FDARA Section 902 Annual Report on Inspections

FY 2023

Facility Inspections Necessary for the Approval of Specified Human Drugs and Medical Devices

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Acronym List

Abbreviation	Description
ANDA	Abbreviated New Drug Application
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
CMC	Chemistry, Manufacturing, and Controls
CR	Complete Response
CY	Calendar Year
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDARA	FDA Reauthorization Act of 2017
FY	Fiscal Year
IA	Import Alert
NAI	No Action Indicated
NDA	No Action Indicated
ORA	Office of Regulatory Affairs
OAI	Official Action Indicated
PAI	Pre-Approval Inspection
PMA	Pre-Market Approval
VAI	Voluntary Action Indicated
WL	Warning Letter

Introduction

A. Background

On August 18, 2017, the FDA Reauthorization Act (FDARA) (Public Law 115-52) became law. FDARA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to revise and extend the user fee programs for drugs, medical devices, and biosimilar biological products, and for other purposes.

Section 902 of FDARA requires the Food and Drug Administration (FDA) to annually publish on FDA's website information related to inspections of facilities necessary for approval of a drug or a device that were conducted during the previous fiscal year.
Section 902 of FDARA, as recently amended[1], states:

1. ANNUAL REPORT ON INSPECTIONS.

Not later than 120 days after the end of each fiscal year, the Secretary of Health and Human Services shall post on the website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or approval of a device under section 515 of such Act (21 U.S.C. 360e) that were conducted during the previous fiscal year. Such information shall include the following:

1) The median time following a request from staff of the Food and Drug Administration reviewing an application or report to the beginning of the inspection, including –

    (A) the median time for drugs described in 505(j)(11)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(11)(A)(i));

    (B) the median time for drugs for which a notification has been submitted in accordance with section 506C(a) of such Act (21 U.S.C. 356c(a)) during the previous fiscal year; and

    (C) the median time for drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C.356e) at the time of such request.

2) The median time from the issuance of a report pursuant to section 704(b) of the Federal

[1] Effective December 29, 2022, FDARA section 902 was amended by section 3617 of the Food and Drug Omnibus Reform Act of 2022 (FDORA; title III of division FF of the Consolidated Appropriations Act, 2023).

Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)) to the sending of a Warning Letter (WL), issuance of an Import Alert (IA), or holding of a Regulatory Meeting for inspections for which the Secretary concluded that regulatory or enforcement action was indicated, including the median time for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1)

3) The median time from the sending of a warning letter, issuance of an IA, or holding of a Regulatory Meeting related to conditions observed by the Secretary during an inspection, to the time at which the Secretary concludes that corrective actions to resolve such conditions have been taken.

4) The number of facilities that failed to implement adequate corrective or preventive actions following a report issued pursuant to such section 704(b), resulting in a withhold recommendation for an application under review, including the number of such facilities manufacturing each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

B. Report Elements

This report satisfies the annual reporting requirement set forth by FDARA section 902 for Fiscal Year (FY) 2023. The report contains data on inspections necessary for the approval of specified human drugs and medical devices. FDA notes the following regarding specific report elements:

- With respect to drug-related inspections, section 902 is limited by its terms to information related to inspections of facilities necessary for approval of drugs under section 505 of the FD&C Act. Biological products, including biosimilars, licensed under section 351 of the Public Health Service Act, are not included in this report.

- Section 902 is limited by its terms to information related to inspections of facilities, which we view as referring to facilities subject to inspection under section 704(a)(1) of the FD&C Act.

- Section 902 refers to information related to inspections of facilities necessary for approval of a drug. FDA views this provision as generally requiring information not only with respect to approval of original new drug applications or abbreviated new drug applications but also with respect to approval of supplements to such applications, including both prior approval supplements and changes being effected supplements.

- With respect to device-related inspections, section 902 is limited by its terms to information related to inspections of facilities necessary for approval of a device under

section 515 of the FD&C Act.[2] Because humanitarian device exemptions are granted under section 520(m), information concerning humanitarian use devices is not included in this report. FDA views section 902 as requiring information not only with respect to approval of a premarket approval application, but also with respect to approval of supplements to such applications.

- FDA views section 902(1) (A), (B), and (C) to only be relevant to drug products and not devices.

- Section 902 as amended by FDORA 3617 uses the term "report pursuant to section 704(b)." FDA interprets this phrase to refer to FDA Form 483,[3] *Inspectional Observations*, which is the list of observations made by FDA investigators during an inspection that is left with the management of the inspected facility at the conclusion of the inspection. With the exception of the data reported in Tables 1 and 6 below, inspections not resulting in issuance of an FDA Form 483 are excluded from the analysis below.

- Section 902(1) refers to requests from staff of the FDA "reviewing an application or report." FDA understands this statutory provision to refer to staff at the reviewing Center at FDA

- FDA conducts different types of inspections of facilities in which a conclusion of lack of compliance may result in delay of approval of an application. FDA conducts so-called "pre-approval inspections," but it also conducts inspections for other purposes, such as surveillance and for-cause inspections. Because a pre-approval inspection is requested by staff reviewing an application, FDA interprets section 902(1) to apply to pre-approval inspections.

- The result of a pre-approval inspection may be a decision that an application may not be approved. However, a WL, issuance of an IA, or the holding of a Regulatory Meeting would generally follow other types of inspections rather than a pre-approval inspection. For that reason, FDA understands sections 902(2) and (3) to apply to inspections other than pre-approval inspections. Further, because section 902 requires FDA to provide information related to inspections of facilities necessary for approval of a drug or for

[2] We note that the above-noted FDORA amendments removed reference to "clearance of a device under section 510(k)" from FDARA section 902. Moreover, clearance of a device under section 510(k) of the FD&C Act does not require a pre-clearance inspection and clearance is generally not withheld or delayed based on FDA Form 483 observations. Therefore, information regarding clearance of a device under section 510(k) of the Act will not be shown in the tables below.

[3] More information about FDA Form 483 can be found at: www.fda.gov/ICECI/Inspections/ucm256377.htm

approval of a device, FDA reports information under sections 902(2) and (3) concerning facilities that are referenced in a pending application. FDA understands section 902(4) to apply to both pre-approval inspections and other types of inspections.

- We note that by its terms all of section 902 is limited to information related to inspections "that were conducted during the previous fiscal year." Thus, information reported with respect to section 902(2) does not include data concerning inspections that were conducted during fiscal years prior to FY 2023 that resulted in WLs, IAs, or Regulatory Meetings during FY 2023.

- FDA understands section 902(3) to apply, consistent with its terms, to inspections resulting in a WL, issuance of an IA, or the holding of a Regulatory Meeting. We note that there are, at least theoretically, situations in which a surveillance inspection would lead directly to a more serious enforcement action, such as a seizure, injunction, or prosecution, without a WL, IA, or Regulatory Meeting. Such rare circumstances, if they exist, would not be included. We also note that conditions considered resolved during FY 2023 were typically identified during inspections conducted during prior fiscal years.

- FDA understands that section 902(4) refers to the number of facilities that had objectionable conditions observed during an FDA inspection that were conveyed to facility management through an FDA Form 483 issued at the close of the inspection but for which the facility failed to implement adequate corrective or preventive actions, resulting in a withhold recommendation for an application under review.

- FDA understands section 902(1)(A), relating to drugs described in section 505(j)(11)(A)(i) of the FD&C Act (21 U.S.C. 355(j)(11)(A)(i), to mean drugs subject to Original ANDAs—

    - for which there are not more than 3 approved drug products (including the RLD) listed in the active section of the Orange Book, and for which there are no blocking patents and/or exclusivities at the time the original ANDA was submitted by the applicant; and
    - that met the requirements for priority review under section 505(j)(11)(B).

- FDA understands section 902(1)(B), relating to drugs for which a notification was submitted in accordance with section 506C(a) of the FD&C Act (21 U.S.C. 356c(a)) during the previous fiscal year to mean drugs, as defined in section 506C(a), for which we are notified by the manufacturer of a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the supply of that drug in the United States. Data reported for

this metric pertains to those drugs where the notification was submitted before the inspection was requested by staff at the reviewing Center at FDA

- FDA understands section 902(1)(C), relating to drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C.356e), to mean drugs that are listed in the drug shortages database as current shortages on the FDA website. Data reported for this metric pertains to those drugs that were placed on the Drug Shortage list before the inspection was requested by staff at the reviewing Center at FDA.

C. Data Collection and Definitions

The FDA organizations[4] providing information for this Annual Report are:

- Center for Biologics Evaluation and Research (CBER);
- Center for Drug Evaluation and Research (CDER);
- Center for Devices and Radiological Health (CDRH); and
- Office of Regulatory Affairs (ORA).

Throughout the Coronavirus (COVID-19) pandemic, the FDA continued to conduct all inspectional and oversight work determined, on a case by-case basis, to be critical to FDA's public health mission. While some challenges have remained due to COVID-19 travel and other restrictions and impacts[5], FDA returned to a normal cadence of domestic inspections starting October 1, 2021[6]. Additionally, FDA continued to prioritize and accomplish foreign mission-critical, and compliance follow up inspections and to conduct investigations, sample collections and other unplanned work.

With respect to pre-approval facility assessments for drugs, FDA continued to use other tools and approaches where possible, including requesting existing inspection reports from other trusted foreign regulatory partners through mutual recognition and confidentiality agreements,

[4] More information on the FDA product Centers and the Office of Regulatory Affairs can be found at: www.fda.gov/aboutFDA/Centersoffices/default.htm.

[5] For example, on December 29, 2021, FDA implemented temporary changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as the agency further adapted to the evolving COVID-19 pandemic and the spread of the omicron variant (See https://www.fda.gov/news-events/press-announcements/fda-roundup-january-4-2022). Also, FDA inspections in China have been seriously curtailed by travel restrictions in that country. See https://travel.state.gov/content/travel/en/traveladvisories/traveladvisories/china-travel-advisory.html

[6] The COVID-19 public health emergency (PHE) declared by the Department of Health and Human Services under the Public Health Service Act expired on May 11, 2023.

requesting information from applicants, and requesting records and other information directly from facilities and other inspected entities.

1. Human Drugs Data

The data mandated under FDARA section 902 are summarized in four tables in the Human Drugs section.

Table 1 responds to section 902(1) and reports the median time following an Inspection Request from FDA Staff Reviewing an Application or Report to the Beginning of the Inspection in FY 2023.

Table 2 corresponds to section 902(2). The table reports the median time between the issuance of FDA Form 483 and regulatory or enforcement action (i.e., WL, IA, or Regulatory Meeting) during FY 2023. The data include Current Good Manufacturing Practice (CGMP) or "surveillance" inspections of facilities that are referenced in a pending application. That is, CGMP/surveillance inspections "necessary" for approval of a drug or device, and that might result in a withhold recommendation as described in section 902(4) if objectionable conditions are identified during the inspection.

Table 3 corresponds to section 902(3) and reports the median time between the initiation of a Warning Letter, issuance of an Import Alert (IA), or holding of a Regulatory Meeting, and the resolution of the regulatory or enforcement action. This table includes all WL, IA, and Regulatory Meetings resolved in FY 2023, even if the WL, IA, or Regulatory Meeting was initiated prior to FY 2023.

Table 4 corresponds to section 902(4). It reports on the number of facilities with objectionable conditions observed during an FDA inspection that were conveyed to facility management on an FDA Form 483 issued at the close of the inspection but for which the facility failed to implement adequate corrective or preventive actions, resulting in a withhold recommendation for an application under review.

2. Medical Devices Data

The data mandated under FDARA section 902 are summarized in four tables in the Medical Devices section.[7]

Table 6 responds to section 902(1). Table 6 reports the median time between the request of staff reviewing an application or report and the beginning of an inspection in FY 2023.

[7] Data include PMA-approved medical devices involved in the manufacture of blood and human cell-based products.

Table 8 corresponds to section 902(2). The table reports the median time between the FDA Form 483 issuance to the regulatory or enforcement action (i.e., WL, IA, or Regulatory Meeting). The data include all inspections conducted in FY 2023 that concluded with an FDA Form 483 at an establishment associated with a Pre-Market Approval (PMA) and resulted in a WL, IA, or Regulatory Meeting in FY 2023.

Table 9 corresponds to section 902(3) and reports the median time between the initiation of a WL, IA, or Regulatory Meeting and the resolution of the regulatory or enforcement action. This table includes all WL, IA, and Regulatory Meetings resolved in FY 2023, even if the WL, IA, or Regulatory Meeting was initiated prior to FY 2023.

Table 10 corresponds to section 902(4). It reports on the number of device facilities with objectionable conditions observed during an inspection that were conveyed to facility management on an FDA Form 483 issued at the close of the inspection but for which the facility failed to implement adequate corrective or preventive actions, resulting in a withhold recommendation for a pending PMA application.

II. Human Drugs

Median Time between Inspection Request and Beginning of Inspection

In FY 2023, the median time between an inspection request from FDA staff reviewing an application or report to the beginning of an inspection was 108.5 days (Table 1).

Table 1: Median Time Following Inspection Request from FDA Staff Reviewing an Application or Report to the Beginning of the Inspection

Submission Type	FY 2023 Median Time (Calendar Days)	Number of inspections included in analysis
NDA	93.5	49
ANDA	117	139
NDA & ANDA	105	5
All	108.5	193

Category	FY 2023 Median Time (Calendar Days)
Drugs described in section 505(j)(11)(A)(i)	78.5
Drugs for which a notification has been submitted in accordance with section 506C(a) of such Act (21 U.S.C. 356c(a))	--
Drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C.356e)	56

Table 1 reports the median time in calendar days between a Center staff request for a pre-approval inspection (PAI) and the beginning of the inspection by ORA. The data reported in Table 1 includes all requests by reviewing staff where an inspection was initiated, even if no FDA Form 483 was issued at the conclusion of the inspection.

Median Time between Issuance of FDA Form 483 to Regulatory or Enforcement Action

Data in this section are only reported for Surveillance CGMP inspections because PAIs do not result in any of the above-mentioned regulatory actions.

In FY 2023, the median time between issuance of an FDA Form 483 and regulatory or enforcement action was 181 days for WLs, 156 days for Import Alerts, and 178 days for Regulatory Meetings.

Table 2: Median Time between Issuance of FDA Form 483 and Regulatory or Enforcement Action

Submission Type	Median Time FDA 483 to WL (Calendar Days)	Median Time FDA 483 to IA (Calendar Days)	Median Time FDA 483 to Regulatory Meeting (Calendar Days)	Number of actions included in analysis
NDA & ANDA	181	156	178	29

Category	FY 2023 Median Time		
	FDA 483 to WL (Calendar Days)	FDA 483 to IA (Calendar Days)	FDA 483 to Regulatory Meeting (Calendar Days)
Drugs described in section 505(j)(11)(A)(i)	167	--	177.5
Drugs for which a notification has been submitted in accordance with section 506C(a) of such Act (21 U.S.C. 356c(a))	--	--	--
Drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C.356e)	209	--	176

Table 2 reports the median time in calendar days from the close of an inspection that resulted in the issuance of an FDA Form 483 to the initial enforcement action date, for each type of enforcement action specified in section 902 (i.e., WL, IA, and Regulatory Meeting). This statistic is limited to inspections that were issued an FDA Form 483, classified as OAI, and that resulted in a WL, IA, or Regulatory Meeting. There were 2 facilities added to an IA in FY 2023 that were issued an FDA Form 483 for inspections occurring between CY 2017 - 2022 and FY 2023 which were classified final OAI and were named in pending applications (Table 2).

Median Time between Regulatory or Enforcement Action to Resolution of Regulatory or Enforcement Action

In FY 2023, there were 36 resolutions of regulatory or enforcement actions for facilities that were issued an FDA Form 483 that resulted in a WL, IA, or Regulatory Meeting, and were named in a pending application (Table 3).

Table 3: Median Time between Regulatory or Enforcement Action and Resolution

Submission Type	Median Time WL to WL Close Out (Calendar Days)	Median Time IA to IA Lift (Calendar Days)	Median Time Regulatory Meeting to OAI Downgrade (Calendar Days)	Number of actions included in analysis
NDA & ANDA	1349	1471	1166	36

Table 3 reports the median time in calendar days for firms cited in compliance actions enumerated in section 902 (i.e., WL, IA, and Regulatory Meeting) to remediate CGMP issues at a site classified as OAI, including the time for FDA to re-inspect the facility to confirm whether adequate remediation has, indeed, taken place. The compliance action is considered "initiated" the day the WL or IA is issued or the day the Regulatory Meeting takes place. The compliance action is considered "resolved" when the firm has addressed the violations or deviations sufficiently to allow FDA to consider the site compliant, and, in the case of an IA or a WL, the Agency has also removed the facility from the IA and closed the WL.

Significant remediation efforts by the firm to resolve the CGMP issues from an inspection classified as OAI and subsequent re-inspection by the FDA to determine if the CGMP issues have been resolved are usually required before reclassification. It is unlikely that a site will be inspected, a regulatory action (i.e., WL, IA, or Regulatory Meeting) taken, and resolution completed within a single calendar year, which is why information on resolutions occurring in FY 2023 from regulatory actions taken in prior calendar years are being provided with the FY 2023 information. In some instances, firms either chose to not remediate, or never adequately remediate. As a result, CGMP issues observed at their facilities and compliance actions can remain ongoing. Further, only inspections with a CGMP surveillance component and associated with facilities that have been named in a pending NDA or ANDA are reported here, as pre-approval inspections do not typically result in any of the applicable regulatory actions. Finally, only CGMP inspections (other than pre-approval inspections) associated with facilities that have been named in a pending NDA or ANDA are reported here.

Number of Facilities Issued an FDA Form 483 that Failed to Address Identified Objectionable Conditions Resulting in a Withhold Recommendation For an Application Under Review

In FY 2023, 95 facilities had objectionable conditions observed during an FDA inspection that were conveyed to facility management through an FDA Form 483 issued at the close of the inspection for which the facility subsequently failed to implement adequate corrective or preventive actions, resulting in a withhold recommendation for an application under review (Table 4).[8]

[8] 310 applications were subject to a withhold recommendation solely due to a facility-related deficiency following an inspection that occurred between CY 2017 - CY 2022 and FY 2023.

Table 4: Number of Facilities Issued an FDA Form 483 that Failed to Address Identified Objectionable Conditions Resulting in a Withhold Recommendation for an Application Under Review

FY 2023 Count of Facilities
95

Category	FY 2023 Count
Drugs described in section 505(j)(11)(A)(i)	4
Drugs for which a notification has been submitted in accordance with section 506C(a) of such Act (21 U.S.C. 356c(a))	--
Drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C.356e)	4

Table 4 reports on the number of facilities with objectionable conditions observed during an FDA inspection that were conveyed to facility management through an FDA Form 483 issued at the close of the inspection for which the facility subsequently failed to implement adequate corrective or preventive actions, resulting in a withhold recommendation for an application under review.

Withhold recommendations are made through the issuance of a CR letter. CR letters identify all outstanding deficiencies that remain after a substantive review of the application and the application will not be approved until corrections as indicated are made.

Facilities with issues that are not found during an inspection by FDA (i.e., those found during the assessment of the application and addressed by the application review process only, issues found during inspections by partnering regulatory authorities, issues found following a remote evaluation or records request, and facility issues that are found during an inspection but not included in an FDA Form 483) are not included in this count.

III. Medical Devices

Median Time between Inspection Request and Beginning of Inspection

In FY 2023, the median time between an inspection request from FDA staff to the beginning of an inspection was 75 days (Table 6).

Table 6: Median Time Following Inspection Request from FDA Staff Reviewing an Application or Report to the Beginning of the Inspection

Submission Type	FY 2023 Median Time (Calendar Days)	Number of inspections included in analysis
PMA	75	85

Table 6 reports the median time in calendar days between a Center review staff request for a PMA inspection and the beginning of the inspection by ORA. The data reported in Table 6 includes all requests by reviewing staff where an inspection was initiated, even if no FDA Form 483 was issued at the conclusion of the inspection.

Median Time between Issuance of FDA Form 483 to Regulatory or Enforcement Action

In FY 2023, the median time between the issuance of FDA Form 483 and regulatory or enforcement action was 173.5 days (Table 7).

Table 7: Median Time between Issuance of FDA Form 483 and Regulatory or Enforcement Action

Submission Type	Median Time (Calendar Days)	Number of actions included in analysis
PMA	173.5	2

Table 7 reports the median time in calendar days from the close of an inspection associated with a PMA submission that resulted in the issuance of an FDA Form 483 to the initial enforcement action date, for each type of enforcement action specified in section 902 (i.e., WL, IA, and Regulatory Meeting). This statistic is limited to inspections that were issued an FDA Form 483, classified as OAI, and that resulted in a WL, IA, or Regulatory Meeting.

Median Time between Regulatory or Enforcement Action to Resolution of Regulatory or Enforcement Action

In FY 2023, there was no resolution for regulatory or enforcement actions for facilities that were issued an FDA Form 483 that resulted in a WL, IA, or Regulatory Meeting, and were named in a pending PMA application (Table 8).

Table 8: Median Time between Regulatory or Enforcement Action and Resolution

Submission Type	Median Time (Calendar Days)	Number of actions included in analysis
PMA	0	2

Table 8 reports the median time in calendar days from initiation to resolution in FY 2023 for each compliance action (i.e., WL, IA, and Regulatory Meeting) enumerated in section 902. Resolution includes the firm addressing the OAI outcome, and re-inspection and classification of the site as VAI or No Action Indicated (NAI), if appropriate. This includes the median time in calendar days from initiation of a WL to close out of the WL; the median time from adding a facility to an IA to the removal of that facility from the IA; and the median time from the date of a Regulatory Meeting to the reclassification of the site from OAI to VAI or NAI.

Significant remediation efforts by the firm and subsequent re-inspection by the FDA are usually required to determine if the CGMP issues have been resolved at a site classified as OAI; therefore, it is unlikely that a site will be inspected and a regulatory action (i.e., WL, IA, or Regulatory Meeting) taken, and resolution completed within a single calendar year, which is why information on resolutions occurring in FY 2023 from regulatory actions taken in prior calendar years are being provided with the FY 2023 information. Any WL, IA, or Regulatory Meeting resolutions that occurred in FY 2023 are reported in this table.

Table 9: Number of device facilities issued an FDA Form 483 during a PMA inspection that failed to address identified objectionable conditions resulting in a PMA withhold recommendation

Submission Type	FY 2023 Count	Number of application delay actions included in analysis
PMA	0	0

Table 9 reports on the number of device facilities issued an FDA Form 483 during a PMA inspection that identified objectionable conditions which the facility failed to address, resulting in a withhold recommendation for a pending PMA application. Table 9 specifically reports withholds for firms that failed to adequately address any objectionable conditions previously identified in an FDA From 483 prior to the FY23 PMA inspection.

This report was prepared by FDA's Office of Planning, Evaluation, and Risk Management in collaboration with FDA's Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health and Office of Regulatory Affairs. For information on obtaining additional copies, please contact:

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