Department of Health and Human Services
Office of Inspector General
Office of Audit Services

February 2026 | OAS-26-03-024

Food and Drug Administration Fiscal Year 2025 Detailed Accounting Submission and Fiscal Year 2027 Budget Formulation Compliance Report for National Drug Control Activities, and the Accompanying Required Assertions

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

February 24, 2026

TO: Benjamin D. Moncarz
Chief Financial Officer
Food and Drug Administration

FROM: /John D. Hagg/
Acting Deputy Inspector General for Audit Services

SUBJECT: Independent Attestation Review: *Food and Drug Administration Fiscal Year 2025 Detailed Accounting Submission and Fiscal Year 2027 Budget Formulation Compliance Report for National Drug Control Activities, and the Accompanying Required Assertions*, OAS-26-03-024

We have reviewed the attached Food and Drug Administration (FDA) Office of National Drug Control Policy (ONDCP) Detailed Accounting Report, which includes the table of Drug Control Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2025. We also reviewed the Budget Formulation Compliance Report, which includes budget formulation information for the fiscal year ending September 30, 2027, and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information.[1] FDA management is responsible for, and submitted, the Detailed Accounting Report and Budget Formulation Compliance Report, which were prepared in accordance with the ONDCP Circular *National Drug Control Program Agency Compliance Reviews*, dated September 9, 2021 (ONDCP Compliance Reviews Circular). We performed this review as required by 21 U.S.C. section 1704(d)(1) and as authorized by 21 U.S.C. section 1703(d)(7) and in compliance with the ONDCP Compliance Reviews Circular.

It is our responsibility to express a conclusion about the reliability of FDA's Detailed Accounting Report for fiscal year 2025, FDA's Budget Formulation Compliance Report for fiscal year 2027, and management's assertions based on our review.

We conducted our review in accordance with attestation standards established by the American Institute of Certified Public Accountants and the standards applicable to attestation engagements, as described in the U.S. Government Accountability Office publication *Government Auditing Standards* (February 2024). Those standards require that we plan and perform the review to

[1] Although FDA's Budget Formulation Compliance Report was provided to ONDCP as of fiscal year 2025, the budget figures reflect the fiscal year 2027 funding request.

obtain limited assurance about whether any material modifications should be made to the Detailed Accounting Report, Budget Formulation Compliance Report, and management's assertions for them to be in accordance with the criteria. The procedures performed in a review vary in nature and timing from, and are substantially less in extent than an examination, the objective of which is to obtain reasonable assurance about whether management's reports and assertions are in accordance with the criteria in all material respects, in order to express an opinion. Accordingly, we do not express such an opinion.

Notwithstanding the limited nature of the engagement, we believe that the review evidence obtained is sufficient in accordance with attestation standards and appropriate to provide a reasonable basis for our conclusion.

We are required to be independent and to meet our other ethical responsibilities in accordance with relevant ethical requirements related to the engagement.

As part of our review, we performed review procedures on FDA's fiscal year 2025 Detailed Accounting Report and fiscal year 2027 Budget Formulation Compliance Report according to the ONDCP Compliance Reviews Circular's criteria. We limited our work to inquiries and analytical procedures appropriate for an attestation review. Specifically, we performed procedures for the purpose of expressing a conclusion about the reliability of each of the assertions made in FDA's reports. Those procedures included reviewing FDA's drug methodologies and reprogramming or transfer of drug control funds, if applicable. We also performed procedures to determine whether FDA submitted the summer budget timely and whether funding levels represented FDA requests.

Based on our review, we are not aware of any material modifications that should be made to FDA's Detailed Accounting Report for fiscal year 2025 and FDA's Budget Formulation Compliance Report for fiscal year 2027 and management's assertions for them to be in accordance with the ONDCP Compliance Reviews Circular.

FDA's Detailed Accounting Report is included as Attachment A.[2]

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Although this report is an unrestricted public document, the information it contains is intended solely for the information and use of Congress, ONDCP, and FDA. It is not intended to be, and should not be, used by anyone other than those specified parties. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Carla J. Lewis, Assistant Inspector General for Audit Services, at (202) 834-5992 or Carla.Lewis@oig.hhs.gov. Please refer to report number OAS-26-03-024 in all correspondence.

[2] We did not attach the Budget Formulation Compliance Report assertions because they were embedded within the Budget Formulation Compliance Report which contains prospective information.

U.S. FOOD & DRUG ADMINISTRATION

DATE: February 12, 2026

TO: Director
Office of National Drug Control Policy (ONDCP)

THROUGH: Teresa Miranda
Deputy Assistant Secretary for Finance and
Deputy Chief Financial Officer
Assistant Secretary for Financial Resources
Office of the Secretary
Department of Health and Human Services

FROM: Benjamin Moncarz,
Chief Financial Officer
U.S. Food & Drug Administration
BENJAMIN D. MONCARZ -S Digitally signed by BENJAMIN D. MONCARZ -S Date: 2026.02.12 13:52:47 -05'00'

SUBJECT: Fiscal Year 2025 Detailed Accounting Report

In accordance with the requirements of National Drug Control Program Agency Compliance Reviews dated September 9, 2021, FDA provides the following Table of Prior Year Drug Control Obligations by Decision and Drug Control Function:

Drug Control Resources by Decision Unit and Function

Budget Authority (in millions)					
	FY 2025 President's Request	FY 2025 Enacted Resources	Obligations Identified in UFMS Reports	Obligations Recorded by Defined Methodology	Total Obligations
Drug Resources by Decision Unit					
Center for Drug Evaluation and Research	$23.50	$23.50	$ 10.49	$ 4.66	$ 15.15
Operating			$ 10.49	$ -	$ 10.49
Payroll			$ -	$ 4.66	$ 4.66
Center for Devices and Radiological Health	$1.50	$1.50	$ -	$ 0.53	$ 0.53
Operating			$ -	$ -	$ -
Payroll			$ -	$ 0.53	$ 0.53
Office of Inspections and Investigations	$42.29	$42.29	$ 21.10	$ 21.19	$ 42.29
Operating			$ 3.39	$ 9.98	$ 13.37
Payroll			$ 17.71	$ 11.21	$ 28.92
Office of the Chief Scientist	$11.71	$11.71	$ -	$ 2.88	$ 2.88
Operating			$ -	$ 0.50	$ 0.50
Payroll			$ -	$ 2.38	$ 2.38
Office of Operations	$0.50	$0.50	$ -	$ 0.33	$ 0.33
Operating			$ -	$ -	$ -
Payroll			$ -	$ 0.33	$ 0.33
Total Drug Resources by Decision Unit		**$79.50**	**$ 31.59**	**$ 29.58**	**$ 61.17**

U.S. FOOD & DRUG ADMINISTRATION

Budget Authority (in millions)	FY 2025 President's Request	FY 2025 Enacted Resources	Obligations Identified in UFMS Reports	Obligations Recorded by Defined Methodology	Total Obligations
Drug Resources by Function					
Center for Drug Evaluation and Research (CDER)					
Research and Development: Treatment & Prevention		$23.50	$10.49	$4.66	$15.15
Harm Reduction (non-add)		*$10.00*	*$3.81*	$ -	*$3.81*
Center for Device and Radiological Health (CDRH)					
Research and Development: Treatment		$1.50	$ -	$0.53	$0.53
Office of Inspections and Investigations (OII)					
Interdiction		$42.29	$ 21.10	$ 21.19	$ 42.29
Office of the Chief Scientist (OCS)					
Interdiction		$11.71	$0.00	$ 2.88	$2.88
Office of Operations (OO)					
Interdiction		$0.50	$ -	$0.33	$0.33
Total Drug Resources by Function		**$79.50**	**$31.59**	**$29.58**	**$61.17**

Drug Methodology

FDA identified the drug control budget by using the dedicated budget authority for opioids activities. This includes opioid dedicated activities conducted by the Center for Drug Evaluation and Research (CDER), Office of Inspections and Investigations (OII) (formerly Office of Regulatory Affairs (ORA)), the Center for Devices and Radiological Health (CDRH), the Office of Chief Scientist (OCS) and Office of Operations (OO). OCS and OO were newly added offices in FY2025. Under OCS, FDA's Forensic Chemistry Center became the National Forensic Chemistry Center (NFCC) in the Office of Specialty Laboratories and Enforcement Support (OSLES) in FY 2025. This realignment allowed for increased scientific collaborations both within and outside of FDA, ultimately increasing our scientific capabilities and capacity to protect public health. FDA/OII's Division of Information Disclosure Policy (DIDP) relocated to the OO with the FY 2025 reorganization. The Division of Freedom of Information (DFOI) also relocated to the OO. DFOI manages the intake, triaging, and appeals for all FDA FOIA requests, including those related to opioids and drug control.

FDA pulls reports from our accounting system of record, United Financial Management System (UFMS), that identifies $31.59M of the obligations against the drug control budget. The remaining $29.58M is obligated in UFMS as part of FDA's drug control efforts but utilizes a defined methodology to define the funding attributable to opioids spending.

For OII's opioids work, about $21.10M can be identified in a UFMS report and tracked by Common Accounting Number (CAN). The remaining $21.19M is obligated in UFMS as part of the broader field component of the Human Drugs program but requires a defined methodology to define the funding attributable to the opioids spending. To note, an additional $11.21M should have been recorded in UFMS payroll reports, however due to the workforce reductions, the Mass Allocation for OII's Office of Imports Operations was not updated in a timely manner. OII conducted a manual calculation of what the total should have been if it was able to complete the updates and those costs are reflected under the defined methodology amount. Due to the matrix nature of OII's work, tracking all expenditures in UFMS is difficult. Therefore, to ensure the best tracking of the obligation of resources by program, project, and activity (PPA), OII utilizes a defined methodology that focuses on the OII Field Workplan which outlines, in detail, the foreign, import, and domestic workload for OII field offices. OII budget staff analyzes the

data to ensure that the OII work being accomplished throughout the year remains in line with the PPAs. This methodology is also used to ensure OII is spending the appropriate level of resources on opioids related work for both payroll and operating costs.

For CDER's opioids work, about $10.49M can be identified in a UFMS report and tracked by CAN for opioid-related research and operating costs. Approximately $4.66M of payroll funds are obligated in UFMS, but the costs are not easily distinguishable, and a defined methodology is used to determine the opioids spending. CDER tracks Opioids payroll offline using Integrated Budget and Acquisition Planning System (IBAPS) payroll data. Each identified Opioids position's actual expenses are captured from IBAPS. The remaining FY 2025 Enacted Resources (approximately $8.35M) were unspent due to FY25 budgetary limitations, including operation under a Continuing Resolution and workforce reductions, and revisions to funding approval and allocation procedures for new and continuing research.

For CDRH's opioids work, about $0.5M can be identified in a UFMS report and is tracked by CAN, acquisition description, and FTE workload. These costs are the average for 2 Full Time Equivalents (FTE). The remaining FY 2025 enacted resources (approximately $1M) were unspent.

For OCS' opioids-related work, approximately $2.9M can be identified in UFMS but was not fully tracked using opioid-specific CANs in FY 2025. Of this total, approximately $2.4M represents payroll obligations recorded in UFMS, and approximately $504K represents operating costs attributable to opioid-related activities. OCS employs a defined methodology to track opioid-related spending. Specifically, OCS identifies opioid-related positions and activities based on program responsibilities and workload alignment. Payroll costs for these identified opioid-related positions are tracked offline using UFMS payroll reports and internal staffing analyses to estimate the proportion of time and cost attributable to opioid-related work. Operating costs are similarly reviewed and attributed based on documented opioid-related projects, contracts, and activities. This defined methodology enables OCS to capture and report opioid-related obligations.

For OO's opioids work, about $0.3M of payroll funds were obligated in UFMS, but the costs were not easily distinguishable, and a defined methodology was used to determine the opioids spending. OO received 2 FTE from the Office of Regulatory Affairs in FY 2025 as part of a major reorganization. The funding for those FTE was provided by Congress through a special initiative and supported FDA's drug control activities. Those support efforts continued in OO in FY 2025 and are attributable to the drug control budget. The estimated workload was 2 FTE and OO validated the $0.3M payroll spent by comparing actual spending to the number of onboarded opioid staff at year end. The $163K average cost per employee is within salary standards. The amount is lower than budgeted due to workforce and operational changes that occurred in FY 2025.

Methodology Modifications

I assert that the methodology for reporting drug control resources as required by Section 7.b.(5) of the Circular remained largely the same with the inclusion of two new offices, Office of the Chief Scientist and Office of Operations and the name change from Office of Regulatory Affairs (ORA) to the Office of Investigations and Inspections (OII).

Material Weakness or Other Findings

N/A

Reprogramming's or Transfers

N/A

Other Disclosures

N/A

Obligations by Budget Decision Unit

I assert the obligations reported by budget decision units are actual obligations from FDA's financial accounting system (UFMS) and can be identified by a standard report or based on a defined methodology to track payroll and operating expenses (ex. IBAPS Payroll reporting, analysis of OII Field Workplan).

Drug Methodology

I assert that the drug methodology used to calculate obligations of budget resources for FDA's opioids activities included in the National Drug Control Budget was reasonable and accurate in accordance with the criteria listed in Section 7.b.(2) of the Circular.

(a) Data: FDA pulls reports from our accounting system of record, United Financial Management System (UFMS), that identified $31.59M of the obligations against the drug control budget. The remaining $29.58M was obligated in UFMS as part of FDA's drug control efforts but utilizes a defined methodology to define the funding attributable to opioids spending
(b) Financial Systems: FDA pulls reports from our accounting system of record, United Financial Management System (UFMS), FBIS and IBAPS.

Application of Drug Methodology

I assert that the drug methodology disclosed in this report was the actual methodology used to generate the table required by Section 7.b.(3) of the Circular.

Material Weakness or Other Findings

I assert there are no material weaknesses, other findings by independent sources, or other known weaknesses, including those identified in the Agency's Annual Statement of Assurance, which may affect the presentation of prior year drug-related obligations as required by Section 7.b.(4) of the Circular.

Methodology Modifications

I assert that the methodology for reporting drug control resources as required by Section 7.b.(5) of the Circular remained largely the same.

Reprogramming or Transfers

I assert that the data presented are associated with obligations against FDA's financial plan as required by Section 7.b.(6) of the Circular. FDA had no reportable reprogramming's or transfers in FY 2025 related to drug-control obligations.

Fund Control Notices

FDA has not received any Fund Control Notices from ONDCP. Therefore, I assert that FDA is in compliance with Section 7.b.(7) of the Circular.

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