Report to Congress

Annual Report on Inspections of Establishments

FY 2025

Background

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144) was signed into law. FDASIA section 705 amended section 510(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 USC 360(h), including to require under section 510(h)(6) that the Food and Drug Administration (FDA or the Agency) make available on an annual basis through the Agency's website reports on inspections of establishments registered under section 510 of the FD&C Act. Following minor amendments to section 510(h)(6) by section 3101(a)(2)(H) of the 21st Century Cures Act (Public Law 114-255) and section 901(e) of the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52), the reporting requirements under section 510(h)(6) ("Annual Report on Inspections of Establishments") of the FD&C Act were more substantially amended on December 29, 2022, by section 3616(c) of the Food and Drug Omnibus Reform Act of 2022 (FDORA) (title III of division FF of Public Law 117-328).

Section 510 of the FD&C Act requires establishments that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs, human biologics regulated as drugs, and devices to register with FDA and submit to FDA a listing of every such product they manufacture, prepare, propagate, compound, or process for commercial distribution in the United States. This information helps FDA maintain a catalog of all human and veterinary drugs, biological products, and devices in commercial distribution in the United States. FDA uses the Official Establishment Inventory (OEI), a database maintained by the Office of Inspections and Investigations (OII), as well as other databases to identify the registered establishments that are subject to inspection.

Section 704(a) of the FD&C Act provides FDA with authority for inspections, specifically providing authority for FDA to enter, at reasonable times, and inspect, at reasonable times and within reasonable limits and in a reasonable manner, facilities under the jurisdiction of the FD&C Act. An inspection is a careful, critical, official examination of a facility to determine its compliance with applicable statutory and regulatory requirements of the FDA.

Additionally, section 510 of the FD&C Act includes requirements to establish a risk-based schedule for the inspection of drug and device establishments. The risk-based schedule must consider the known safety risks of the establishments, including the inherent risk of the drug or device manufactured, prepared, propagated, compounded, or processed at the establishment, the record, history, and nature of recalls linked to the establishment, and the inspection frequency and history of the establishment.

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Acronym List

API	Active Pharmaceutical Ingredient
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CGMP	Current Good Manufacturing Practice
CVM	Center for Veterinary Medicine
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDARA	FDA Reauthorization Act of 2017
FDASIA	Food and Drug Administration Safety and Innovation Act
FDF	Finished Dosage Form
FDORA	Food and Drug Omnibus Reform Act of 2022
FDP	Finished Drug Product
FY	Fiscal Year (October 1 – September 30)
MRA	Mutual Recognition Agreements
OII	Office of Inspections and Investigations (formerly known as ORA)
QS	Quality Systems
R&L	Registration and Listing

I. Introduction

A. Information Presented in This Report

Section 510(h)(6) ("Annual Report on Inspections of Establishments") of the FD&C Act, as most recently amended by FDORA section 3616(c), states:

> (6) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.
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> Not later than May 1 of each year, the Secretary shall make available on the Internet Web site of the Food and Drug Administration a report regarding—
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> (A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year;
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> (ii) the number of such registered establishments in each region of interest;
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> (iii) the number of such domestic establishments and the number of such foreign establishments, including the number of establishments in each region of interest, that the Secretary inspected in the previous fiscal year;
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> (iv) the number of inspections to support actions by the Secretary on applications under section 505 of this Act or section 351 of the Public Health Service Act, including the number of inspections to support actions by the Secretary on supplemental applications, including changes to manufacturing processes, the Secretary conducted in the previous fiscal year;
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> (v) the number of routine surveillance inspections the Secretary conducted in the previous fiscal year, including in each region of interest;
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> (vi) the number of for-cause inspections the Secretary conducted in the previous fiscal year, not including inspections described in clause (iv), including in each region of interest; and
>
> (vii) the number of inspections the Secretary has recognized pursuant to an agreement entered into pursuant to section 809, or otherwise recognized, for each of the types of inspections described in clauses (v) and (vi), including for inspections of establishments in each region of interest.

(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug or a finished drug product, the number of each such type of establishment;

(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A); and

(D) the status of the efforts of the Food and Drug Administration to expand its recognition of inspections conducted or recognized by foreign regulatory authorities under section 809, including any obstacles to expanding the use of such recognition.

Section 510(h)(7) of the FD&C Act states:

(7) REGION OF INTEREST.—For purposes of paragraph (6)(A), the term “region of interest’’ means a foreign geographic region or country, including the People’s Republic of China, India, the European Union (EU), the United Kingdom, and any other country or geographic region, as the Secretary determines appropriate.

This report satisfies the annual reporting requirement set forth by section 510(h)(6) of the FD&C Act for FY 2025.

B. Data Collection and Definitions

The FDA product Centers included in this Annual Report are:

- Center for Biologics Evaluation and Research (CBER)
- Center for Drug Evaluation and Research (CDER)
- Center for Veterinary Medicine (CVM)
- Center for Devices and Radiological Health (CDRH)

Data for the registration information contained in this report were generated by FDA's registration databases for FY 2025. Data for the inspection information contained in this report were generated from OII's eNSpect Inspection tracking system for FY 2025. The data consist of the numbers of inspections conducted at drug and device establishments to evaluate compliance with current good manufacturing practice (CGMP) requirements, including both surveillance inspections for drugs and Quality Systems (QS) regulations inspections for devices, as applicable. These routine drug and device inspections will hereafter be referred to collectively as "CGMP inspections." The hours of work spent preparing for, conducting, and documenting CGMP inspections, as reported by eNSpect from FDA staff, were used to calculate the percentage of OII's field medical product non-user fee funding that supported those inspections.

Table 1 shows data about registered drug and device establishments. Table 2 provides data about registered establishments based on regions of interest. Based on section 510(h)(7) of the FD&C Act, FDA understands "region of interest," as used in section 510(h)(6), to mean either an individual country, or some other geographic region that FDA determines is an appropriate "region of interest" for which we have some particular concern or interest that the Agency believes warrants inspections specific to that area. Tables 4 through 7 show data about inspections of domestic and foreign establishments. The numbers reported in Table 4 are only for CGMP inspections. However, registered drug and device establishments are subject to other types of inspections, such as product-specific inspections, pre-approval and pre-license inspections, and for-cause inspections. Therefore, while Table 1 shows registered drug and device establishments, Table 4 shows the specific subset of the CGMP domestic and foreign inspections FDA conducted at those establishments. Table 10 shows the percentage of the OII field medical product non-user fee funding involved in conducting domestic and foreign drug and device establishment CGMP inspections.

Definitions of key terms used throughout this report can be found in Appendix A.

II. Drug and Device Establishment Registration

A. Domestic and Foreign Drug and Device Establishments

As of September 30, 2025, 8,895 domestic and 4,816 foreign drug establishments registered with FDA, bringing the total number of FY 2025 registered drug establishments to 13,711, pursuant to section 510 of the FD&C Act.

In FY 2025, a total of 29,178 medical device establishments registered with FDA.[1]

Table 1 provides data about domestic and foreign registered drug and device establishments in FY 2025.

Table 1. Number of Domestic and Foreign Registered Drug and Device Establishments.

Location	Drug Registered Establishments	Device Registered Establishments
Domestic	8,895	13,328
Foreign	4,816	15,850
Total	**13,711**	**29,178**

B. Registered Establishments in Each Foreign Region of Interest

In FY 2025, there were a total of 20,666 registered establishments across 5 "Regions of Interest." FY 2025 establishment registration results are presented in Table 2.

Table 2. Number of Registered Drug and Device Establishments in Each Foreign Region of Interest.

Region of Interest	Number of Registered Establishments
China	6,553
European Union	4,830
India	1,417
United Kingdom	793
Rest of the World (foreign)	7,073
Total	**20,666**

[1] For the purposes of this report, CDRH registration counts reflect the total number of firms that registered during the year, including those that deactivated their registrations later in the year. The breakdown by establishment type included in the Medical Device User Fee Act (MDUFA) quarterly report covers only those that were still active at the end of each quarter or fiscal year.

III. Registered Drug Establishments by Type

In FY 2025, a total of 4,384 establishments registered as Finished Drug Product (FDP) establishments and 1,951 establishments registered as Active Pharmaceutical Ingredient (API) establishments.

Table 3 below provides a breakdown of the number of establishments that registered as FDP and API establishments in FY 2025.

For the purposes of this report, if an establishment manufactures, prepares, propagates, compounds, or processes both FDP and API, it is counted as an FDP establishment. API establishments are involved solely in the production of an API. The "Other" category includes but is not limited to establishments that manufacture, prepare, propagate, compound, or process medical gases or medicated feed; and blood establishments that register through the registration system maintained by CBER. This report excludes drug establishments registered under FD&C Act section 503B as Outsourcing Facilities or those seeking to compound drugs under the conditions of section 503A.

Table 3. Types of Registered Drug Establishments.

	FDP	API	Other	Total
FY 2025	4,384	1,951	7,376	13,711

The data sources for the reported FDP and API establishments are the registration databases maintained by FDA centers for human drugs and biologics and animal drugs.

IV. Domestic and Foreign Establishment Inspections

A. Domestic and Foreign Drug and Device Establishments Inspected in FY 2025

Section 510(h)(6)(A)(iii) of the FD&C Act requires FDA to report on the number of domestic and foreign drug and device establishments that FDA inspected in the prior fiscal year broken down by "region of interest." FDA understands that the requirement to report on certain establishment inspections under section 510(h)(6)(A)(iii) applies to establishments that registered under section 510, based on their engaging in the manufacturing, preparation, propagation, compounding, or processing of a drug or device. Table 4 shows that in FY 2025, FDA completed a total of 3,732 such inspections.

Table 4. Number of Domestic and Foreign Drug and Device Establishments Inspected in each Region of Interest.

Region of Interest	FY 2025
China	218
European Union	227
India	217
United Kingdom	51
United States	2,740
Rest of the World* (foreign)	279
Total	**3,732**

* Switzerland, while located within the geographic boundary of the European Union, is not an EU member and is therefore included in Rest of the World. Norway and Iceland are also included with "Rest of the World" and not the EU.

These inspection numbers include CGMP inspections for drugs and QS inspections for class II and class III devices. However, the number of CGMP inspections does not include other types of inspections that FDA conducts (such as product-specific or pre-approval inspections of drug establishments and inspections of class I device establishments).

B. Domestic and Foreign Drug and Device Establishments Inspections Conducted to Support Actions on Applications, Including Supplemental Applications, and Changes to Manufacturing Processes

FDA understands that clause (iv) of section 510(h)(6)(A) of the FD&C Act refers to inspections to support actions on applications under section 505 of the FD&C Act or PHS Act section 351 and interprets this clause as referring to pre-approval and pre-license inspections of drugs and biological products, and any other inspections regarding manufacturing activity that would support agency action on such applications.

The data in Table 5 conveys the number of inspections conducted in FY 2025 to support actions by the Secretary on applications under section 505 of the FD&C Act or section 351 of the PHS Act, the number of inspections to support actions by the Secretary on supplemental applications, and the number of inspections concerning changes to manufacturing processes.

Table 5. Number of Inspections Conducted to Support Actions on Applications, Including Number of Inspections to Support Actions on Supplemental Applications, and Number of Inspections Regarding Changes to Manufacturing Processes.

Region of Interest	Number of Inspections
China	36
European Union	15
India	35
United Kingdom	2
United States	53
Rest of the World* (foreign)	15
Total	**156**

* Switzerland, while located within the geographic boundary of the European Union, is not an EU member and is therefore included in Rest of the World. Norway and Iceland are also included with "Rest of the World" and not the EU.

C. Routine Surveillance Inspections and For-Cause Inspections Conducted by FDA

FDA performs various types of inspections to ensure regulatory compliance and consistency in manufacturing and to minimize potential consumer exposure to adulterated products. Surveillance inspections are used to monitor manufacturing practices as well as the quality of FDA-regulated products, while for-cause inspections are conducted as the result of a complaint or when the Agency has reasons to believe an establishment has quality problems.

The reporting requirements under sections 510(h)(6)(A)(v) and (vi) of the FD&C Act refer to routine surveillance inspections and for-cause inspections that were conducted by FDA. FDA understands information reported under clause (v) to be a subset of information reported under clause (iii), which broadly addresses inspections during the prior fiscal year of registered drug and device establishments. As shown in Table 6, FDA conducted a total of 3,377 surveillance inspections and 355 for-cause inspections in FY 2025 across the various regions of interest.

Table 6. Number of Routine Drug and Device Surveillance Inspections and For-Cause Inspections.

Region of Interest	Surveillance Inspections	For-Cause Inspections
China	211	7
European Union	199	28
India	186	31
United Kingdom	45	6
United States	2,480	260
Rest of the World* (foreign)	256	23
Total	**3,377**	**355**

* Switzerland, while located within the geographic boundary of the European Union, is not an EU member and is therefore included in Rest of the World. Norway and Iceland are also included with "Rest of the World" and not the EU.

D. Routine Surveillance Inspections and For-Cause Inspections Conducted by Foreign Regulatory Agencies

Section 510(h)(6)(A)(vii) of the FD&C Act requires that FDA report on foreign inspections that are recognized through a mutual recognition agreement (MRA) for the types of inspections described in clauses (v) and (vi), i.e., "routine surveillance inspections" and certain "for-cause inspections." Only FDA-regulated drug products for human and animal use and biological products for human use are included in the MRA inspections scope; medical devices are not covered.

Table 7 shows that in FY 2025, 392 routine surveillance inspections and 1 for-cause inspection were conducted by foreign regulatory agencies that FDA has recognized across five regions of interest.

Table 7. Number of Routine Drug Surveillance Inspections and For-Cause Inspections Conducted by Foreign Regulatory Agencies.[2]

Region of Interest	Number of Routine Surveillance Inspections Recognized	For-Cause Inspections Recognized
China	0	0
European Union	368	0
India	0	0
United Kingdom	24	1
Rest of the World* (foreign)	0	0
Total	**392**	**1**

* Switzerland, while located within the geographic boundary of the European Union, is not an EU member and is therefore included in Rest of the World. Norway and Iceland are also included with "Rest of the World" and not EU.

[2] The foreign regulatory agencies that performed inspections in the specified regions of interest are "third country" (likely a combination of in-country and third country) parties and not necessarily agencies based in the respective regions of interest.

E. FDA's Efforts to Expand Recognition of Inspections Conducted or Recognized by Foreign Regulatory Authorities

The FD&C Act requires FDA to report on the status of its efforts to expand its recognition of inspections conducted or recognized by foreign regulatory authorities under section 809, including any obstacles to expanding the use of such recognition.

Mutual recognition agreements (MRAs) between FDA and foreign regulatory authorities allow drug inspectors to rely upon information from drug inspections conducted within each other's borders. MRAs allow us to:

- Yield greater efficiencies for United States and foreign regulatory systems by avoiding duplication of inspections; and
- Reallocate resources towards inspection of drug manufacturing facilities with potentially higher public health risks across the globe.

FDA has implemented use of third-country inspections to expand the scope of its MRAs. FDA also continues to find authorities capable of meeting FDA requirements for animal drug inspections. In FY2025, FDA found five new veterinary authorities capable under our MRA with the EU. The use of the third-country inspections and expansion of the EU MRA to these five new veterinarian authorities allows FDA to gain efficiencies and expand the use of our MRA. FDA is working with our foreign counterparts to complete the assessments of all the EU veterinary authorities. FDA continues to explore opportunities to expand use of MRAs.

V. Percentage of FDA Budget Used to Fund Establishment Inspections

FDA is able to provide the percentage of OII's field medical product program resources (OII's budget authority funding received for work in support of Field Biologics, Field Medical Devices & Radiological Health, Field Human Drugs, and Field Animal Drugs) involved in conducting CGMP surveillance inspections of domestic and foreign drug and device establishment by fiscal year. In addition to CGMP surveillance inspections, OII conducts many other types of establishment inspections, such as product-specific, pre-approval, and pre-license inspections, Good Laboratory Practice inspections, bioequivalence inspections, and inspections of clinical investigators, institutional review boards, and application sponsors.

The OII total non-user fee funding for FY 2025 was $761,580,000. Approximately $275,636,000 of this amount was devoted to field medical product programs (hereafter referred to as "field medical product non-user fee funding"), while the remaining $485,944,000 was devoted to field programs for other products (e.g., human and animal foods). The total field medical product non-user fee funding is calculated by adding the non-user fee appropriated funding for human drugs, human biologics regulated as drugs, animal drugs, and devices and radiological health field programs.

Table 8. Non-User Fee Funding[3].

OII Non-User Fee Funding	FY 2025
Medical Product Programs	$275,636,000
Field Programs for Other Products	$485,944,000
Total	**$761,580,000**

The field medical product non-user fee funding includes all field activities that support FDA's programs related to human biologics regulated as drugs, human drugs, animal drugs, and medical devices, by assessing compliance with applicable laws and regulations. These activities include inspecting establishments, conducting sample collection for analyses, examining products offered for entry into the United States, and certain emergency preparedness and response activities for FDA-regulated medical products. Of the $275,636,000 field medical product non-user fee funding, approximately $143,638,000 was used for domestic drug and device establishment CGMP inspections, and approximately $77,168,000 was used for foreign drug and device establishment CGMP inspections during FY 2025.

[3] Please note the OII Non-User Fee Funding for FY 2025 reflects funding levels prior to the FDA Reorganization which was effective beginning in FY 2025.

Table 9. Medical Product Non-User Fee Funding.

Medical Product Non-user Fee Funding	FY 2025
Domestic drug and device establishment CGMP inspections	$143,638,000
Foreign drug and device establishment CGMP inspections	$77,168,000
Total	**$220,806,000**

The numbers reported above are derived from the total FDA investigator hours reported in the Field Accomplishments and Compliance Tracking System (FACTS) for the field medical product inspections. The estimated cost of these hours was then used to calculate the percentage of the field medical product non-user fee funding used for both domestic and foreign drug and device establishment CGMP inspections. These percentages are based solely on the estimated cost for FY 2025 of OII's field program resources. Field program resources include operational costs, such as inspections of establishments and support personnel. These percentages do not include other resources related to the reported inspections, such as resources utilized in resulting compliance or enforcement activities involving inspected establishments.

In FY 2025, the percentage of the field medical product non-user fee funding used to fund domestic drug and device establishment CGMP inspections was approximately 52.11 percent.[4]

The percentage of the field medical product non-user fee funding used to fund foreign drug and device establishment CGMP inspections was approximately 28 percent.

Table 10 below shows the percentage of the OII field medical product non-user fee funding involved in conducting domestic and foreign drug and device establishment CGMP inspections in FY 2025.

In addition to the total non-user fee funding described above, user fee funds are authorized to support OII's field medical product program under amendments[5] made to the FD&C Act by the Prescription Drug User Fee Amendments of 2022 (PDUFA VII), the Generic Drug User Fee Amendments of 2022 (GDUFA III), the Medical Device User Fee Amendments of 2022 (MDUFA V), the Animal Drug User Fee Amendments of 2023 (ADUFA V), the Animal Generic Drug User Fee Amendments of 2023 (AGDUFA IV), the

[4] This percentage does not include inspections of animal drug establishments conducted by the states under a contract with FDA.

[5] The PDUFA, MDUFA, GDUFA, and BSUFA user fee programs were reauthorized for FY 2023-2027 under amendments to the FD&C Act made by the FDA User Fee Reauthorization Act of 2022, Division F of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (P.L. 117-180, September 30, 2022).

Biosimilar User Fee Amendments of 2022 (BsUFA III), and the Compounding Quality Act. These numbers were not included in the calculations for this report.

Table 10. OII Percentage of Non-User Fee Funding.

OII Percentage of Non-user Fee Funding	FY 2025
Domestic drug and device establishments CGMP Inspections as Percentage of OII Field Medical Product Budget	52.11%
Foreign drug and device establishments CGMP Inspections as Percentage of OII Field Medical Product Budget	28.00%
Total drug and device establishments CGMP Inspections as Percentage of OII Field Medical Product Budget	**80.11%**

Appendix A: Definitions of Key Terms

Active Pharmaceutical Ingredient - means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredients do not include intermediates used in the synthesis of the substance. (21 CFR 207.1)

Device – means : an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term 'device' does not include software functions excluded pursuant to section 520(o) of the FD&C Act. (Section 201(h)(1) of the FD&C Act (21 U.S.C. 321(h)(1)))

Drug - means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). (Section 201(g) of the FD&C Act (21 U.S.C. 321(g)))

Finished Drug Product - means a finished dosage form (e.g., tablet, capsule, or solution) that contains at least one active pharmaceutical ingredient, generally, but not necessarily, in association with other ingredients in finished package form suitable for distribution to pharmacies, hospitals, or other sellers or dispensers of the drug product to patients or consumers. (21 CFR 207.1)

Mutual Recognition Agreement – An agreement that allows FDA and foreign regulatory authorities to rely on each other's factual findings from inspections to maximize inspection coverage and increase efficiency rendering a safer United States drug supply.

Regions of Interest – a foreign geographic region or country, including the People's Republic of China, India, the European Union, the United Kingdom, and any other country or geographic region, as the Secretary determines appropriate. (Section 510(h)(7) of the FD&C Act.)

Rest of the World – a foreign geographic region or country outside the defined "regions of interest." Switzerland, while located within the geographic boundary of the European Union, is not an EU member and is therefore included in Rest of the World. Norway and Iceland are also included with "Rest of the World" and not EU.

This report was prepared by FDA's Performance Management Staff in collaboration with the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), the Center for Veterinary Medicine (CVM), and the Office of Inspections and Investigations (OII)). For information on obtaining additional copies, please contact:

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