HOPESTONE CAPITAL & CONSULTING

FDA Inspection & Form 483 Analyzer

User's Guide

Version 1.0 | Application Build 15.8
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Purpose: This guide explains how to select an FDA-registered company and establishment, analyze inspection history, review citation and public-record evidence, research a named investigator, generate an AI-assisted Analysis Brief, and prepare FOIA requests.

Contents

1. About the Analyzer

The Hopestone FDA Inspection & Form 483 Analyzer is a regulatory-intelligence tool for researching FDA inspection activity associated with a company and a specific registered establishment. It combines structured FDA inspection data, establishment registration information, posted citation records, available public documents, regional inspection activity, user-reviewed evidence, and optional AI-assisted narrative analysis.

What the analyzer is designed to do

- Identify FDA-registered establishments and FEI numbers associated with a selected company.
- Summarize known inspection activity and final inspection classifications.
- Show NAI, VAI, and OAI history by company and establishment.
- Retrieve FDA citation details by Inspection ID when available.
- Identify whether Form 483, EIR, Warning Letter, closeout, or related public records were located.
- Compare nearby inspection activity for the selected establishment.
- Research a specifically named FDA investigator using public FDA and HHS evidence.
- Generate an integrated Analysis Brief using the evidence loaded into the tool.
- Prepare FOIA request content for records that are not publicly available.

Important: The analyzer supports regulatory research and management review. It does not predict who FDA will assign, the exact scope of a future inspection, or the outcome of an inspection.

2. Before You Begin

Recommended browser

Use a current version of Chrome, Edge, Firefox, or Safari. The application stores selected company preferences and some reviewed evidence in the browser, so private-browsing mode may prevent saved information from persisting.

Data and network access

- The server must be able to reach FDA Data Dashboard, openFDA, FDA public pages, and configured geocoding services.
- The AI-generated Analysis Brief requires a server-side OpenAI API key. When the key is unavailable, the tool can produce a rules-based automated evidence summary.
- Public record availability varies. Form 483s and EIRs are not posted for every inspection.

3. Quick Start

1. In Company search, type at least three characters.
2. Select the correct FDA applicant or company name from the suggestion list.
3. Select the correct registered establishment. Confirm the establishment name, FEI, address, owner/operator, and activities.

4. Select a reporting period or use All history.
5. Select Analyze Inspections if the analysis does not run automatically.
6. Review Overview, Inspection History, Company & Site Trends, and Public Records.
7. Open Inspection Intelligence and select Generate Analysis Brief.
8. Use Copy Summary or Download Brief as needed.
9. Use FOIA Requests for missing Form 483s, EIRs, or related records.

4. Company and Establishment Selection

Company search

Begin typing the company name. The suggestion list uses FDA device applicant information to normalize the company name and begin establishment research. Select a suggestion rather than relying only on manually entered text.

Registered establishment

After the company is selected, the analyzer retrieves matching registered establishments. A company may have multiple facilities, subsidiaries, historical names, or owner/operator relationships. Select the facility that matches the intended inspection site.

Field	How to use it
Legal establishment name	Confirm the inspected legal entity, not only the parent brand.
FEI number	Use as the primary facility identifier when matching inspection records.
Registration number	Confirms the FDA registration record associated with the facility.
Owner/operator	Helps distinguish subsidiaries and related legal entities.
Registered address	Confirm city, state/region, country, and street location.
Establishment activities	Confirm that the facility's registered activities match the intended site.

Saved company

Save Company stores the selected company in the current browser. Clear Saved Company removes the preference. Saving a company does not make it the default for other users.

5. Analysis Criteria and Filters

Date range

Select specific start and end dates or use Last 3 years, Last 5 years, Last 10 years, or All history. The selected period controls the inspection records used in tables, charts, and the Analysis Brief.

Inspection classification

Classification	Meaning
NAI - No Action Indicated	FDA did not identify objectionable conditions or practices requiring action.
VAI - Voluntary Action Indicated	Objectionable conditions were found, but FDA did not recommend administrative or regulatory action.
OAI - Official Action Indicated	FDA recommended or initiated administrative or regulatory action.
Classification unavailable	The connected record did not provide a final classification.

Document availability filters

Use Form 483, EIR, and follow-up filters when narrowing inspection history. These fields represent what the analyzer located or could publicly account for; they do not prove that an unlocated document does not exist.

6. Overview

Overview provides a high-level summary for the selected company, establishment, date range, and filters.

Metric	Interpretation
Known inspection activity	Unique inspection events identified for the selected scope.

Final classification records	Inspection events with a connected final classification.
Unique establishments	Number of establishments represented in the active results.
NAI / VAI / OAI	Count of inspection classifications by outcome.
Form 483s available	Count of inspections with a verified, available Form 483 link.
Entered observations	User-reviewed observations stored in the browser.
Linked Warning Letters	Warning Letters linked through reviewed or public evidence.
Median inspection duration	Median duration when reliable start and end dates are present.

7. Inspection History and Regional Comparison

Inspection history table

The table lists inspection-level records and project-area detail. FDA may return more than one row for a single Inspection ID when multiple project areas or classifications apply. The analyzer deduplicates overview totals while retaining row-level details.

- Select a column heading to sort. Select it again to reverse the order.
- Use Search inspection history to find an establishment, FEI, date, classification, or project area.
- Open available public links to review the source record.
- Use Export inspection history to download the active results.

Regional comparison

Nearby FDA Inspection Activity compares the selected establishment with other FDA inspections within the chosen radius, lookback period, and product type. Distances may use verified establishment coordinates or estimated city/state coordinates.

10. Select the distance and lookback period.
11. Confirm the Product type.
12. Select Get FDA Data.
13. Review verified, estimated, and unknown-distance counts.

14. Use sortable columns to review establishment, distance, inspection date, product type, classification, public records, and follow-up status.

Regional limitations: Regional results provide local inspection context. They do not identify the investigator who will be assigned or establish the scope of a future inspection.

8. Company & Site Trends

Company & Site Trends presents an FDA-style timeline of inspection events for the selected establishment. Use the timeline to understand chronology, changes in classification, project-area history, and citation detail.

Timeline interaction

- Hover over an inspection marker for a concise FDA-style summary.
- Select a marker to display the selected Inspection ID, establishment, FEI, location, date, project areas, classifications, source information, and public-record status.
- Review Inspection Details for each project-area row associated with the selected Inspection ID.
- Review Inspection Citations Details for Act/CFR references, short descriptions, and long descriptions returned by FDA.

Citation interpretation: Posted citation descriptions may not reproduce the exact wording or complete set of observations in the final Form 483 or classification correspondence.

9. Public Records

Public Records consolidates the analyzer's accounting of documents and public regulatory actions associated with the selected inspection history.

- Form 483: inspectional observations issued at the conclusion of an inspection.
- EIR: Establishment Inspection Report.
- Warning Letter: formal FDA correspondence describing significant violations.
- Closeout Letter: FDA correspondence indicating that Warning Letter issues were adequately addressed based on information available to FDA.
- FDA profile or source record: the public FDA page or dataset record used by the analyzer.

A record shown as not located or missing means that the analyzer did not verify a public document. FOIA may still be required.

10. Investigators

The Investigators tab does not predict likely local investigators or generate candidate lists. Research begins only after the user enters the name of a known or announced investigator.

Named investigator research

15. Enter the investigator's full name.
16. Run the focused public-record search.
17. Review FDA and HHS records, FDA-hosted PDFs, Warning Letters, inspection documents, and evidence already associated with the selected company.
18. Confirm that the record refers to the correct person before saving or relying on the result.

Privacy and accuracy: Do not infer identity from a similar name alone. Directory results and document mentions require review before they are treated as evidence.

11. Inspection Intelligence and Analysis Brief

Inspection Intelligence combines inspection history, classification trajectory, FDA citation evidence, reviewed observations, public-record gaps, and readiness priorities into one integrated output.

Generate Analysis Brief

Select Generate Analysis Brief after company and establishment data are loaded. The workflow retrieves citation evidence, generates the regulatory narrative, calculates evidence gaps, identifies historically observed themes, and enables Copy Summary and Download Brief.

Content of the brief

- Verified inspection chronology and classification trajectory.
- Citation themes and recurring CFR references.
- Regulatory escalation or resolution signals supported by the loaded evidence.
- Latest connected inspection status.
- Historically observed focus areas and readiness priorities.
- Missing evidence and recommended actions.
- Evidence limitations and public-record gaps.

AI operating modes

Mode	Description
Enhanced AI analysis	Uses the configured server-side OpenAI model to write a narrative from supplied evidence.
Automated evidence analysis	Uses deterministic rules when an AI provider is not configured or unavailable.

Evidence control: The model is instructed to use only the evidence supplied by the analyzer and not invent products, investigators, Warning Letters, remediation, closeout actions, dates, inspection scope,

or FDA conclusions.

Reviewed Citation & Observation Evidence

This collapsible section allows users to manually add reviewed observations, associate evidence with an inspection, and export reviewed observation information. Manual entries should identify their source and review status.

12. FOIA Requests

Use FOIA Requests when a needed inspection record is not publicly available. The tool prepares request language based on the selected company, establishment, FEI, Inspection ID, date, and requested document type.

Recommended request details

- Legal establishment name and address.
- FEI number.
- Inspection ID and inspection date or date range.
- Document requested, such as Form 483, EIR, exhibits, response correspondence, or closeout records.
- Requester name, organization, email, phone, and mailing address.

Review generated text before submission. FDA may require clarification, fees, or narrowing of a broad request.

13. Saving and Exporting Information

Function	Result
Save Company	Stores the selected company in the current browser.
Export inspection history	Downloads active inspection rows after filters and exclusions.
Copy Summary	Copies the generated Analysis Brief narrative to the clipboard.
Download Brief	Downloads the integrated inspection analysis brief.
Export observations	Downloads user-reviewed observation information.

Browser storage: Saved company preferences and reviewed evidence may be stored locally in the browser. Clearing browser storage, changing browsers, or using private mode may remove them.

14. Data Interpretation and Limitations

- FDA structured data may contain multiple project-area rows for one inspection.
- The FDA public inspection database is not necessarily a comprehensive list of every inspection.
- A Form 483 is not a final agency determination of legal violation.
- A final inspection classification applies to FDA's evaluation of the inspection and may differ by project-area row in the source data.
- Public Form 483, EIR, Warning Letter, investigator, and closeout information may be incomplete.
- City/state geocodes are estimates and are not verified establishment coordinates.
- AI-generated interpretation must be reviewed by a knowledgeable regulatory professional.
- The analyzer does not predict future inspection timing, investigator assignment, scope, or outcome.

15. Troubleshooting

Issue	Recommended action
No company suggestions appear	Enter at least three characters, wait briefly, refresh with Ctrl+F5, and confirm the connector service is running.
Wrong establishment appears	Select a different registered establishment and verify legal name, FEI, address, owner/operator, and activities.
Known inspection is missing	Confirm the correct FEI and legal entity, expand the date range, and review related facilities or historical names.
Citation details are unavailable	Confirm the Inspection ID and public citation status. FDA may not return citation detail for every inspection.
Regional results show unknown distance	The source record may lack usable coordinates. Retry data retrieval or review unknown-distance records.

AI analysis does not run	Confirm inspection evidence is loaded and the server health response shows the AI feature configured. The fallback summary should run without an API key.
Saved company disappears	Browser storage may have been cleared or private-browsing mode may be active.
A tab appears blank	Refresh with Ctrl+F5. Confirm the latest build was installed and the browser is not serving cached HTML.

16. Glossary

Term	Definition
CAPA	Corrective and Preventive Action.
EIR	Establishment Inspection Report.
FEI	FDA Establishment Identifier.
FOIA	Freedom of Information Act.
Form 483	Inspectional Observations issued by FDA investigators at the conclusion of an inspection.
NAI	No Action Indicated.
OAI	Official Action Indicated.
Project area	FDA inspection program or work area associated with an inspection record.
VAI	Voluntary Action Indicated.

Support: For application support or questions about the analyzer, contact Hopestone Capital &

Consulting through the contact information provided on the Hopestone website.