GRx + BIOSIMS 2026

Generic Drug Manufacturing

CDER Compliance Areas of Focus

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Disclaimer

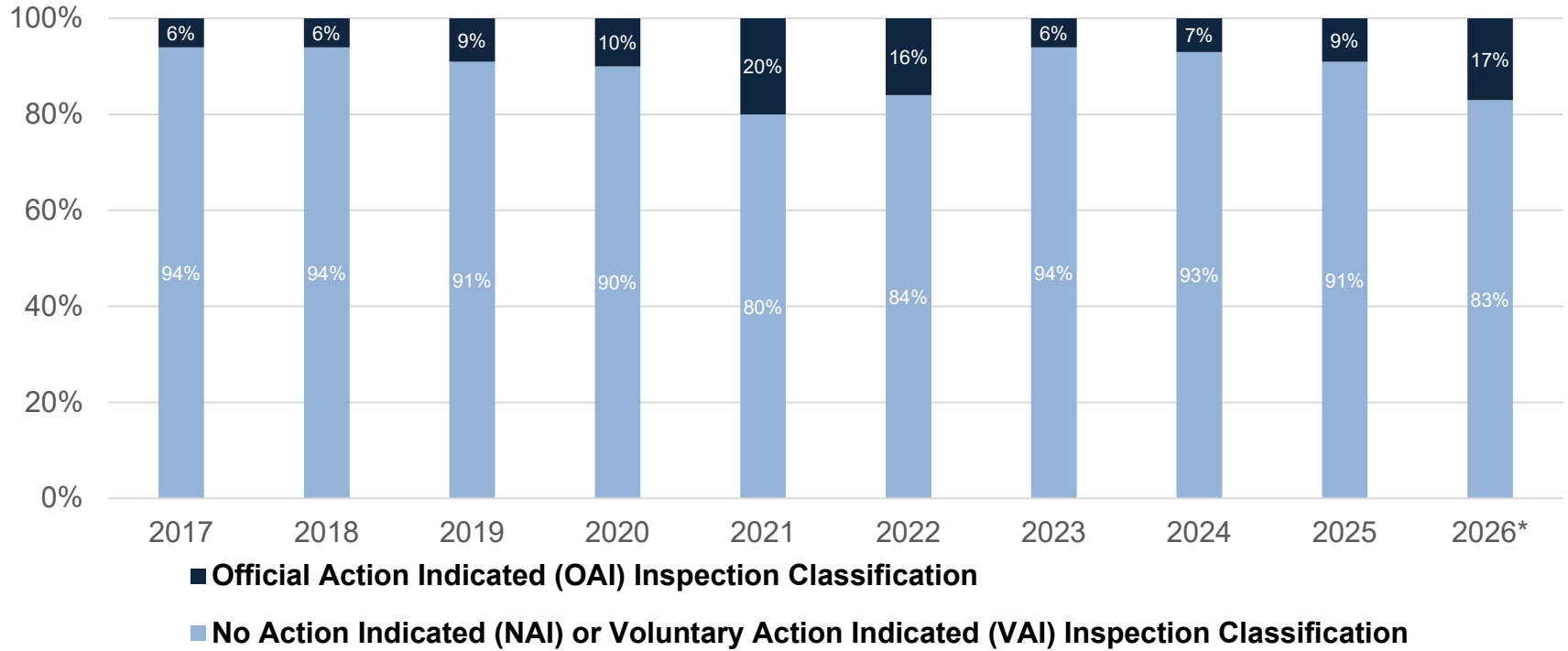
The views and opinions expressed in this presentation are those of the authors and do not necessarily represent official policy or position of the Food and Drug Administration.

Today's Topics

- Select compliance metrics and case studies
- Quality and compliance expectations
- National Drug Code (NDC) revision

Surveillance Inspection Classification Rates for Generic Drug Manufacturing Facilities by Fiscal Year

Most surveillance inspections of generic drug facility inspections result in NAI or VAI classification



** FY2026 inspection classifications are still in progress*

Generic and Biosimilar Recalls Classified in FY26

GENERIC DRUGS

192 recall events

325 products*

Top Reasons

1. Failed impurities/degradation specifications
2. CGMP deviations
3. Failed dissolution specifications

BIOSIMILARS

4 recall events

4 products*

Top Reason

Lack of assurance of sterility

*Each recalled product may involve thousands of units. See the FDA Enforcement Report for detailed recall information.

Common Violations in Generic Drug Manufacturing Facility Warning Letters, FY20-FY26

FDA cited failures in the following areas:

1. Out of specification results and discrepancy investigations
2. Sterility assurance and prevention of objectionable microbes
3. Aseptic processing and area controls
4. Quality unit responsibilities
5. Equipment cleaning and maintenance

CASE STUDY 1

Data Integrity and Sterility Failures

Warning letter violations include:

Inaccurate records

“Colony forming unit (cfus) counts had been recorded as if incubation was actively in progress. In interviews conducted by your management, your analysts confirmed these samples were not collected.”

Inaccurate electronic records controls

“Your firm has no means of tracking or retrieving records of failed leak tests.”

Poor aseptic practices

“Our investigators observed multiple instances of inappropriate aseptic behavior in which operators blocked unidirectional airflow at critical locations without implementing adequate corrective measures…”

Result: Recall, import alert, warning letter, drug production suspended

CASE STUDY 2

Data Integrity Failures

Warning letter violations include:

Deliberate conduct

“Your team leader had instructed staff to discard the bioburden plates with significant growth and had manipulated camera timestamps to create backdated documentation.”

Deception

“Pages were removed from your logbook and replaced with newly fabricated pages.”

Requires Systemic Change

Removing personnel and employing a consultant may not be adequate.

Result: Recall, import alert, warning letter, drug production suspended

GUIDANCE DOCUMENT

Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection

MARCH 2026

Download the Draft Guidance Document | Read the Federal Register Notice

Draft | Level 1 Guidance

Not for implementation. Contains non-binding recommendations.

Docket Number: FDA-2025-D-1504

Issued by: Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Center for Veterinary Medicine
Office of Inspections and Investigations

The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled “Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection.” This guidance is intended for foreign and domestic human and animal drug manufacturing establishments inspected by FDA whose

GUIDANCE DOCUMENT

Post-Warning Letter Meetings Under GDUFA

JUNE 2025

Download the Final Guidance Document | Read the Federal Register Notice

Final | Level 1 Guidance

Docket Number: FDA-2023-D-3370

Issued by: Center for Drug Evaluation and Research
Office of Inspections and Investigations

The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Post-Warning Letter Meetings Under GDUFA.” This guidance provides information on the implementation of the Post-Warning Letter Meeting process for certain drug manufacturing facilities, a program enhancement agreed upon by

Achieving Sustainable CGMP Compliance

- Ensure strong executive management oversight
- Create environment where all employees accept their responsibility to assure quality
- Ensure you have well-designed facilities, equipment, and processes
- Engineer quality system to proactively identify and effectively remediate emerging quality risks
- Implement long-term systemic remediations

NDC Revision Final Rule



- Final rule published March 5, 2026
- Effective date is March 7, 2033
- Standardizes the NDC to a 6-4-2 format and allows non-linear barcodes on labeling
- Covers all drugs subject to NDC assignment
- All sectors of U.S. healthcare will be impacted
- Pharmacies, clinics, manufacturers, health IT vendors, wholesale distributors, and government agencies must prepare before the effective date

NDC Revision Final Rule Timeline



Resources: NDC Revision Final Rule

Julian Chun's session

Tomorrow at 1:30 p.m.

FDA workshop

View the recording: Revising the National Drug Code Format and Drug Label Barcode Requirements

Ask questions

NDC final rule: eDRLS@fda.hhs.gov

DSCSA and the NDC final rule: drugtrackandtrace@fda.hhs.gov



Wrap-up

- **Proactive quality assurance**

Foundation of sustainable CGMP compliance

- **FDA guidance**

Supports proactive compliance

- **NDC format revision**

Requires all manufacturers to be proactive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