U.S. FOOD & DRUG ADMINISTRATION

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

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

June 8, 2023

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Office of Regulatory Affairs

Office of Medical Device & Radiological Health Operations

U.S. Food and Drug Administration

INVESTIGATOR
FOOD AND DRUG ADMINISTRATION
PUBLIC HEALTH SERVICE
FDA
1

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Minneapolis District 250 Marquette Ave. South, Suite 600 Minneapolis, MN 55401 Industry information: www.fda.gov/oc/industry	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	STREET ADDRESS
Topline Pharmaceuticals "T.L.P."	2136 Elbe Place
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Jackson, MN 55326	Tablet Repacker

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Sidney H. Rogers	Sidney H. Rogers, Investigator	10/7/2008

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 of 1 PAGES

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*

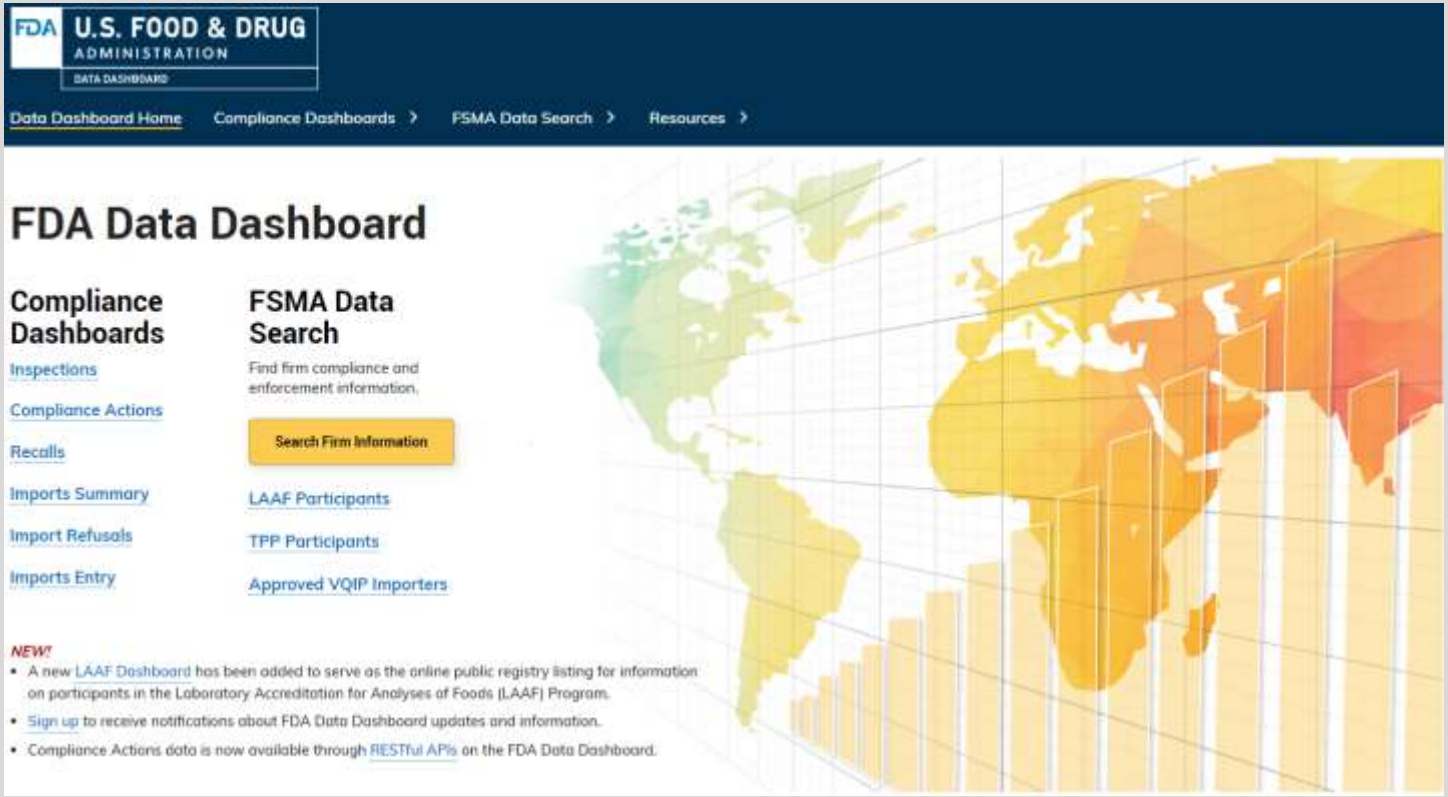
Inspections ending between 10/1/2021 and 9/30/2022

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**

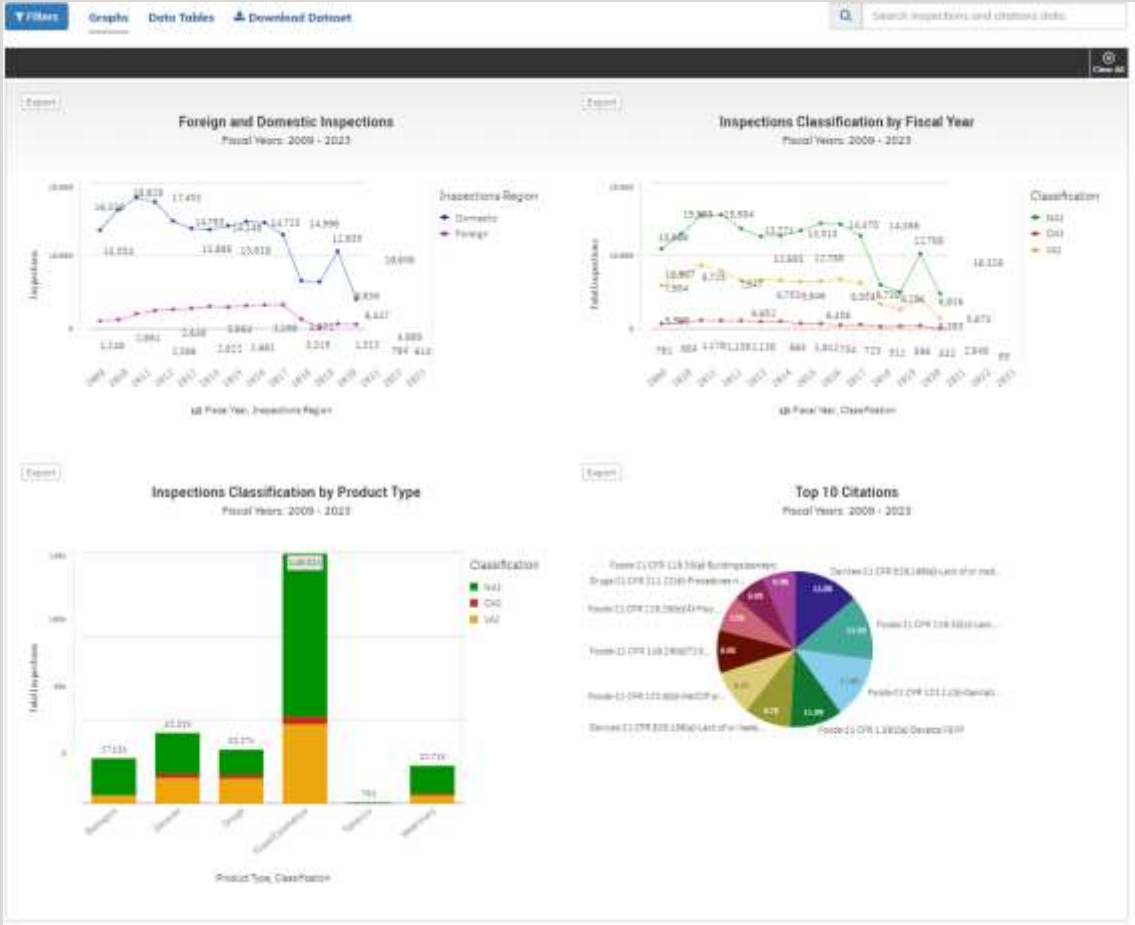
In FY 2022, ORA conducted 956 device inspections.

datadashboard.fda.gov/ora/index.htm

FDA Data Dashboard



FDA Data Dashboard



Filters | Graphs | Data Tables | Download Dataset | Search inspections and citations data

Product Type: Devices | Clear All

Inspections Details

Help | Download Inspections Dataset

Record Count: 42,318

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

FEI Number	Legal Name	City	State	Zip	Country/Area	Fiscal Year	Inspection ID	Posted Citations	Inspection End Date	Classification	Project Area	Product Type	Additional Details
3015937318	Intera Oncology, Inc.	Wellesley	Massachu...	02481	United States	2023	1202500	No	04/05/2023	No Action Indicated (NAI)	Compliance: Devices	Devices	-
3015937318	Intera Oncology, Inc.	Wellesley	Massachu...	02481	United States	2023	1202500	No	04/05/2023	No Action Indicated (NAI)	Postmarket Assurance: Devices	Devices	-
3013408718	Toaster Labs, Inc.	Seattle	Washington	98109	United States	2023	1201733	Yes	04/04/2023	Voluntary Action Indicated (VAI)	Compliance: Devices	Devices	-
3013408718	Toaster Labs, Inc.	Seattle	Washington	98109	United States	2023	1201733	Yes	04/04/2023	Voluntary Action Indicated (VAI)	Postmarket Assurance: Devices	Devices	-
3011796723	Republic Spine, LLC	Boca Raton	Florida	33431	United States	2023	1201991	No	04/03/2023	No Action Indicated (NAI)	Compliance: Devices	Devices	-
3011796723	Republic Spine,	Boca	Florida	33431	United States	2023	1201991	No	04/03/2023	No Action Indicated	Postmarket	Devices	-

Inspections Citations Details

CFR Reference | FDCA Reference | Download Citations Dataset

Record Count: 46,438

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

Inspection ID	FEI Number	Legal Name	Inspection End Date	Program Area	Act/CFR Number	Short Description	Long Description
1201733	3013408718	Toaster Labs, Inc.	04/04/2023	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	3013408718	Toaster Labs, Inc.	04/04/2023	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	3013408718	Toaster Labs, Inc.	04/04/2023	Devices	21 CFR 820.100(a)	Lack of or inadequate procedures	Procedures for corrective and preventive action have not been adequately established.
1201929	3000120916	Precision Optics Corporation, Inc.	03/31/2023	Devices	21 CFR 820.90(b)(2)	Product rework procedures. Lack of or inadequate procedures	Procedures for rework of nonconforming product have not been adequately established.
1201929	3000120916	Precision Optics Corporation, Inc.	03/31/2023	Devices	21 CFR 820.100(a)	Lack of or inadequate procedures	Procedures for corrective and preventive action have not been adequately established.
1201929	3000120916	Precision Optics	03/31/2023	Devices	21 CFR 820.198(a)	Lack of or inadequate	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"

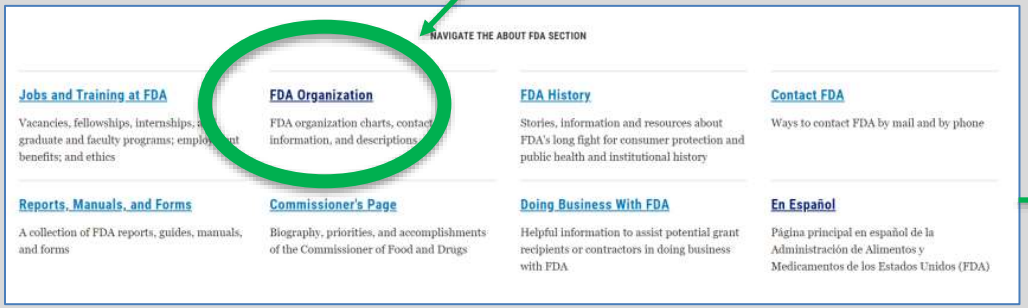
ORA FOIA Electronic Reading Room | FDA

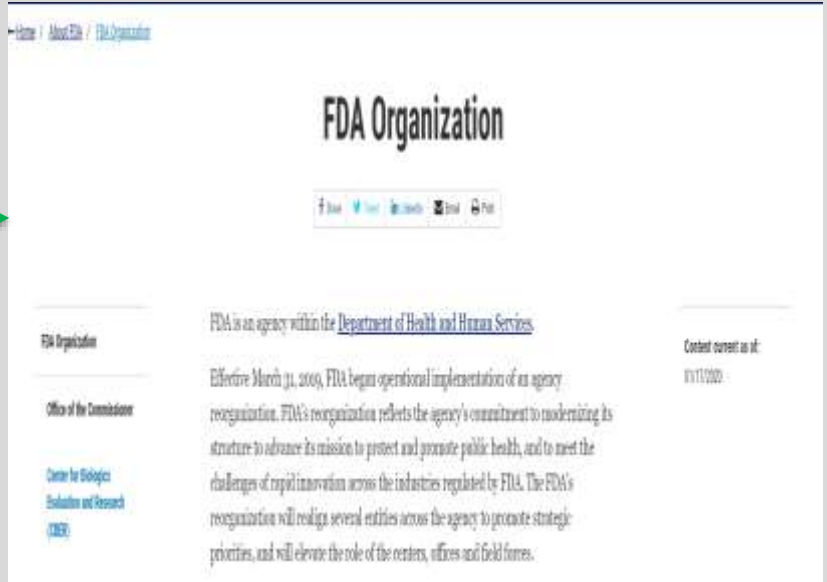
Access ORA FOIA Reading Room

- www.fda.gov
- Select “About FDA”

Access ORA FOIA Reading Room

- Select “FDA Organization”





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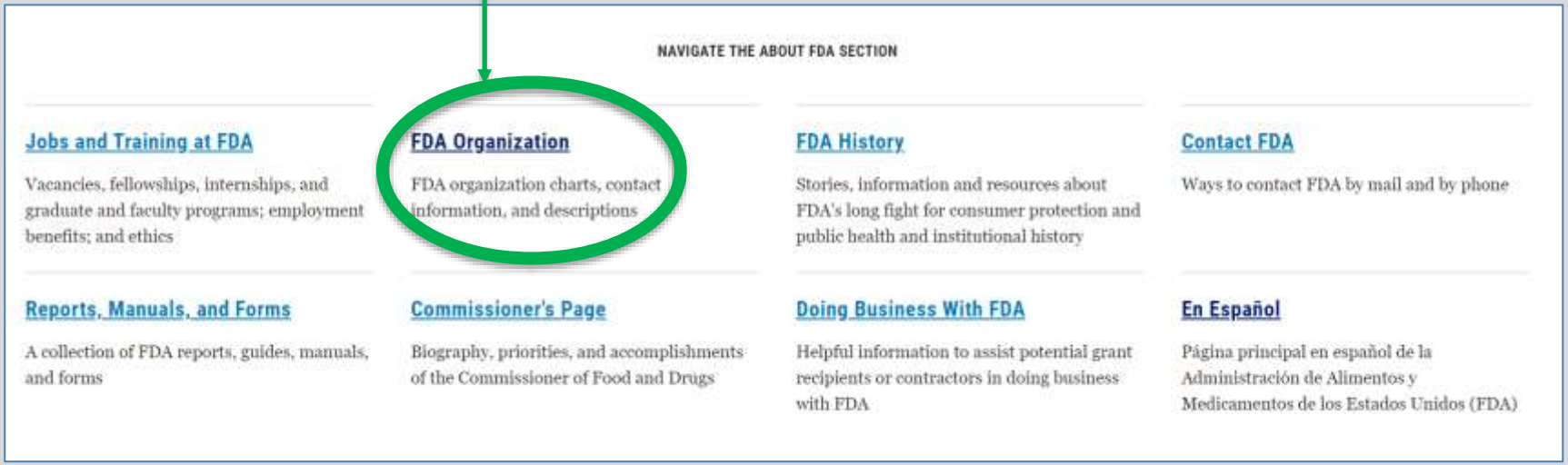
- Select “FDA Organization”



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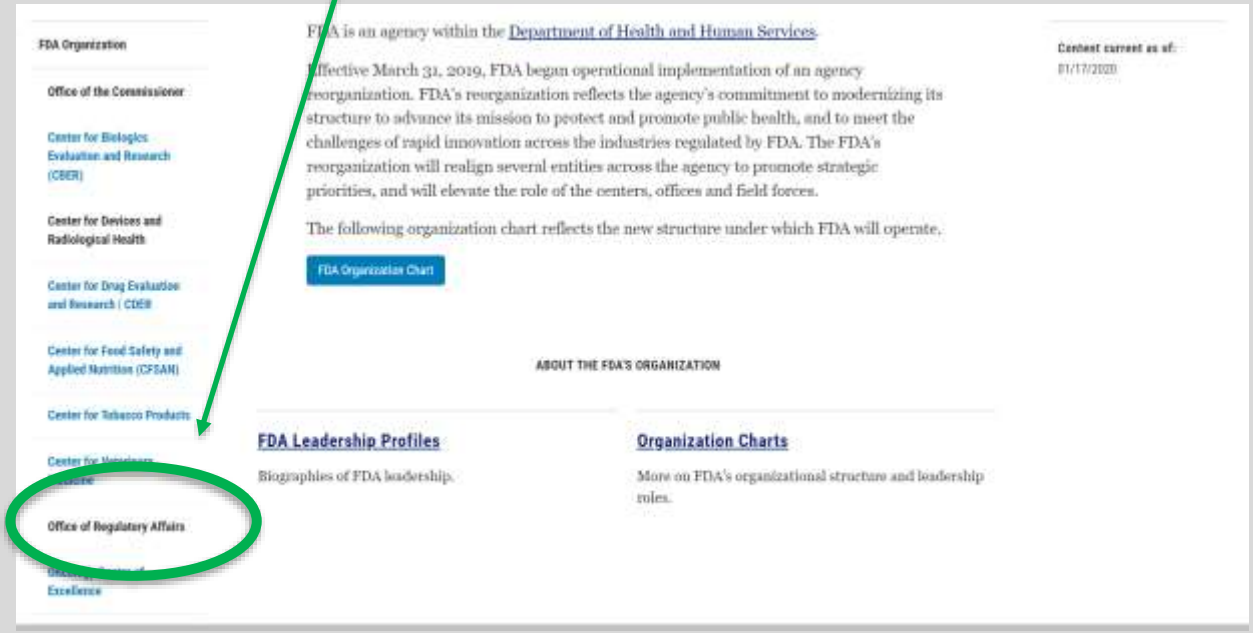

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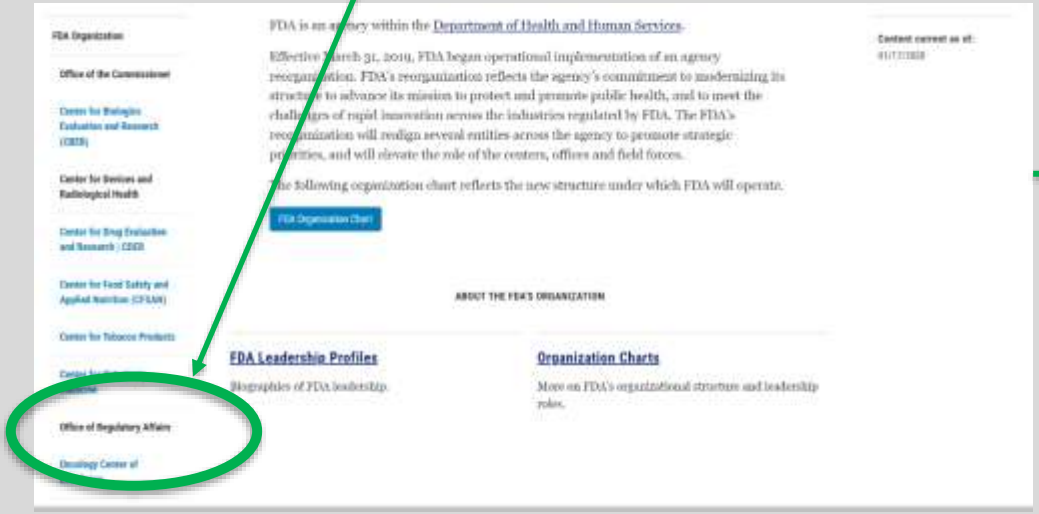

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ORA FOIA Electronic Reading Room

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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 ORAOSPOPFOIReadingRoom@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

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FOIA Record Type

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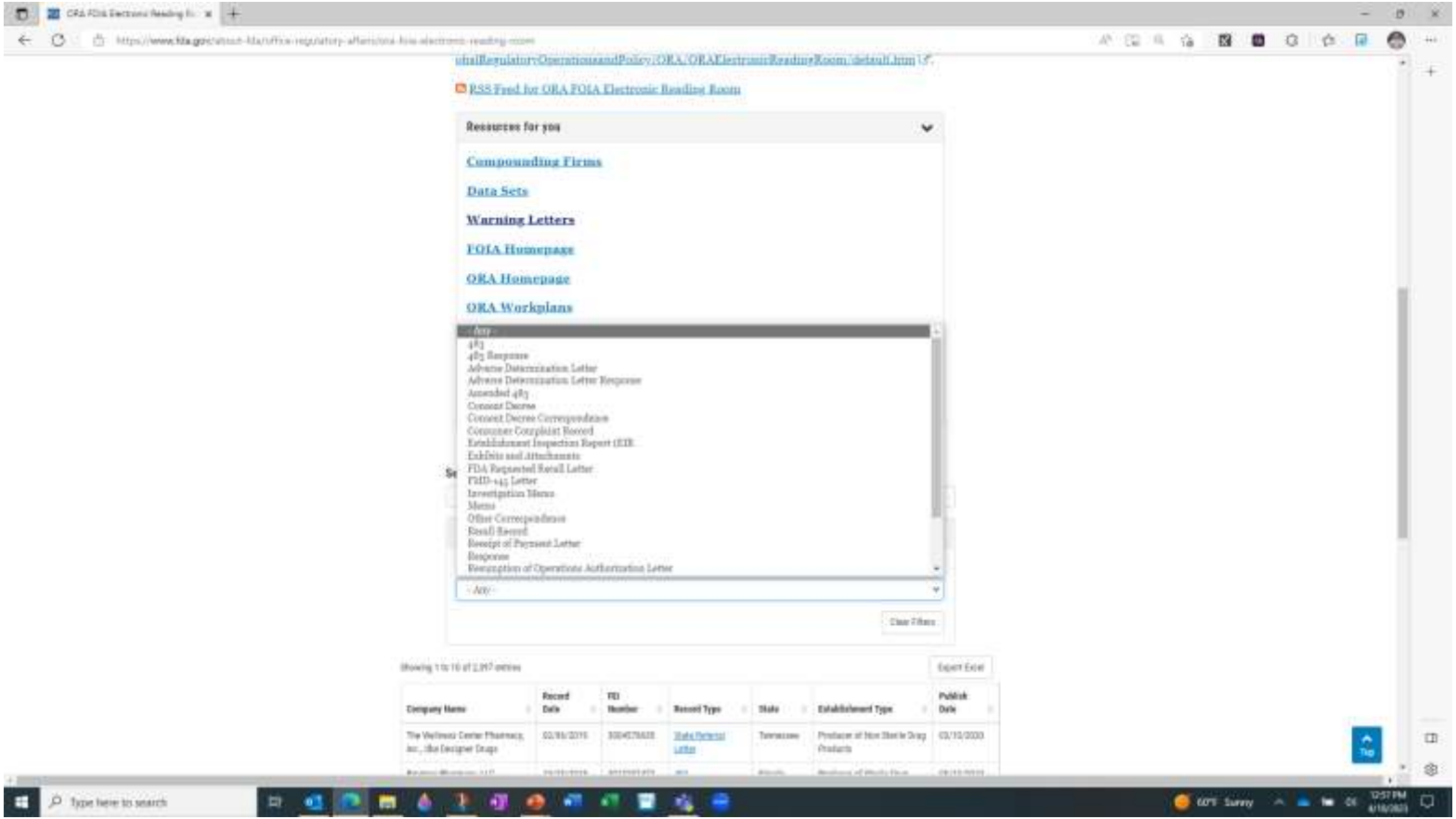
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483 Response
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Consent Decree Correspondence
Consumer Complaint Record
Establishment Inspection Report (EIR)
Exhibits and Attachments
FDA Requested Recall Letter
FMD-145 Letter
Investigation Memo
Memo
Office Correspondence
Recall Record
Receipt of Payment Letter
Response
Resumption of Operations Authorization Letter
Company Name
Record Date
FEI Number
Record Type
State
Establishment Type
Publish Date

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
Pacifico 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	04/19/2019
Sentara Enterprises	12/16/2015	3011627411	483	Virginia	Producer of Sterile Drug Products	04/19/2019
Qualgen LLC	02/04/2016	3011286349	483	Oklahoma	Outsourcing Facility	04/19/2019

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