

FDA Warning and Untitled Letter Analytics in Cortellis

Save time preparing for FDA inspections with analytics that make it easy to pinpoint Warning and Untitled Letters by inspector, citation, date, recipient, type location and more.

Analytics Tools



Side by Side Viewer



FDA Drugs and Biologics Warning and Untitled Letters



FDA Drugs and Biologics Advisory Committee Meetings

1. Access Analytics at the bottom of the Regulatory Home Page and **select FDA Drugs and Biologics warning and untitled letters.**
2. The Analytic opens in a new tab. The **Overview** section provides information about the analytic's scope, terminologies and rules.
3. **Click the top tabs** to open the reports (e.g. Letters by year).

Click pies or bars in the charts to view corresponding citations & letters in Details section

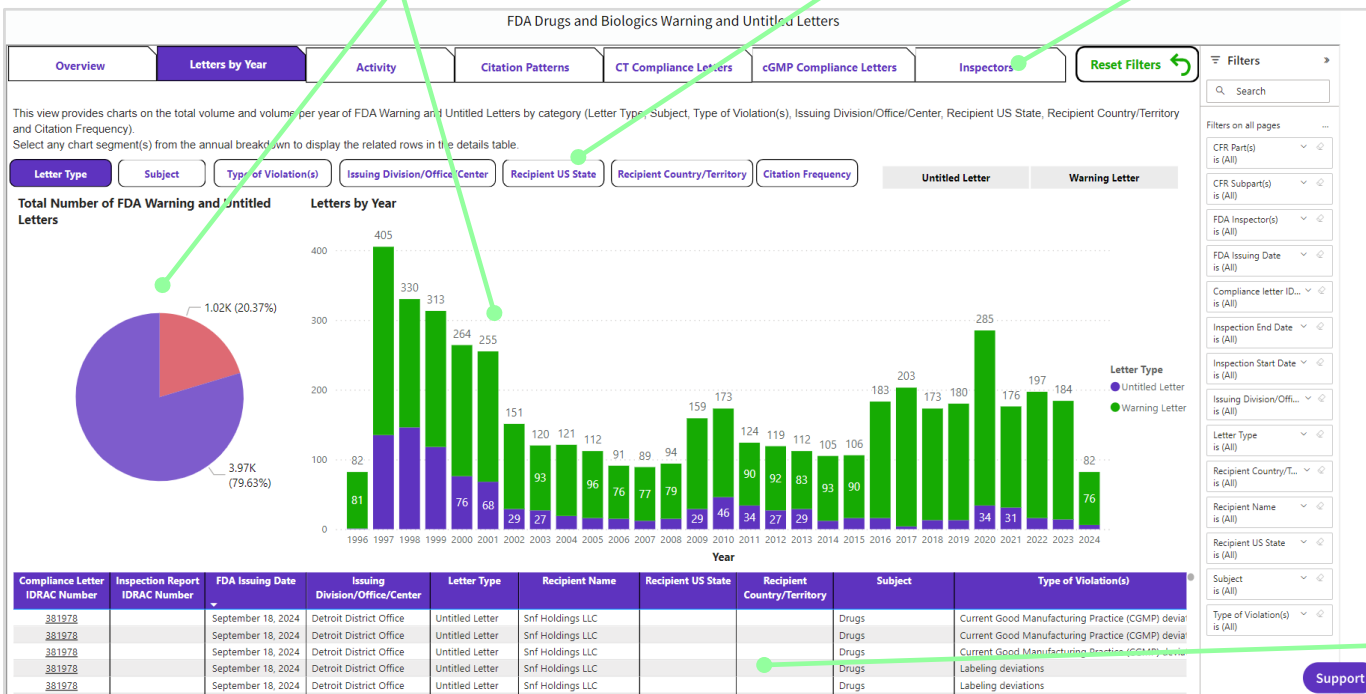
Click buttons to change view by category

Select headings to open each report

Hide or reset filters

Dynamic filters allow you to pinpoint compliance letters by date, subject, inspector, and more

Details section breaks down the specifics of letters that matches your filtering



Click links to open Warning Letters

Example: FDA inspector Christopher M. Jenner is visiting your site. You need to find Warning and Untitled Letters he issued in the last 5 years and understand the issues he found during previous inspections so you can prepare.

FDA Drugs and Biologics Warning and Untitled Letters

Overview

Letters by Year

Activity

Citation Patterns

CT Compliance Letters

cGMP Compliance Letters

Inspectors

Reset Filters

Filters

This tab is limited to letters containing inspector names. Select item(s) from the Inspector Ranking table to display the chart containing the total number of letters per year per selected inspector(s). Related information is displayed in the details table.

Inspector Ranking

| Inspector | Number of Letters |
|-------------------------|-------------------|
| Hull, Kimberly M. | 1 |
| Hunt, Nicholas L. | 1 |
| Huntington, Jennifer L. | 2 |
| Hustedt, Joel D. | 1 |
| Isbill, Shirley H. | 1 |
| Jangchup, Tenzin. | 1 |
| Jariwala, Jay V. | 1 |
| Jassal, Charanjeet S. | 1 |
| Jenner, Christopher M. | 1 |
| Jennings, Lisa R. | 2 |
| Jennings, Robert W. | 1 |
| Jim, Cynthia | 6 |
| Joanne M. Schlossin | 1 |
| Johnson, Ingrid Y. | 2 |
| Johnson, Jeffery A. | 1 |
| Johnson, Jennifer C. | 1 |
| Jones, Latorie S. | 3 |
| Jones, Marvin D. | 3 |

Letter Count by Year and Inspector

Inspectors

- Abaonza, Kristin M.
- Agrawal, Atul J.
- Aiken, Teena H.
- Alavi, Amir
- Althar, Lisa M.
- Ameri, Yasamin
- Anderson, Kelly I.
- Annes, Margaret M.
- Antwi, Lewis K.
- Aspinwall, Colleen M.
- Ayala, Dianiris C.
- Ayoub, Natalie J.
- Babbitt, Mark W.

| Compliance Letter ID | Inspection Report ID | FDA Issuing Date | Issuing Division/Office/Center | Letter Type | Recipient Name | Recipient US State | Recipient Country/Territory | Subject | Type of Violation(s) |
|----------------------|----------------------|------------------|--------------------------------|----------------|----------------|--------------------|-----------------------------|--------------------------|----------------------|
| 319715 | 330801 | October 9, 2020 | Los Angeles District Office | Warning Letter | RLC Labs Inc. | Arizona | USA | Finished pharmaceuticals | Adulterated product |
| 319715 | 330801 | October 9, 2020 | Los Angeles District Office | Warning Letter | RLC Labs Inc. | Arizona | USA | Finished pharmaceuticals | Adulterated product |
| 319715 | 330801 | October 9, 2020 | Los Angeles District | Warning Letter | RLC Labs Inc. | Arizona | USA | Finished pharmaceuticals | Adulterated product |

WARNING LETTER
Kevin R. Bender, M.D./DBC Research Corporation
MARCS-CMS 680072 – MAY 02, 2024

Delivery Method:
VIA UNITED PARCEL SERVICE AND VIA E-MAIL

Reference #:
24-HFD-45-04-01

Product:
Drugs

Recipient:
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United States

Issuing Office:
Center for Drug Evaluation and Research | CDER
United States

WARNING LETTER

Dear Dr. Bender:

This Warning Letter informs you of objectionable conditions observed during the U.S. Food and Drug Administration (FDA) inspection conducted at your clinical site between December 5 and December 16, 2022. Investigator Angelica Chica, representing FDA, reviewed your conduct of the following clinical investigations:

- Protocol XXX, "XXX," of the investigational drug product XXX, performed for XXX (formerly performed for XXX).
- Protocol XXX, "XXX," of the investigational drug product XXX, performed for XXX.
- Protocol XXX, "XXX," of the investigational drug product XXX, performed for XXX.

For more information contact Customer Service at LSH.support@clarivate.com.