

## Report in Brief

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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.