The FDA Drug Inspectorate Updates

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History of Pre-Announced and Unannounced Inspections

- FDA conducts approximately 12,000 domestic inspections each year.
- FDA conducts approximately 3,000 foreign inspections each year in more than 90 countries.
- The Agency's primary purpose for pre-announcing certain types of inspections, is to ensure that the appropriate records and personnel will be available so that an effective inspection can be executed.
- Foreign inspections have been generally pre-announced in advance, partly due to:
  - logistics such as arranging travel and access to facilities
  - securing visas
  - personnel safety
  - coordination of translators in countries where English is not the primary language
  - and partly because of the high costs of conducting foreign inspections
- A Form FDA 482, Notice of Inspection, is not issued during inspections outside the country, unless firm is a U.S. military facility.

Foreign Unannounced Inspection Pilot

- FDA began implementation of the Foreign Unannounced Inspection Pilot (FUIP) in March 2022.

- Unannounced inspections (under the Pilot) have occurred in:
  - India
  - China

- Human drug manufacturing facilities.

Foreign Unannounced Inspection Pilot

- Published December 2022 - UNANNOUNCED FOREIGN FACILITY INSPECTIONS PILOT PROGRAM (Foreign Unannounced Inspection Pilot - FUIP)

- Charge: Increase unannounced surveillance inspections of foreign human drug establishments and evaluate the differences between domestic and foreign human drug establishments, including the impact of announcing inspections in advance of an inspection.

- Evaluate:
  - number and type of violations
  - significant differences between each type of inspection
  - costs and benefits
  - barriers to conducting unannounced inspections
  - any challenges to achieving parity between domestic and foreign human drug establishment inspections
  - approaches for mitigation

Foreign Unannounced Inspection Pilot

- Status
  - In Progress
    - ~61% Complete
- Challenges
  - Staffing
  - Logistics
  - Cost
- Pilot Evaluation
  - In Progress

Expansion of FDA Unannounced Inspections

- Over last five years, FDA has been increasing the number of unannounced foreign human drug inspections.
- FDA issued a News Release on 05/06/2025 (FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities | FDA)
  - FDA intends to expand the use of unannounced inspections at foreign manufacturing facilities that produce foods, essential medicines, and other medical products intended for American consumers and patients.
  - Expansion aims to create parity between domestic and foreign inspections and ensure that product entering the US is safe.
  - FDA is authorized to take regulatory action against any firm that seeks to delay, deny, or limit an inspection, or refuses to permit entry for an unannounced drug or device inspection.
  - Global inspections generate real-time intelligence that strengthens enforcement and safety.

Generic Drug User Fee Amendments (GDUFA)

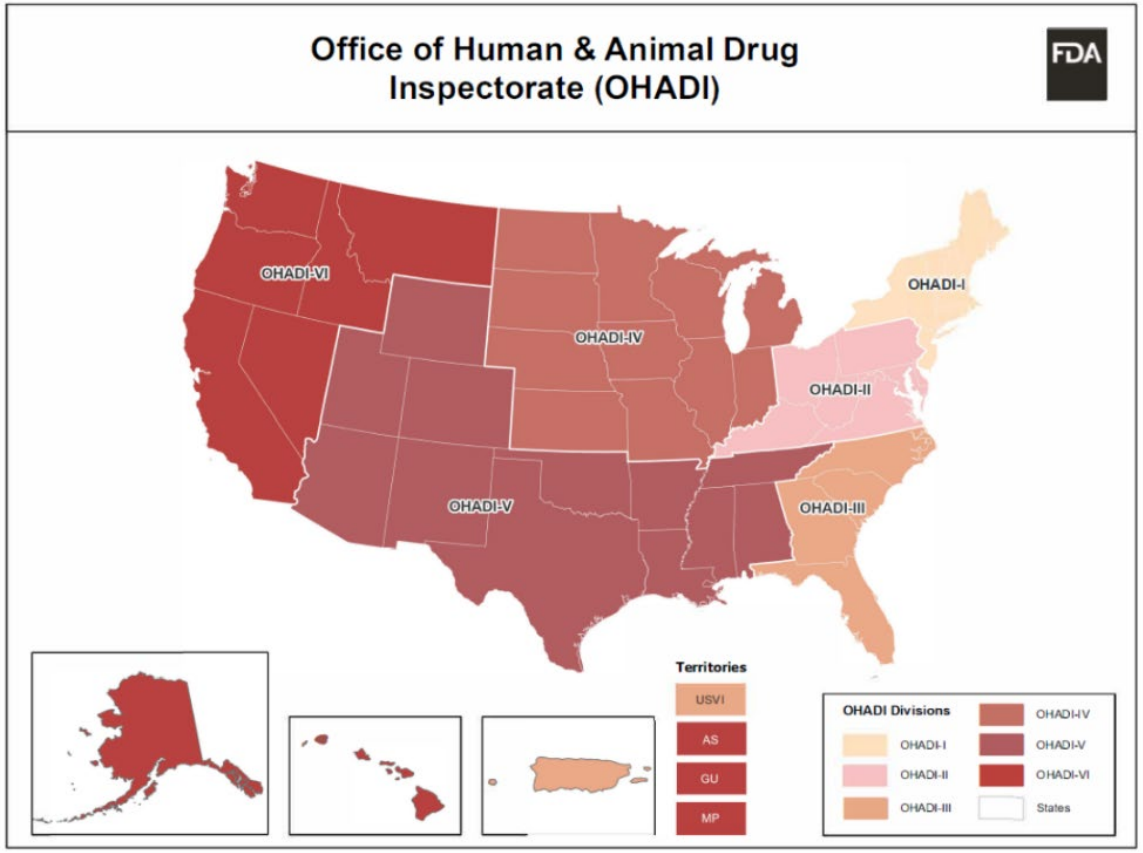
- GDUFA authorizes FDA to collect fees for certain generic human drug applications, drug master files, and facilities.
- The FDA GDUFA Paid Facilities List, as of 03/07/2025, includes approximately the following number of facilities:
  - ~1,444 facilities = 2025
  - ~1,438 facilities = 2024
  - ~1,401 facilities = 2023
  - ~1,389 facilities = 2022
  - ~1,345 facilities = 2021
- These fees along with non-user fee appropriations, fund personnel involved in generic drug regulations, including those inspecting generic drug facilities.

Office of Human & Animal Drug Inspectorate (OHADI)

- On October 1, 2024, there was an FDA Reorganization.
  - Office of Regulatory Affairs to Office of Inspections and Investigations

- 210 total Investigators in OHADI*
  - 87 Investigators funded by GDUFA user fees
  - 20 Investigators on the Foreign Drug Cadre

- Foreign Office Workforce
  - China and India



*Preliminary as of 10/21/2025

Inspectorate Priorities

- Risk Based Inspections
- Domestic Inspections
- Foreign Inspections
  - Increased Foreign Unannounced Inspections
- Inspectional Efficiency
- Inspectional Workforce Capacity
  - Training
  - Recruitment and Retention

U.S. FOOD & DRUG ADMINISTRATION

THANK YOU