

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE FOOD AND DRUG
ADMINISTRATION DID NOT SUBMIT
CLEARANCE DOCUMENTS FOR ANY
AUDIT RECOMMENDATIONS DURING
FISCAL YEARS 2015 AND 2016
BUT HAS SINCE MADE
SIGNIFICANT PROGRESS**

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August 2019
A-07-18-03231

Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: August 2019

Report No. A-07-18-03231

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

HHS, Food and Drug Administration (FDA), is subject to Federal audits of its internal activities as well as Federal and non-Federal audits of activities performed by its grantees and contractors. As a followup to these audits, FDA is responsible for resolving Federal and non-Federal audit report recommendations related to its activities, grantees, and contractors within 6 months after formal receipt of the audit reports. HHS, OIG, prepares and forwards to FDA monthly stewardship reports that show the status of these reported audit recommendations.

Our objectives were to determine whether FDA resolved audit recommendations in a timely manner during Federal fiscal years (FYs) 2015 and 2016 and to identify all unresolved audit recommendations that were due for resolution as of September 30, 2016.

How OIG Did This Review

We reviewed the “Outstanding Audits and Actions Taken by Cognizance” stewardship reports to identify all outstanding audit recommendations that FDA resolved during FYs 2015 and 2016, as well as all outstanding recommendations that remained unresolved and were due for resolution as of September 30, 2016. These stewardship reports identified 17 audit reports and 166 corresponding recommendations.

The Food and Drug Administration Did Not Submit Clearance Documents for Any Audit Recommendations During Fiscal Years 2015 and 2016 but Has Since Made Significant Progress

What OIG Found

FDA did not submit an OIG clearance document for any of the 166 audit recommendations during FYs 2015 and 2016, and as a result, all of them were outstanding, and listed on the stewardship report as past due for resolution, as of September 30, 2016. However, for 134 of the 166 recommendations (from 7 information technology audit reports), FDA did address the audit recommendations in detail, to include statements of corrective actions, in its comments on those reports. These 166 past-due recommendations were procedural in nature; none of them involved dollar amounts such as recommended disallowances.

FDA had some audit resolution guidelines in place during our audit period; however, they did not address the submission of clearance documents to OIG. As a result, FDA did not submit any clearance documents within the required 6-month resolution period. Also, FDA did not perform periodic, formal reconciliations between OIG’s stewardship reports and its own audit resolution records. FDA officials attributed audit resolution issues to reassignment of audit resolution responsibilities within FDA before our audit period. Since our audit period, though, FDA has made significant progress in resolving audit recommendations. As of May 1, 2019, FDA had submitted clearance documents for 134 of the 166 recommendations (over 80 percent of the audit recommendations) that were past due as of September 30, 2016.

What OIG Recommends

We recommend that FDA finalize and implement formal policies and procedures for the resolution of audit recommendations, promptly resolve the 32 remaining recommendations that were past due as of September 30, 2016, and reconcile each month OIG’s audit resolution information with FDA’s audit resolution records and follow up on any differences noted.

FDA concurred with all of our recommendations and described corrective actions that it had taken or planned to take. FDA stated that it was updating its procedures to ensure that FDA submits clearance documents along with its corrective action plans to OIG. In addition, FDA stated that it was actively working to submit clearance documents and corrective action plans for all outstanding recommendations. Finally, FDA stated that it was reconciling the OIG stewardship report with FDA’s audit resolution records.

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INTRODUCTION

WHY WE DID THIS REVIEW

The U.S. Department of Health and Human Services (HHS), Food and Drug Administration (FDA), is subject to Federal audits of its internal activities as well as Federal and non-Federal audits of activities performed by its grantees and contractors. These audits ensure that recipients of Federal awards have complied with applicable Federal requirements related to management and use of funds. As a followup to these audits, FDA is responsible for resolving Federal and non-Federal audit report recommendations related to its activities, grantees, and contractors within 6 months after formal receipt of the audit reports. The HHS Office of Inspector General (OIG) prepares and forwards to FDA monthly stewardship reports that show the status of these reported audit recommendations.

In keeping with our mission of helping to safeguard HHS funds, we focused in this review on the timeliness of FDA's audit resolution process. This process includes, in response to each Federal and non-Federal audit report on FDA's internal activities or on activities performed by FDA's grantees and contractors, the issuance of a management decision and the submission of an OIG clearance document (OCD) to OIG within the required 6-month period.¹ We are not reviewing the actual corrective actions taken by FDA.

In a previous OIG audit report (A-07-06-03083, Feb. 15, 2007; Appendix B), we found that FDA did not always resolve audit recommendations in accordance with Federal requirements during calendar years (CYs) 2003 through 2005. We included the results of our previous review in this audit report to compare them with the current-period results.

OBJECTIVES

Our objectives were to determine whether FDA resolved audit recommendations in a timely manner during Federal fiscal years (FYs) 2015 and 2016 and to identify all unresolved audit recommendations that were due for resolution as of September 30, 2016.

BACKGROUND

FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our Nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA works to advance the

¹ In this context, the term "management decision" refers to the evaluation by the cognizant HHS operating division's (OpDiv) management of the audit findings and corrective action plan and the issuance of a written decision as to what corrective action is necessary. The OpDiv's management uses an OCD to report to OIG the management decision and actions taken on recommendations; OIG then uses the OCD as the source document to clear recommendations from the stewardship report.

public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping members of the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. FDA also plays a significant role in the Nation's counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

Federal Audits

Section 4(a) of the Inspector General Act of 1978 (5 U.S.C. App.), as amended, directs OIG to conduct audits of agency programs and activities. Under this authority, OIG conducts audits of internal FDA activities, as well as activities performed by FDA grantees and contractors. These audits are intended to provide independent assessments of FDA programs and operations and to help promote economy and efficiency. OIG uses its own resources to conduct audits in accordance with generally accepted government auditing standards (GAGAS) and oversees audit work conducted by independent auditors.

Non-Federal Single Audits

Office of Management and Budget (OMB) Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations*,² requires that non-Federal entities (such as FDA grantees) that expend \$500,000³ or more in Federal awards in a year⁴ have a Single Audit or program-specific audit (also referred to as an "A-133 audit"), pursuant to the provisions of OMB Circular A-133, Subpart B, __.200.⁵ These A-133 audits, conducted by independent auditors, are conducted in accordance with GAGAS and OMB Circular A-133. These audits include an examination of the entity's financial records and financial statements, testing of the entity's internal controls, and a review of the entity's compliance with requirements related to expenditures of selected Federal awards. The final audit report contains comments from the entity, including corrective actions planned or taken to address the findings.

² This circular was made applicable by HHS regulations at 45 CFR § 74.26(a). The circular was relocated to 2 CFR part 230. (HHS has promulgated new grant regulations and cost principles at 45 CFR part 75 that apply to awards made on or after December 26, 2014.) None of the audits in our review were subject to the new rule, as they were of awards made prior to that date.

³ The expenditure level for Federal awards was raised to \$750,000 for FYs beginning on or after December 26, 2014 (45 CFR § 75.501(a)).

⁴ Some State and local governments that are required by constitution or statute that was in effect January 1, 1987, to be audited less frequently than annually are permitted to undergo audits biennially. Nonprofit organizations are also allowed to have biennial audits under certain conditions (OMB Circular A-133, § _____.220).

⁵ Commercial entities that met the \$500,000 threshold during the audit period could elect to conduct either an A-133 audit or a financial-related audit (45 CFR § 74.26(d)(i)).

Audited entities transmit their final A-133 audit reports to the Federal Audit Clearinghouse (FAC).⁶ In turn, OIG, National External Audit Review Center (NEAR), receives A-133 audit reports from the FAC. NEAR performs a desk review of each A-133 audit report that contains findings related to direct HHS funding to determine whether there are any issues with the report and whether the report meets GAGAS and OMB Circular A-133 requirements.⁷ NEAR prepares a transmittal letter and attachment that summarize the audit findings and recommendations and that identify the Federal agency responsible for resolution (cognizant Federal agency). NEAR then distributes the transmittal letter and attachment to the grantee and the cognizant Federal agency.

Federal Requirements Regarding Timeliness of Audit Resolution

In resolving Federal audit recommendations, FDA must comply with OMB Circular A-50, *Audit Followup*, which requires resolution of audit recommendations within a maximum of 6 months after issuance of a final audit report. In resolving non-Federal audit recommendations, FDA must comply with OMB Circular A-133 for audits of grantees that received awards in FYs beginning prior to December 26, 2014, and with 45 CFR § 75.521(d) for audits of grantees that received awards in FYs beginning on or after that date.⁸ OMB Circular A-133 requires resolution within 6 months after receipt of the final report by the Federal Government, and 45 CFR § 75.521(d) requires resolution within 6 months of acceptance of the audit report by the FAC.

FDA's Audit Resolution Process

According to FDA officials, audit resolution responsibilities are broken out by audit types. The resolution of program audits is the responsibility of the FDA audit liaison. The resolution of information technology (IT) audits is the responsibility of FDA's Office of Information Management and Technology (OIMT). The resolution of Single Audits is the responsibility of FDA's Office of Acquisitions and Grants Services (OAGS).

FDA's *Guidelines for Responding to GAO and OIG Program Audits*⁹ (Guideline) formalizes some procedures for FDA to follow in resolving program audit recommendations. The Guideline

⁶ The FAC operates on behalf of OMB to disseminate A-133 audit reports to Federal agencies.

⁷ After our audit period, HHS made significant changes to the roles and responsibilities for processing Single Audits. Effective October 1, 2018, the Office of the Assistant Secretary for Financial Resources within HHS, Office of the Secretary, took over the responsibility from NEAR for assigning the audit recommendations from Single Audit reports to the HHS OpDiv responsible for resolution. NEAR maintained the desk review function, but instead of reviewing all Single Audit reports with findings, NEAR began on that date to use a risk-based approach to identify selected audit reports to review.

⁸ See footnote 2. Although none of the audits in this review were subject to 45 CFR part 75, we included the relevant provision from the current regulation in this report to support the validity of our recommendations.

⁹ The acronym GAO refers to the U.S. Government Accountability Office. The Guideline as published does not show its issuance date; however, FDA officials told us that it has been in place since CY 2010.

requires FDA to forward its final management decision to OIG within 6 months of the final report issuance date. The Guideline does not, however, include specific policies about preparing an OCD and submitting it to OIG for removal of the associated recommendation(s) from the stewardship report.

The *HHS Plan of Action and Milestones Guide, Version 1.0*, dated March 2013 (the POA&M), provides OIMT with guidance for following up on weaknesses identified during OIG IT audits, as well as weaknesses that are found from other sources such as internal audits and monitoring. The POA&M does not provide specific policies about OIG audit recommendation resolution and thus does not address the preparation of an OCD and its submission to OIG for removal of the associated recommendation(s) from the stewardship report.

Stewardship Reports

The OIG Audit Planning and Implementation group prepares and forwards to FDA (and other HHS OpDivs as appropriate) monthly stewardship reports on the status of audit recommendations reported in Federal and non-Federal audits. These reports identify all audit reports and corresponding recommendations issued for the selected period and provide the management decisions and the date of that action, or indicate that no action has as yet been taken.

HOW WE CONDUCTED THIS REVIEW

We reviewed the “Outstanding Audits and Actions Taken by Cognizance” stewardship reports to identify all outstanding audit recommendations that FDA resolved during FYs 2015 and 2016, as well as all outstanding audit recommendations that remained unresolved and were due for resolution as of September 30, 2016. These stewardship reports identified 17 audit reports and 166 corresponding recommendations.^{10, 11} The issuance dates for these audit reports ranged from October 12, 2007, through March 6, 2015.

We did not review FDA’s overall internal control structure. Rather, we reviewed only those internal controls related to our objective.

We conducted this performance audit in accordance with GAGAS. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a

¹⁰ Of the 17 audit reports and 166 corresponding recommendations identified in these stewardship reports, 10 were Federal audit reports that had a total of 141 corresponding recommendations, while 7 were non-Federal audit reports that had a total of 25 corresponding recommendations.

¹¹ In contrast, as reported in our previous review of CYs 2003 through 2005, the relevant stewardship reports identified 16 audit reports with 314 corresponding outstanding recommendations. The total of 314 outstanding recommendations that we reported in our previous review excluded recommendations that were unresolved but not due for resolution until after the end of the previous audit period. That methodology was similar to the methodology we used in the current review.

reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes our audit scope and methodology.

FINDINGS

FDA did not submit an OCD for any of the 166 audit recommendations during FYs 2015 and 2016, and as a result, all of them were outstanding, and listed on the stewardship report as past due for resolution, as of September 30, 2016. However, for 134 of the 166 recommendations (from the 7 information technology (IT) audit reports that were within our audit scope), FDA did address the audit recommendations in detail in its comments on the reports. Specifically, FDA's comments on those IT audit reports included its concurrence or nonconcurrence with each recommendation as well as the corrective actions that it had taken or planned to take. All 166 past-due recommendations were procedural in nature and typically involved policies and procedures and internal controls; none of them involved dollar amounts such as recommended disallowances.

FDA had some audit resolution guidelines in place during our audit period; however, they did not address the submission of OCDs to OIG to ensure that audit recommendations were cleared from the stewardship report. As a result, FDA did not submit any OCDs to OIG within the required 6-month resolution period. In addition, FDA did not provide copies of the OIG stewardship reports to some of its audit resolution officials and did not perform periodic, formal reconciliations between OIG's stewardship reports and its own audit resolution records.

According to FDA officials, sometime after issuance of our previous report on FDA's resolution of audit recommendations (A-07-06-03083, Feb. 15, 2007; Appendix B) and after FDA submitted its last OCD in January 2008, FDA's audit resolution responsibilities were reassigned to different offices. In that reassignment of duties, though, the relevant policies and procedures regarding OCD submission were not passed along. As a result, the FDA offices to which audit resolution responsibilities were reassigned were not aware of the requirement to submit OCDs to OIG during the audit period.

Without resolving all audit recommendations in a timely manner, FDA runs the risk of noncompliance with Federal requirements and mismanagement of Federal funds. The prompt resolution of audit recommendations helps ensure that Federal funds are effectively and efficiently used to carry out the activities for which they were authorized.

Since our audit period, though, FDA has made significant progress in resolving audit recommendations. Specifically, as of May 1, 2019, FDA had submitted OCDs for 134 of the 166 recommendations (over 80 percent of the audit recommendations) that were past due as of September 30, 2016.

FEDERAL REQUIREMENTS AND FDA GUIDELINES

In resolving Federal audit recommendations, FDA must comply with OMB Circular A-50. In resolving non-Federal audit recommendations, FDA must comply with OMB Circular A-133 for audits of grantees that received awards in FYs beginning prior to December 26, 2014, and with 45 CFR § 75.521(d) for audits of grantees that received awards in FYs beginning on or after that date (footnote 2).

OMB guidance requires “prompt resolution and corrective actions on audit recommendations. Resolution shall be made within a maximum of six months after issuance of a final report or, in the case of audits performed by non-Federal auditors, six months after receipt of the report by the Federal Government. Corrective action should proceed as rapidly as possible” (OMB Circular A-50, § 8.a.(2)).

OMB guidance states: “The entity responsible for making the management decision shall do so within six months of receipt of the [non-Federal] audit report. Corrective action should be initiated within six months after receipt of the audit report and proceed as rapidly as possible” (OMB Circular A-133, § _____.405(d)).

Federal regulations provide the following management decision time requirements: “The HHS awarding agency or pass-through entity responsible for issuing a management decision must do so within six months of acceptance of the audit report by the FAC. The auditee must initiate and proceed with corrective action as rapidly as possible and corrective action should begin no later than upon receipt of the audit report” (45 CFR § 75.521(d)).

FDA’s Guideline (footnote 9) formalizes some procedures for FDA to follow in resolving program audit recommendations. The Guideline requires FDA to forward its final management decision to OIG within 6 months of the final report issuance date. It does not, however, include specific policies about preparing an OCD and submitting it to OIG for removal of the associated recommendation(s) from the stewardship report.

FDA DID NOT RESOLVE AUDIT RECOMMENDATIONS IN ACCORDANCE WITH FEDERAL REQUIREMENTS

FDA Did Not Submit Any Clearance Documents to the Office of Inspector General During the Audit Period

FDA did not submit an OCD for any of the 166 audit recommendations identified in the relevant stewardship reports, and as a result, all of them were outstanding, and listed on the stewardship report as past due for resolution, as of September 30, 2016.

In contrast, as reported in our previous review of CYs 2003 through 2005,¹² FDA resolved 306 of the 314 audit recommendations that were due for resolution, as reflected in the OCDs that FDA submitted during that period. Of those 306 audit recommendations, 287 (93.8 percent) were not, however, resolved within the required 6-month resolution period. Table 1 below shows the timeframes for resolving these recommendations for both reviews.

Table 1: Timeliness of Audit Recommendations Resolved in FYs 2015 and 2016 Compared With Those Resolved in CYs 2003 Through 2005

Timeframe To Resolve Recommendation	Current Audit FYs 2015 and 2016		Previous Audit CYs 2003 Through 2005	
	Number of Resolved Recommendations	Percentage of Total	Number of Resolved Recommendations	Percentage of Total
Within 6-month resolution period	0	0.0%	19	6.2%
Not resolved within 6-month resolution period:				
6+ months to 1 year	0	0.0%	286	93.5%
1+ year	0	0.0%	1	0.3%
Subtotal (not resolved within 6-month resolution period)	0	0.0%	287	93.8%
Total	0	0.0%	306	100.0%

FDA Had Recommendations That Were Unresolved and Due for Resolution

As of September 30, 2016, FDA had not submitted OCDs for 166 audit recommendations (which accounted for all outstanding recommendations for FYs 2015 and 2016) that were past due for resolution.¹³ However, for 134 of the 166 recommendations (from the 7 IT audit reports that were within our audit scope), FDA did address the audit recommendations in detail in its comments on the reports. Specifically, FDA's comments on those IT audit reports included its concurrence or nonconcurrence with each recommendation as well as the corrective actions that it had taken or planned to take. All 166 past-due recommendations were procedural in nature and typically involved policies and procedures and internal controls; none of them involved dollar amounts such as recommended disallowances.

As of December 31, 2005 (the end of the period covered by our previous report), FDA had not resolved eight audit recommendations that were past due for resolution. There were no dollar amounts associated with these recommendations, all eight of which were resolved between 1 and 2 years after their required 6-month resolution periods. Therefore, between the period covered by our previous review and the period covered by our current review, FDA had a significant increase in the total number of unresolved audit recommendations that were past

¹² A-07-06-03083.

¹³ Of the 166 recommendations that were unresolved and past due for resolution, 141 were conveyed in Federal audit reports, and 25 were conveyed in non-Federal audit reports.

due for resolution. Tables 2 and 3 below present information on the timeframes for our current review and the timeframes for our previous review, respectively.¹⁴

Table 2: Unresolved Audit Recommendations Past Due for Resolution as of September 30, 2016

Timeframe Beyond Required Resolution Date	Number of Recommendations	Percentage of Total Recommendations	Average Days Beyond Required Resolution Date
6+ months to 1 year	1	0.6%	365.0
1+ year to 2 years	48	28.9%	455.6
2+ years to 3 years	36	21.7%	781.3
3+ years to 4 years	17	10.2%	1,368.0
4+ years to 5 years	35	21.1%	1,644.7
5+ years	29	17.5%	2,730.6
Total	166	100.0%	

Table 3: Unresolved Audit Recommendations Past Due for Resolution as of December 31, 2005

Timeframe Beyond Required Resolution Date	Number of Recommendations	Percentage of Total Recommendations	Average Days Beyond Required Resolution Date
6+ months to 1 year	0	0.0%	0.0
1+ year to 2 years	8	100.0%	627.6
2+ years to 3 years	0	0.0%	0.0
3+ years to 4 years	0	0.0%	0.0
4+ years to 5 years	0	0.0%	0.0
5+ years	0	0.0%	0.0
Total	8	100.0%	

FDA DID NOT HAVE POLICIES AND PROCEDURES RELATED TO SUBMITTING CLEARANCE DOCUMENTS FOR AUDIT RECOMMENDATIONS AND DID NOT PERFORM PERIODIC, FORMAL RECONCILIATIONS

FDA had some audit resolution guidelines in place during our audit period; however, they did not address the submission of OCDs to OIG to ensure that audit recommendations were cleared from the stewardship report. As a result, FDA did not submit any OCDs to OIG within the required 6-month resolution period. In addition, FDA did not provide copies of the OIG stewardship reports to some of its audit resolution officials and did not perform periodic, formal reconciliations between OIG's stewardship reports and its own audit resolution records.

According to FDA officials, sometime after issuance of our previous report on FDA's resolution of audit recommendations (A-07-06-03083, Feb. 15, 2007; Appendix B) and after FDA submitted

¹⁴ A-07-06-03083.

its last OCD in January 2008, FDA's audit resolution responsibilities were reassigned to different offices. In that reassignment of duties, though, the relevant policies and procedures regarding OCD submission were not passed along. As a result, the FDA offices to which audit resolution responsibilities were reassigned were not aware of the requirement to submit OCDs to OIG during the audit period. However, since our audit period, FDA has made significant progress in resolving audit recommendations, as we discuss in greater detail below.

FDA DID NOT ALWAYS ENSURE THAT FEDERAL FUNDS WERE EFFECTIVELY AND EFFICIENTLY USED

Without resolving all audit recommendations in a timely manner, FDA runs the risk of noncompliance with Federal requirements and mismanagement of Federal funds. The prompt resolution of audit recommendations helps ensure that Federal funds are effectively and efficiently used to carry out the activities for which they were authorized.

FDA AUDIT RESOLUTION HAS MADE SIGNIFICANT PROGRESS SINCE OUR AUDIT PERIOD

During our audit period, OAGS did not have documented policies and procedures for Single Audit resolution and lacked informal procedures related to preparing an OCD and submitting it to OIG for removal of the associated recommendation(s) from the stewardship report. Since the end of our audit period, FDA implemented the Single Audit Resolution Framework, dated April 2, 2018 (the Framework), to provide the policies and procedures for OAGS to follow in resolving Single Audit recommendations. The Framework requires OAGS to prepare an OCD whenever an audit finding has been resolved and then submit it to OIG for removal of the associated recommendations from the stewardship report (the Framework § 2.12).

Subsequent to our audit period, FDA began to address some of the issues with the audit resolution process. During the time of our audit work, FDA officials told us that they were in the process of updating FDA's policies and procedures to include submission of an OCD. These officials added that all of FDA's audit resolution officials are now being provided copies of the monthly stewardship reports. Also during the time of our audit work, FDA and OIG began meeting and began coordinating more closely to address FDA's unresolved recommendations. As of May 1, 2019, FDA had submitted OCDs for 134 of the 166 recommendations (over 80 percent of the audit recommendations) that were past due as of September 30, 2016.

RECOMMENDATIONS

We recommend that the Food and Drug Administration:

- finalize and implement formal policies and procedures for resolving program and IT audit recommendations, similar to the Framework that FDA has implemented for resolving Single Audit recommendations, which include issuing management decisions and submitting related OCDs to OIG within the required 6-month resolution period;

- promptly resolve the 32 outstanding audit recommendations (166 that were past due as of September 30, 2016, less 134 resolved after the end of our audit period); and
- reconcile each month the OIG stewardship reports (or the HHS electronic Single Audit recommendation listing for audits processed on or after October 1, 2018) with FDA's audit resolution records and follow up on any differences noted.

FDA COMMENTS

In written comments on our draft report, FDA concurred with all of our recommendations and described corrective actions that it had taken or planned to take. FDA stated that it was updating its procedures to ensure that FDA submits OCDs along with its corrective action plans to OIG. In addition, FDA stated that it was actively working to submit OCDs and corrective action plans for all outstanding recommendations. Finally, FDA stated that it was reconciling the OIG stewardship report with FDA's audit resolution records.

FDA's comments are included in their entirety as Appendix C.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the “Outstanding Audits and Actions Taken by Cognizance” stewardship reports to identify all outstanding audit recommendations that FDA resolved during FYs 2015 and 2016, as well as all outstanding audit recommendations that remained unresolved and were due for resolution as of September 30, 2016. These stewardship reports identified 17 audit reports and 166 corresponding recommendations (footnotes 10 and 11). The issuance dates for these audit reports ranged from October 12, 2007, through March 6, 2015.

We did not review FDA’s overall internal control structure. Rather, we reviewed only those internal controls related to our objective.

We conducted our audit work from September 2018 to May 2019.

METHODOLOGY

To accomplish our objectives, we:

- reviewed applicable sections of OMB Circulars A-50 and A-133, HHS regulations at 45 CFR part 75, and other applicable Federal requirements;
- reviewed FDA’s policies and procedures for resolving audit recommendations;
- interviewed FDA’s staff and reviewed documentation provided by FDA officials;
- obtained FDA’s “Outstanding Audits and Actions Taken by Cognizance” stewardship reports for our audit period and used them to:
 - identify the total number of recommendations that were resolved timely or untimely;¹⁵
 - quantify the total number of recommendations that were unresolved and beyond the required resolution period by:
 - including only the recommendations that had no decision date documented or that had a decision date that was after our audit period (indicating that a management decision had not been made as of the end of our audit period) and

¹⁵ For this step we noted that there were no recommendations that had the “management decision” data field populated, which indicated that no recommendations were resolved during our audit period.

- quantifying the timeframe beyond the required resolution date for those recommendations by calculating the number of days between the required resolution date and the last day of our audit period (September 30, 2016); and
 - determine whether there were any dollar amounts associated with any unresolved recommendations that were beyond the required resolution period as of September 30, 2016; and
- discussed the results of our audit with FDA officials on May 15, 2019.

We conducted this performance audit in accordance with GAGAS. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

**APPENDIX B: PREVIOUSLY ISSUED
OFFICE OF INSPECTOR GENERAL REPORTS**

Report Title	Report Number	Date Issued
<i>The Substance Abuse and Mental Health Services Administration Resolved Approximately One-Third of Its Audit Recommendations, None in Accordance With Federal Timeframe Requirements</i>	<u>A-07-19-03233</u>	7/18/2019
<i>Although the Administration for Community Living Resolved Nearly All Audit Recommendations, It Did Not Always Do So in Accordance With Federal Timeframe Requirements</i>	<u>A-07-18-03232</u>	4/1/2019
<i>Although the Centers for Disease Control and Prevention Resolved Nearly All Audit Recommendations, It Did Not Always Do So in Accordance With Federal Timeframe Requirements</i>	<u>A-07-17-03226</u>	2/25/2019
<i>Although the Centers for Medicare & Medicaid Services Has Made Progress, It Did Not Always Resolve Audit Recommendations in Accordance With Federal Requirements</i>	<u>A-07-18-03228</u>	1/15/2019
<i>The Indian Health Service Did Not Always Resolve Audit Recommendations in Accordance With Federal Requirements</i>	<u>A-07-17-03227</u>	9/24/2018
<i>The Administration for Children and Families Did Not Always Resolve Audit Recommendations in Accordance With Federal Requirements</i>	<u>A-07-17-03225</u>	7/2/2018
<i>Review of the Centers for Disease Control and Prevention's Resolution of Audit Recommendations</i>	<u>A-07-09-03131</u>	5/26/2010
<i>Administration for Children and Families Resolution of Audit Recommendations</i>	<u>A-07-09-03118</u>	10/28/2009
<i>Centers for Medicare & Medicaid Services Resolution of Audit Recommendations</i>	<u>A-07-07-04112</u>	11/19/2008
<i>Indian Health Service's Resolution of Audit Recommendations</i>	<u>A-07-06-03077</u>	3/9/2007
<i>Administration on Aging's Resolution of Audit Recommendations</i>	<u>A-07-06-03084</u>	2/21/2007
<i>Food and Drug Administration's Resolution of Audit Recommendations</i>	<u>A-07-06-03083</u>	2/15/2007



APPENDIX C: FDA COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

DATE: July 17, 2019

TO: Daniel R. Levinson, Inspector General

FROM: Director, Public Health Strategy and Analysis

SUBJECT: FDA's General Comments to OIG's Draft Report Titled "The Food and Drug Administration Did Not Submit Clearance Documents for Any Audit Recommendations During Fiscal Years 2015 and 2016, but Has Since Made Significant Progress" (A-07-18-03231)

Enclosed are the Food and Drug Administration's general comments to the Office of Inspector General's OIG Draft Report, "The Food and Drug Administration Did Not Submit Clearance Documents for Any Audit Recommendations During Fiscal Years 2015 and 2016 but Has Since Made Significant Progress" (A-07-18-03231).

We appreciate the opportunity to review and comment on this draft report prior to publication.

A handwritten signature in black ink, appearing to read "Lisa Rovin", is positioned above the printed name.

Lisa Rovin, J.D.
Director, Public Health Strategy and Analysis

Attachment

FDA's General Comments to OIG's Draft Report Titled "The Food and Drug Administration Did Not Submit Clearance Documents for Any Audit Recommendations During Fiscal Years 2015 and 2016, but Has Since Made Significant Progress" (A-07-18-03231)

This memo is in response to the June 18, 2019, Department of Health and Human Services, Office of Inspector General (OIG) draft audit report titled "The Food and Drug Administration Did Not Submit Clearance Documents for Any Audit Recommendations During Fiscal Years 2015 and 2016 but Has Since Made Significant Progress" (A-07-18-03231), and its three recommendations.

The Food and Drug Administration (FDA) is committed to resolving OIG's recommendations. It is FDA's policy and practice to submit to OIG statements of corrective actions in response to draft reports, and to follow-up with OIG within 6 months of the final report on the status of those corrective actions.

As OIG notes, FDA has audit resolution guidelines in place to ensure that OIG's recommendations are addressed, but those guidelines, for about the past decade, did not address the submission of an OIG form entitled, "OIG Clearance Document" (OCD). We believe that is because in 2008, FDA's audit resolution responsibilities were reassigned to different offices, and although the agency continued to provide OIG with detailed corrective actions to address OIG recommendations, the requirement for submitting the OCD form to OIG was inadvertently dropped from the process. In 2018, OIG reminded FDA of the requirement to submit the OCD form, and soon after, FDA submitted an OCD form to OIG that covered 134 of OIG's recommendations from 7 Information Technology audits. FDA notes that the agency had previously provided to OIG substantive correction actions to address these 134 Information Technology recommendations.

As a result of the 2018 interactions between FDA and OIG about the OCD requirement, and in concurrence with OIG's recommendations in this draft report, FDA is updating its procedures to ensure that FDA submits an OCD form to OIG along with its substantive corrective action plans, actively working to submit OCD forms along with the substantive corrective action plans for all the outstanding recommendations, and reconciling the OIG stewardship report with the agency's audit resolution records.