

Monthly Pharmacy Cases Received Sept 23

As of 2023-12-14 12:27:59 Mountain Standard Time/MST • Generated by Camille Farley • Sorted by Opened Date (Ascending)

Filtered By

Date Field: Opened Date equals Last Month (11/1/2023 to 11/30/2023)

Show: All cases

Units: Hours

Status equals Case Received,Under Investigation,Legal Action,Information Only

Conduct Unit equals Healthcare

Professions equals Pharmacy

Case Number	Opened Date	Professions	Profession Subtype	Complaint Types	Status
148674	11/20/2023	Pharmacy	Class B-Dispensing Medical Practioner Clinic	Inspection	Under Investigation
148675	11/20/2023	Pharmacy		Unlicensed Practice	Under Investigation
148832	11/28/2023	Pharmacy	Class C-Distributing	Inspection	Under Investigation
Total	Count	3			

Monthly Pharmacy Inspections Sept 23

As of 2023-12-14 12:27:52 Mountain Standard Time/MST • Generated by Camille Farley • Sorted by Inspection Date (Ascending)

Filtered By

Show: All inspections

Date Field: Inspection Date equals Last Month (11/1/2023 to 11/30/2023)

Inspection Type equals New, Probation, Random

Case	Inspection Date	Inspection Classification	Inspection Type
148292	11/1/2023, 11:30 AM	Class E-Veterinary Pharmaceutical Facility	Random
148591	11/7/2023, 12:00 PM	Non-Sterile Compounding	Random
148591	11/7/2023, 12:00 PM	Class A-Retail	Random
148832	11/8/2023, 12:00 PM	Class C-Distributing	New
148470	11/9/2023, 10:00 AM	Class C-Wholesaler	New
148504	11/13/2023, 9:00 AM	Class B-Dispensing Medical Practitioner Clinic	New
148674	1/13/2023, 12:00 PM	Class B-Dispensing Medical Practitioner Clinic	Random
148586	1/14/2023, 12:00 PM	Automated Pharmacy System	Random
148584	1/14/2023, 12:00 PM	Class A-Retail	Random
148586	1/14/2023, 12:00 PM	Class A-Retail	Random
148584	1/14/2023, 12:00 PM	Automated Pharmacy System	Random
148573	11/15/2023, 9:00 AM	Class B-Dispensing Medical Practitioner Clinic	New
148576	1/15/2023, 10:00 AM	Class B-Dispensing Medical Practitioner Clinic	New
148783	1/15/2023, 12:00 PM	Class A-Retail	Random
145725	1/15/2023, 12:00 PM	Class B-Pharmaceutical Administration Facility	New
148610	1/16/2023, 11:00 AM	Class A-Retail	Random
148682	1/20/2023, 10:30 AM	Class A-Retail	Random
148710	1/21/2023, 10:00 AM	Class A-Retail	Random
148850	1/27/2023, 12:00 PM	Non-Sterile Compounding	Random
148850	1/27/2023, 12:00 PM	Class A-Retail	Random
148850	1/27/2023, 12:00 PM	Automated Pharmacy System	Random
Total	Count	21	

Monthly Pharmacy Citations Sept 23

As of 2023-12-14 12:27:13 Mountain Standard Time/MST • Generated by Camille Farley • Sorted by Date Issued (Ascending)

Filtered By

Show: All citations

Date Field: Date Issued equals Last Month (11/1/2023 to 11/30/2023)

Profession equals pharmacy

Date Issued	Case	DOPL Citation: Citation Number	Profession	Violation Type
11/2/2023	148228	103125	Pharmacy	Pharmacy Violation
11/7/2023	147465	103139	Pharmacy	Unlicensed Practice
11/20/2023	148591	103161	Pharmacy	Pharmacy Violation
11/29/2023	148780	103177	Pharmacy	Pharmacy Violation
11/29/2023	148796	103189	Pharmacy	Pharmacy Violation
11/29/2023	148796	103179	Pharmacy	Pharmacy Violation
Total	Count	6		

Monthly Pharmacy Closed Cases Sept 2023

As of 2023-12-14 12:29:50 Mountain Standard Time/MST • Generated by Camille Farley • Sorted by Closed Date (Ascending)

Filtered By

Date Field: Closed Date equals Last Month (11/1/2023 to 11/30/2023)

Show: All cases

Units: Days

Conduct Unit equals Healthcare

Professions equals Pharmacy

Case Number	Closed Date	Professions	Profession Subtype	Complaint Types	Closure Code	Status
147837	11/1/2023	Pharmacy	Pharmacist	Other Criminal Conduct	Letter of Concern	Closed
148082	11/2/2023	Pharmacy	Class D	Pharmacy Violation	Letter of Concern	Closed
148024	11/2/2023	Pharmacy	Class B-Hospital Clinic	Inspection	Random Inspection; Voluntary Compliance	Closed
148228	11/2/2023	Pharmacy	Class A-Retail	Pharmacy Violation	Administrative Action	Closed
148292	11/2/2023	Pharmacy	Class E-Veterinary Pharmaceutical Facility	Inspection	New Inspection	Closed
147645	11/3/2023	Pharmacy	Class A-Retail	Pharmacy Violation	Voluntary Compliance	Closed
148281	11/6/2023	Pharmacy	Class B-Branch	Inspection	New Inspection	Closed
148352	11/6/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
147465	11/7/2023	Pharmacy	Class D	Pharmacy Violation	Administrative Action	Closed
148020	11/8/2023	Pharmacy	Class B-Hospital Clinic	Inspection	Random Inspection	Closed
148472	11/13/2023	Pharmacy	Class E-Non Drug or Device Central Processing Pharmacy	Inspection	New Inspection	Closed
148470	11/13/2023	Pharmacy	Class C-Wholesaler	Inspection	New Inspection	Closed
148103	11/13/2023	Pharmacy	LDP	Inspection	New Inspection	Closed
148504	11/15/2023	Pharmacy	Class B-Dispensing Medical Practitioner Clinic	Inspection	New Inspection	Closed
148573	11/15/2023	Pharmacy	Class B-Dispensing Medical Practitioner Clinic	Inspection	New Inspection	Closed
148576	11/16/2023	Pharmacy	Class B-Dispensing Medical Practitioner Clinic	Inspection	New Inspection	Closed
148584	11/16/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
148610	11/16/2023	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
148586	11/20/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
148682	11/20/2023	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
148591	11/21/2023	Pharmacy	Class A-Retail	Inspection	Administrative Action; Letter of Concern; Random Inspection	Closed
148710	11/21/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
145725	11/27/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	New Inspection	Closed
148783	11/27/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
148812	11/28/2023	Pharmacy	LDP	Inspection	New Inspection	Closed
148300	11/28/2023	Pharmacy	Pharmacist	Ethical Standards	Unfounded	Closed
148796	11/29/2023	Pharmacy	Class A-Retail	Inspection	Administrative Action; Random Inspection	Closed
148182	11/30/2023	Pharmacy	Class C-Wholesaler	Pharmacy Violation	Letter of Concern	Closed
148780	11/30/2023	Pharmacy	Class A-Retail	Inspection	Administrative Action; Random Inspection	Closed
Total	Count	29				



Drug Supply Chain Security Act (DSCSA) Portal in CDER NextGen

The FDA's [CDER NextGen Portal](#) (CDER NextGen) now includes a Drug Supply Chain Security Act (DSCSA) portal that enables the FDA and trading partners to communicate when the FDA requests information related to investigations of suspect or illegitimate products or during a recall.

The DSCA portal is used to:

- Confirm basic information and points of contact for trading partners
- Notify trading partners when they have messages from the FDA
- Enable trading partners to respond to FDA messages and upload documents

Where is the DSCSA portal?

Access the DSCSA portal through [CDER NextGen](#).

Does the DSCSA portal require specialized software or hardware?

No. The DSCSA portal does not require specialized software or hardware, although users must register for an account.

Is the DSCSA portal able to access a trading partner's individual systems and data?

No. A trading partner's information cannot be accessed by the FDA through this portal. Trading partners use the portal to respond to FDA requests for information, including uploading documents.

When will the FDA ask a trading partner to use the DSCSA portal?

The FDA will ask a trading partner to use the DSCSA portal when the agency is investigating suspect or illegitimate products or during a recall. Trading partners will be notified via email when they have a message in the portal.

Which file formats can be uploaded into the DSCSA portal?

- DOC or DOCX (Microsoft Word)
- JSON (JavaScript Object Notation)
- PDF (Portable Document Format)
- XLS or XLSX (Microsoft Excel)
- XML (Extensible Markup Language)

Which resources are available to help trading partners learn how to use the DSCSA portal?

See the following guides and video tutorials for additional information about using the DSCSA portal:

- [FAQs for FDA's DSCSA portal](#): Common questions and answers about the DSCSA submission process
- [FDA's DSCSA portal reference guide](#): Step-by-step guide for submitting DSCSA information in the CDER NextGen DSCSA portal
- **Video Tutorials**: Step-by-step video tutorials for submitting DSCSA information through the CDER NextGen DSCSA portal (accessible after signing in)
 - Trading partner confirmation in the CDER NextGen DSCSA portal
 - Initial submission in the CDER NextGen DSCSA portal
 - Submitting responses to FDA information requests in the CDER NextGen DSCSA portal

• Content current as of:

11/27/2023

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