



# CY 2021

## ***FDARA Section 902 Annual Report on Inspections***

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



## ***Acronyms***

**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  
**IA** – Import Alert  
**NAI** – No Action Indicated  
**NDA** – New Drug Application  
**ORA** – Office of Regulatory Affairs  
**OAI** – Official Action Indicated  
**PAI** – Pre-Approval Inspection  
**PMA** – Pre-Market Approval  
**TPLC** – Total Product Life Cycle  
**VAI** – Voluntary Action Indicated  
**WL** – Warning Letter

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## ***Introduction***

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### **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 publicly report information related to inspections of facilities necessary for approval of a drug or a device. FDARA section 902 requires that the FDA make a report regarding facility inspections related to drug and device approvals available on an annual basis through the Agency's website. Section 902 of FDARA states:

#### **ANNUAL REPORT ON INSPECTIONS.**

Not later than March 1 of each year, the Secretary of Health and Human Services shall post on the internet website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), approval of a device under section 515 of such Act (21 U.S.C. 360e), or clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)) that were conducted during the previous calendar 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, and the median time from the beginning of an inspection to the issuance of a report pursuant to section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)).
- (2) The median time from the issuance of a report pursuant to such section 704(b) to the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting for inspections for which the Secretary concluded that regulatory or enforcement action was indicated.
- (3) The median time from the sending of a warning letter, issuance of an import alert [IA], or holding of a regulatory meeting to resolution of the regulatory or enforcement action indicated for inspections for which the Secretary concluded that such action was indicated.
- (4) The number of times that a facility was issued a report pursuant to such section 704(b) and approval of an application was delayed due to the issuance of a withhold recommendation.

## Report Elements

This report satisfies the annual reporting requirement set forth by FDARA section 902 for Calendar Year (CY) 2021. 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, approved 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. Thus, data regarding inspections of separate sites at which bioavailability tests are performed or data from such tests are analyzed are not included in this report.
- Section 902 refers to information related to inspections of facilities necessary for approval of a drug. The FDA views this provision as requiring information not only with respect to approval of original new drug applications (NDA) or abbreviated new drug applications (ANDA) 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 or clearance of a device under section 510(k) of the FD&C Act.<sup>1</sup> Because humanitarian device exemptions are granted under section 520(m), information concerning humanitarian use devices is not included in this report. The 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.
- Section 902 uses the term “report pursuant to section 704(b).” The FDA interprets this phrase to refer to Form FDA 483<sup>2</sup>, Inspectional Observations, which is the list of observations made by FDA investigators during inspections that is provided to 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 a Form FDA 483 are excluded from the analysis below.
- Section 902(1) refers to requests from staff of the FDA “reviewing an application.” The FDA understands this statutory provision to refer to staff at the reviewing Center at FDA.
- The 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, if approvable. The 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 reviewing staff, the FDA interprets section 902(1) to apply to pre-approval inspections. The result of a pre-approval inspection may be a decision that

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<sup>1</sup> However, clearance of a device under section 510(k) of the FD&C Act does not require a pre-clearance inspection and clearance is not withheld or delayed based on Form FDA 483 observations. Therefore, information regarding clearance of a device under section 510(k) of the Act will not be shown in the tables below.

<sup>2</sup> More information about Form FDA 483 can be found at: [www.fda.gov/ICECI/Inspections/ucm256377.htm](http://www.fda.gov/ICECI/Inspections/ucm256377.htm)

an application is not approved; however, a warning letter (WL), issuance of an import alert (IA), or the holding of a Regulatory Meeting would generally follow other types of inspections rather than a pre-approval inspection. For that reason, the FDA views sections 902(2) and (3) as applying to inspections other than pre-approval inspections. Because section 902 requires the FDA to provide information related to inspections of facilities necessary for approval of a drug or for approval or clearance of a device, the FDA reports, under sections 902(2) and (3), information concerning facilities that are referenced in a pending application. The FDA understands section 902(4) to apply to both pre-approval inspections and other types of inspections.

- By its terms section 902 is limited to information related to inspections “that were conducted during the previous calendar year.” However, actions reported with respect to sections 902(2) and (3) can take more than one year to occur, so the data concerning WLs, IAs, or Regulatory Meetings during CY 2021 or resolutions of previous actions during CY 2020 are included in this report even though in some cases they reflect actions related to inspections conducted prior to CY 2021.
- Section 902(2) refers to Regulatory Meetings “for inspections for which the Secretary concluded that regulatory or enforcement action was indicated.” The FDA understands this phrase to limit the reporting request to Regulatory Meetings based on inspections that FDA has classified as Official Action Indicated (OAI). The FDA sometimes holds Regulatory Meetings with respect to facilities that it classifies as Voluntary Action Indicated (VAI) to discuss the proposed voluntary action, but such meetings are not included in the results reported here. In this report, accordingly, the term “Regulatory Meeting” refers to a meeting with respect to a facility that the FDA has classified as OAI.
- The 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. There are 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 will not be included.
- Section 902(4) refers to situations in which approval of an application was delayed due to the issuance of a withhold recommendation. The FDA views this provision as applying to those situations in which the “withhold recommendation” was because of the lack of compliance at the facility determined by a site inspection that resulted in a Form FDA 483 issuance at the close of the inspection. Thus, the FDA reports those situations in which the inspection of the facility is specifically used or cited as the only reason for delaying or denying approval. The FDA is not including in the report situations in which approval is denied or delayed for other reasons not related to inspections so that approval could not occur even if there were no inspection assessment findings.
- The FDA has excluded from the data presented in the tables below any inspection associated with certain drug-device combination products where the device constituent part of a combination product was inspected under a CDRH program and that could impact the assessment of an application under review by CDER.

## Data Collection and Definitions

The FDA organizations<sup>3</sup> 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).

FDA continued throughout the Coronavirus (COVID-19) pandemic to conduct all inspectional and oversight work determined on a case by-case to be critical to FDA's public health mission. With respect to pre-approval inspections 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, requesting information from applicants, and requesting records and other information directly from facilities and other inspected entities. 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. As of July 2021, FDA began a gradual transition to standard operations.

Due to the ongoing pandemic our CY 2021 median time to inspection increased significantly because FDA's pause on non-mission-critical inspections resulted in delays in NAI and VAI inspections that were in progress.

### Human Drugs Data

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

Tables 1 and 2 respond to paragraph 1 of the statute. Table 1 reports the median time between the request of staff reviewing an application and the beginning of an inspection in CY 2021. Table 2 reports the median time between the beginning of the inspections and the issuance of a Form FDA 483 for inspections completed in CY 2021.

Table 3 corresponds to paragraph 2 of the statute. The table reports the median time between the Form FDA 483 issuance and the regulatory or enforcement action (i.e., WL, IA, or Regulatory Meeting). The data include all Current Good Manufacturing Practice (CGMP) inspections conducted in CY 2017, 2018, 2019, 2020 or 2021 that concluded with a Form FDA 483 and resulted in a WL, IA, or Regulatory Meeting in 2021.

Table 4 corresponds to paragraph 3 of the statute and reports the median time between the initiation of a WL, IA, or Regulatory Meeting, and the resolution of the regulatory or enforcement

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<sup>3</sup> More information on the FDA product Centers and the Office of Regulatory Affairs can be found at: [www.fda.gov/aboutFDA/Centersoffices/default.htm](http://www.fda.gov/aboutFDA/Centersoffices/default.htm).

action. This table includes all WL, IA, and Regulatory Meetings resolved in CY 2021, even if the WL, IA, or Regulatory Meeting was initiated prior to CY 2021.

Table 5 corresponds to paragraph 4 of the statute. It reports on the number of applications that received a Complete Response (CR) letter in CY 2021 delaying approval due to a facility withhold recommendation resulting from an inspection that ended between CY 2017 and CY 2021 with the issuance of a Form FDA 483 where the inspection findings deficiency was the only deficiency cited in the CR letter and resulted in the delay of approval.

## **Medical Devices Data**

The data mandated under FDARA section 902 are summarized in five tables in the Medical Devices section.<sup>4</sup>

Tables 6 and 7 respond to paragraph 1 of the statute. Table 6 reports the median time between the request of staff reviewing an application and the beginning of an inspection in CY 2021. Table 7 reports the median time between the beginning of the inspection and the issuance of a Form FDA 483 for inspections completed in CY 2021.

Table 8 corresponds to paragraph 2 of the statute. The table reports the median time between the Form FDA 483 issuance to the regulatory or enforcement action (i.e., WL, IA, or Regulatory Meeting). The data include all inspections conducted in CY 2020 or 2021 that concluded with a Form FDA 483 at an establishment associated with a Pre-Market Approval (PMA) and resulted in a WL, IA, or Regulatory Meeting in CY 2021.

Table 9 corresponds to paragraph 3 of the statute 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 CY 2021, even if the WL, IA, or Regulatory Meeting was initiated prior to CY 2021.

Table 10 corresponds to paragraph 4 of the statute. It reports on the number of PMA reviews that were stopped in CY 2021 due to deficiencies found during CGMP compliance review documented on a Form FDA 483 from an inspection that ended in CY 2020 or CY 2021 with the issuance of a Form FDA 483 and resulted in a delay of the PMA.

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<sup>4</sup> Data include PMA approved medical devices involved in the manufacture of blood and human cell-based products.

## ***Human Drugs***

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### **Median Time between Inspection Request and Beginning of Inspection**

In CY 2021, the median time between an inspection request from FDA staff to the beginning of an inspection was 145 days (Table 1).

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

Submission Type	CY 2021 Median Time (Calendar Days)	Number of inspections included in analysis
NDA	130	26
ANDA	158	24
NDA & ANDA	43	1
All	145	51

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 Form FDA 483 was issued at the conclusion of the inspection.

### **Median Time between Beginning of Inspection and Issuance of Form FDA 483**

In CY 2021, the median time between the beginning of a PAI and the issuance of a Form FDA 483 was 9 days (Table 2).

**Table 2: Median Time between Beginning of Inspection and Issuance of Form FDA 483**

Submission Type	CY 2021 Median Time (Calendar Days)	Number of inspections included in analysis
NDA	9	18
ANDA	9	18
NDA & ANDA	9	1
All	9	37

Table 2 reports the median time in calendar days from the start of a PAI to the issuance of a Form FDA 483. Form FDA 483 is issued at the close of an inspection only when the investigator(s) observed conditions that may constitute violations of the FD&C Act. Inspections that have not resulted in a Form FDA 483 being issued are not included in this statistic.

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

In CY 2021, the median time between issuance of a Form FDA 483 (which may have been the result of an inspection going back to the beginning of FDARA 902 in CY 2017) and enforcement action was 162.5 days for WLs, 125 days for Import Alerts, and 234 days for Regulatory Meetings. There was 1 facility added to an IA in CY 2021 that was issued a Form FDA 483 for inspections occurring between CY 2017 or 2021 which was classified final OAI and were named in a pending application (Table 3).

**Table 3: Median Time between Issuance of Form FDA 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	162.5	125	234 <sup>5</sup>	10

Table 3 reports the median time in calendar days from the close of an inspection that resulted in the issuance of a Form FDA 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 a Form FDA 483 and that resulted in a WL, IA, or Regulatory Meeting. Data in this section are only reported for CGMP inspections because PAIs do not result in any of the above-mentioned regulatory actions. The only CGMP inspections considered for this report are those associated with facilities that are referenced in a pending NDA or ANDA application with the FDA.

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

In CY 2021, there were 13 resolutions for regulatory or enforcement actions for facilities that were issued a Form FDA 483 that resulted in a WL, IA, or Regulatory Meeting, and were named in a pending application (Table 4).

**Table 4: 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	950	--	604	13

Table 4 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

<sup>5</sup> Note, this excludes Regulatory Meetings held after a Warning Letter or similar compliance action has occurred, where the purpose of the regulatory meeting typically is to discuss the adequacy of the firm's response to the compliance action.

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 the site to be reclassified by FDA as VAI or No Action Indicated (NAI), and, in the case of an IA or a WL, the Agency has also removed the facility from the IA or closed the WL.

Significant remediation efforts by the firm to resolve the CGMP issues at a site 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 CY 2021 from regulatory actions taken in prior calendar years are being provided with the CY 2021 information. In some instances, firms either chose to not remediate, or never adequately remediate, CGMP issues observed at their facilities and compliance actions remain open indefinitely. Further, only inspections with a CGMP surveillance component are reported here, as pre-approval inspections do not result in any of the applicable regulatory actions. Finally, only CGMP inspections associated with facilities that have been named in a pending NDA or ANDA are reported here.

### **Application Delay due to Issuance of Withhold Recommendation**

In CY 2021, 201 applications were delayed solely due to a facility-related withhold recommendation (Table 5).

**Table 5: Number of Times Application Approval was Delayed due to Withhold Recommendation**

Submission Type	CY 2021 Count	Number of CR actions included in analysis
NDA	18	19
ANDA	183	185
All	201 <sup>6</sup>	204

Table 5 reports on the number of applications that were “delayed” through the issuance of a CR letter in CY 2021 due to a withhold recommendation because of the lack of compliance at a facility found during an inspection completed between CY 2017 and CY 2021. 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. This report includes applications that received a CR letter only because a facility named in the application was determined not to be in compliance as a result of an FDA inspection.

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<sup>6</sup> A total of 2612 CRs were issued in CY 2021 for Original Applications and CMC supplements. Of these 2612 CRs, 204 CR actions were issued only due to a facility deficiency. Of the 204 CR actions that were issued only due to a facility deficiency, 201 CR actions were issued due to an inspection that occurred between CY 2017 and CY 2021.

Facility 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 a Form FDA 483) are not included in this count. Additionally, only Chemistry, Manufacturing, and Controls (CMC) supplements are included in this data. Other supplement types were excluded because they do not routinely involve the assessment of facilities in determining approvability of the submission.

## Medical Devices

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### Median Time between Inspection Request and Beginning of Inspection

In CY 2021, the median time between an inspection request from FDA staff to the beginning of an inspection was 173 days (Table 6).

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

Submission Type	CY 2021 Median Time (Calendar Days)	Number of inspections included in analysis
PMA	173	31

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 Form FDA 483 was issued at the conclusion of the inspection. Due to the ongoing pandemic, our CY 2021 median time to inspection significantly increased due to the evaluation of each PMA and the determination that many were not critical to public health.

### Median Time between Beginning of Inspection and Issuance of Form FDA 483

In CY 2021, the median time between the beginning of a PMA inspection and the issuance of a Form FDA 483 was 3.5 days (Table 7).

**Table 7: Median Time between Beginning of Inspection and Issuance of Form FDA 483**

Submission Type	CY 2021 Median Time (Calendar Days)	Number of inspections included in analysis
PMA	3.5	14

Table 7 reports the median time in calendar days from the start of the PMA inspection to the issuance of a Form FDA 483. Form FDA 483 is issued at the close of an inspection only when the investigator(s) observed conditions that may constitute violations of the FD&C Act.

Inspections that have not resulted in a Form FDA 483 being issued are not included in this statistic.

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

In CY 2021, there was 1 instance of an WL, IA, or Regulatory Meeting resulting from a Form FDA 483 issued at establishments associated with a PMA submission. Therefore, a median time is not applicable (Table 8).

**Table 8: Median Time between Issuance of Form FDA 483 and Regulatory or Enforcement Action**

Submission Type	Median Time (Calendar Days)	Number of actions included in analysis
PMA	85	1

Table 8 reports the median time in calendar days from the close of an inspection that resulted in the issuance of a Form FDA 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 a Form FDA 483 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 CY 2021, there was one resolution for regulatory or enforcement actions for facilities that were issued a Form FDA 483 that resulted in a WL, IA, or Regulatory Meeting, and were named in a pending PMA application (Table 9).

**Table 9: Median Time between Regulatory or Enforcement Action and Resolution**

Submission Type	Median Time (Calendar Days)	Number of actions included in analysis
PMA	0	1

Table 9 reports the median time in calendar days from initiation to resolution in CY 2021 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 CY 2021 from regulatory actions taken in prior calendar years are being provided with the CY 2021 information. Any WL, IA, or Regulatory Meeting resolutions that occurred in CY 2021 are reported in this table.

#### **Application Delay due to Issuance of Withhold Recommendation**

In CY 2021, there were 3 PMA approvals delayed due to the issuance of a Form FDA 483 at the close of an inspection (Table 10).

**Table 10: Number of Times a Facility was Issued a Form FDA 483 and Application Approval was Delayed**

Submission Type	CY 2021 Count	Number of application delay actions included in analysis
PMA	3	8

Table 10 reports on the number of applications that were delayed in CY 2021 due to the issuance of a Form FDA 483 at the close of inspections completed between CY 2020 and CY 2021. PMA approvals can be withheld in instances when ORA performed a PMA, PAI, and a Form FDA 483 was issued and resulted in a decision by the Center to withhold approval until the issues are resolved. Further, PMA approvals can be withheld in instances when ORA performed a non-PMA inspection, and a Form FDA 483 was issued and resulted in a decision by the Center to withhold approval until the issues are resolved.

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**Department of Health and Human Services  
Food and Drug Administration**

This report was prepared by FDA's Office of Planning with the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and the Office of Regulatory Affairs (ORA). For information on obtaining additional copies contact:

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