Select “FDA Organization”

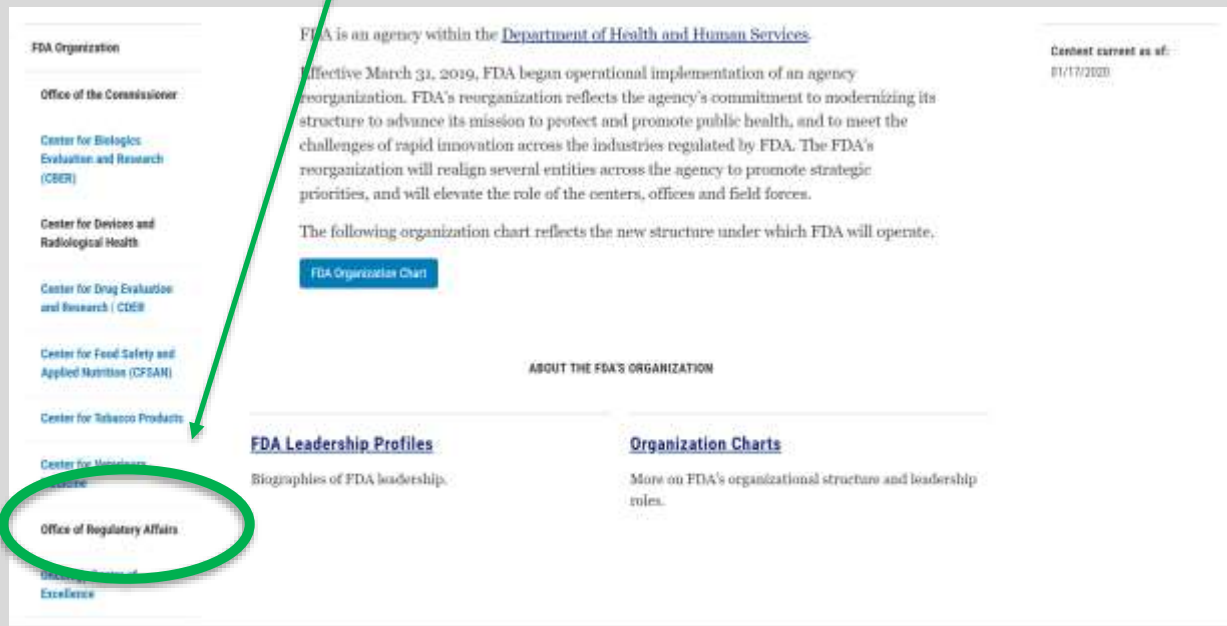


NAVIGATE THE ABOUT FDA SECTION

<p>Jobs and Training at FDA</p> <p>Vacancies, fellowships, internships, and graduate and faculty programs; employment benefits; and ethics</p>	<p>FDA Organization</p> <p>FDA organization charts, contact information, and descriptions</p>	<p>FDA History</p> <p>Stories, information and resources about FDA's long fight for consumer protection and public health and institutional history</p>	<p>Contact FDA</p> <p>Ways to contact FDA by mail and by phone</p>
<p>Reports, Manuals, and Forms</p> <p>A collection of FDA reports, guides, manuals, and forms</p>	<p>Commissioner's Page</p> <p>Biography, priorities, and accomplishments of the Commissioner of Food and Drugs</p>	<p>Doing Business With FDA</p> <p>Helpful information to assist potential grant recipients or contractors in doing business with FDA</p>	<p>En Español</p> <p>Página principal en español de la Administración de Alimentos y Medicamentos de los Estados Unidos (FDA)</p>

Access ORA FOIA Reading Room

- Select “Office of Regulatory Affairs”



The screenshot shows the FDA Organization page. On the left is a sidebar with a list of FDA entities. A green arrow points from the text 'Select “Office of Regulatory Affairs”' to the 'Office of Regulatory Affairs' link, which is circled in green. The main content area contains text about FDA's reorganization and a link to the 'FDA Organization Chart'. Below this, there are sections for 'FDA Leadership Profiles' and 'Organization Charts'.

FDA Organization

- Office of the Commissioner
- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health
- Center for Drug Evaluation and Research (CDER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Tobacco Products
- Center for Veterinary Medicine
- Office of Regulatory Affairs**
- Office of Science and Research
- Office of Surveillance and Compliance
- Office of Training and Development
- Office of the Chief of Staff
- Office of the Inspector General
- Office of the Legal Counsel
- Office of the Secretary
- Office of the Under Secretary
- Office of the Assistant Secretary for Health
- Office of the Assistant Secretary for International and Global Health
- Office of the Assistant Secretary for Policy and Planning
- Office of the Assistant Secretary for Public Health and Safety
- Office of the Assistant Secretary for Regulatory Affairs
- Office of the Assistant Secretary for Science and Research
- Office of the Assistant Secretary for Surveillance and Compliance
- Office of the Assistant Secretary for Training and Development
- Office of the Assistant Secretary for the Chief of Staff
- Office of the Assistant Secretary for the Inspector General
- Office of the Assistant Secretary for the Legal Counsel
- Office of the Assistant Secretary for the Secretary
- Office of the Assistant Secretary for the Under Secretary

FDA is an agency within the [Department of Health and Human Services](#).

Effective March 31, 2019, FDA began operational implementation of an agency reorganization. FDA's reorganization reflects the agency's commitment to modernizing its structure to advance its mission to protect and promote public health, and to meet the challenges of rapid innovation across the industries regulated by FDA. The FDA's reorganization will realign several entities across the agency to promote strategic priorities, and will elevate the role of the centers, offices and field forces.

The following organization chart reflects the new structure under which FDA will operate.

[FDA Organization Chart](#)

ABOUT THE FDA'S ORGANIZATION

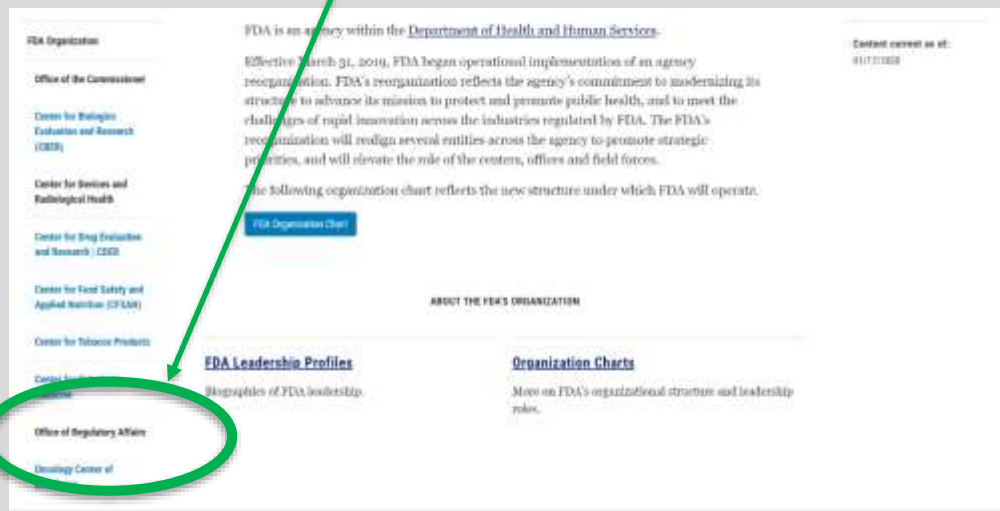
[FDA Leadership Profiles](#)
Biographies of FDA leadership.

[Organization Charts](#)
More on FDA's organizational structure and leadership roles.

Content current as of: 01/17/2020


Access ORA FOIA Reading Room

- Select “Office of Regulatory Affairs”



Access ORA FOIA Reading Room

- Select “ORA FOIA Electronic Reading Room”



The screenshot shows the FDA Office of Regulatory Affairs (ORA) website. On the left is a sidebar with various links. A green arrow points from the text 'Select “ORA FOIA Electronic Reading Room”' to the link 'ORA FOIA Electronic Reading Room' in the sidebar. The main content area features a grid of six photographs showing ORA staff in various settings, including inspecting products and working at computers. Below the grid is a paragraph describing the ORA's mission.

ORA FOIA Electronic Reading Room

The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States. In pursuit of its [mission](#), ORA also works with its state, local, tribal, territorial and foreign counterparts.

ORA FOIA Electronic Reading Room



ORA FOIA Electronic Reading Room

The ORA Electronic Reading Room displays copies of ORA domestic inspection and related records. We are making these records publicly available either (1) proactively at our discretion or (2) because they are "frequently requested" per the Electronic Freedom of Information Act Amendments of 1996. Some records may be redacted to remove non-public information (see 21 CFR Part 20). For publicly available ORA data sets, (such as lists of inspection classifications, 483 observations, etc.), please visit the [data sets](#) page. For other ORA documents, please visit the [ORA home page](#) and the [FDA Warning Letter page](#). For foreign inspection and related records, please search the relevant center reading room page on the main FDA [Electronic Reading Room](#).

In the event you are unable to read these documents or portions thereof, please contact ORA's Division of Information Disclosure Policy ORAOSPOFOIReadingRoom@fda.hhs.gov. If you are unable to find documents that you are looking for you may file a FOIA request for the records at <https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request>.

[Content for the ORA FOIA Electronic Reading Room is available on FDA's website for five years before being archived.](#)

To find FOIA archived content for years prior to 2012, visit <https://wayback.archive-it.org/7993/20170404012657/https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/default.htm> [↗](#).

Content current as of:
04/05/2023

Search

Filter by



FOIA Record Type

- Any -



Clear Filters

ORA FOIA Electronic Reading Room

https://www.fda.gov/oc/2008-10/office-regulatory-affairs/ora-foia-electronic-reading-room

URL: <https://www.fda.gov/oc/2008-10/office-regulatory-affairs/ora-foia-electronic-reading-room>

[RSS Feed for ORA FOIA Electronic Reading Room](#)

Resources for you

- [Compounding Firms](#)
- [Data Sets](#)
- [Warning Letters](#)
- [FOIA Homepage](#)
- [ORA Homepage](#)
- [ORA Workplans](#)

Filter:

- 483
- 483 Response
- Adverse Determination Letter
- Adverse Determination Letter Response
- Appendix 483
- Consent Decree
- Consent Decree Correspondence
- Consent Decree Complaint Record
- Establishment Inspection Report (EIR)
- Exhibits and Attachments
- FDA Requested Recall Letter
- FD-435 Letter
- Investigation Memo
- Memo
- Office Correspondence
- Recall Record
- Receipt of Payment Letter
- Response
- Revocation of Operational Authorization Letter

Clear Filters

Showing 1 to 10 of 2,017 entries

Export Excel

Company Name	Record Date	FDI Number	Record Type	State	Establishment Type	Product	Product Date
The Wellness Center Pharmacy, Inc., aka Ecopier Drugs	02/16/2016	3044576678	Data Request Letter	Tennessee	Producer of New Startle Drug Products		03/10/2016

Windows 10 • 10.0.17134.0 • 10/10/2018 • 10:01 PM

Type here to search

60° Sunny 10:01 PM 4/16/2018

Filter by

FOIA Record Type

483

Clear Filters

Showing 1 to 10 of 1,482 entries

Export Excel

Company Name	Record Date	FEI Number	Record Type	State	Establishment Type	Publish Date
Promise Pharmacy, LLC	10/25/2018	3013207472	483	Florida	Producer of Sterile Drug Products	05/13/2019
Pacificco National, Inc. dba AmEx Pharmacy	05/31/2019	3012034698	483	Florida	Outsourcing Facility	07/22/2019
Puget Sound Drug Corporation dba Key Pharmacy and Compounding Center	06/13/2019	3006089725	483	Washington	Producer of Sterile and Non Sterile Drug Products	07/12/2019
California Specialty Pharmacy Inc.	05/17/2019	3015131323	483	California	Producer of Non Sterile Drug Products	07/12/2019
Pharmacy Plus, Inc. dba Vital Care Compounder	05/16/2019	3010241801	483	Mississippi	Producer of Sterile and Non Sterile Drug Products	07/12/2019
The Pet Apothecary LLC	08/07/2018	3005946041	483	Wisconsin	Producer of Non Sterile Drug Products	07/12/2019
Custom Compounding Center	06/04/2019	3002401385	483	Arkansas	Producer of Non Sterile Drug Products	07/12/2019
Chen Shwezin Inc. dba Park Compounding Pharmacy	10/05/2015	3005256616	483	California	Producer of Sterile Drug Products	04/16/2019
Sentara Enterprises	12/16/2015	3011627411	483	Virginia	Producer of Sterile Drug Products	04/16/2019
Qualigen LLC	02/04/2016	3011286349	483	Oklahoma	Outsourcing Facility	04/16/2019

Showing 1 to 10 of 1,482 entries

First Previous 1 2 3 4 5 ... 149 Next Last

How to Make a FOIA Request

- Must be in writing and should include the following information:
 - requestor's name
 - address
 - telephone number
 - description of records requested
- The records should be identified as specifically as possible
- Include a statement concerning willingness to pay fees

www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm

Summary

- Office of Regulatory Affairs conducts routine, directed, risk based, or follow up inspections
- The Form FDA 483 summarizes observations of deficiencies cited by the investigators
- Inspection documents can be found/requested through the FOIA Reading Room

Resources



Slide Number	Cited Resource	URL
15	FDA Data Dashboard	datadashboard.fda.gov/ora/index.htm
25	ORA FOIA Electronic Reading Room	www.fda.gov/about-fda/office-regulatory-affairs/ora-foia-electronic-reading-room
33	FDA Freedom of Information Act (FOIA)	www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm

Questions

