



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



January 18, 2023

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

FROM: /Amy J. Frontz/
Deputy Inspector General for Audit Services

SUBJECT: Independent Attestation Review: *Food and Drug Administration Fiscal Year 2022 Detailed Accounting Submission and Budget Formulation Compliance Report for National Drug Control Activities, and Accompanying Required Assertions*, A-03-23-00353

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, 2022. We also reviewed the Budget Formulation Compliance Report, which includes budget formulation information for the fiscal year ending September 30, 2024,¹ and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information. 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 2022, FDA's Budget Formulation Compliance Report for fiscal year 2024, 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 (GAO) publication, *Government Auditing Standards* (April 2021). Those standards require that we plan and perform the review to obtain limited assurance about whether any material modifications should be made to the Detailed Accounting Report, Budget Formulation Compliance Report, and management's

¹ Although FDA's Budget Formulation Compliance Report was provided to ONDCP as of fiscal year 2022, the budget figures reflect the fiscal year 2024 funding request.

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 2022 Detailed Accounting Report and fiscal year 2024 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 2022 and FDA's Budget Formulation Compliance Report for fiscal year 2024 and management's assertions for them to be in accordance with the ONDCP Compliance Reviews Circular.

FDA's Detailed Accounting Report and Budget Formulation Compliance Report assertions are included as Attachments A and B.²

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 A-03-23-00353 in all correspondence.

² Only the Budget Formulation Compliance Report assertions are included in Attachment B since the report contains prospective information.



Memorandum

To: Rahul Gupta, Director
Office of National Drug Control Policy

From: Benjamin Moncarz, Chief Financial Officer
U.S. Food & Drug Administration

Benjamin D.
Moncarz -S

 Digitally signed by Benjamin D.
Moncarz -S
Date: 2022.12.09 16:39:17 -05'00'

Date: December 9, 2022

Subject: Detailed Accounting Report and Assertions

In accordance with the requirements of *National Drug Control Program Agency Compliance Reviews* dated September 9, 2021; I make the following assertions regarding the attached annual accounting of drug control funds.

Obligations by Budget Decision Unit

I assert the obligations reported by budget decision units are actual obligations from FDA's financial accounting system and can be identified by a standard report or based on a defined methodology to track payroll and operating expenses.

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.

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 no modifications were made to the methodology for reporting drug control resources as required by Section 7.b.(5) of the Circular.

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 2022 related to drug-control obligations.

Fund Control Notices

FDA has not previously provided a financial plan under Section 9 of the ONDCP Circular, Budget Execution. FY 2022 was the first year that FDA reported on actual obligations and 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.

Attachment:
Drug Control Resources by Decision Unit and Function

Drug Control Resources by Decision Unit and Function**Accounting of Drug Control Funds (\$M)**

Decision Unit & Function	FY 2022 President's Request	Total Enacted Resources	Obligations Identified in UFMS Reports	Obligations Recorded by Defined Methodology	Total Obligations
ORA - Interdiction					
Payroll				30.28	30.28
Operating			0.31	20.91	21.22
ORA Total	54.50	51.50	0.31	51.19	51.50
CDER - Research & Development, Treatment & Prevention, including Harm Reduction					
Operating			19.74	0.18	19.92
Payroll			0.00	0.58	0.58
CDER Total	46.00	20.50	19.74	0.76	20.50
CDRH - Research & Development, Treatment & Prevention					
Operating			0.50	0.00	0.50
CDRH Total	2.00	0.50	0.50	0.00	0.50
FDA Totals:	102.50	72.50	20.55	51.95	72.50

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 Regulatory Affairs (ORA), and the Center for Devices and Radiological Health (CDRH).

FDA pulls reports from our accounting system of record, United Financial Management System (UFMS), that identifies about \$20M of the obligations against the drug control budget. The remaining \$51M is obligated in UFMS as part of the broader Human Drugs program but utilizes a defined methodologies to define the funding attributable to opioids spending.

For ORA's opioids work, about \$308K can be identified in a UFMS report and tracked by CAN. The remaining \$51M is obligated in UFMS as part of the broader field component of the Human Drugs program but requires a standard methodology to define the funding attributable to the opioids spending. Due to the matrix nature of ORA'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), ORA utilizes a methodology that focuses on the ORA Field Workplan which outlines, in detail, the foreign, import, and domestic workload for ORA field offices. ORA budget staff analyzes the data to ensure that the ORA work being accomplished throughout the year remains in line with the PPAs. This methodology is also used to ensure ORA is spending the appropriate level of resources on opioids related work for both payroll and operating costs.

For CDER's work, about \$19.7M can be identified in a UFMS report and tracked by CAN. Approximately \$577K 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. \$182K is obligated in UFMS but part of the WCF AWS Special Assessments and determined by a defined methodology.

CDRH's \$500K in funding can be identified in a UFMS report and is tracked by CAN.

Methodology Modifications

N/A

Reprogramming or Transfers

N/A

Fund Control Notices

N/A

Other Disclosures

N/A



Memorandum

To: Rahul Gupta, Director
Office of National Drug Control Policy

From: Benjamin Moncarz, Chief Financial Officer
U.S. Food & Drug Administration

Date: December 9, 2022

Subject: Assertions Concerning FY 2024 Budget Formulation Summer Submission

Benjamin D. Moncarz -S
Digitally signed by Benjamin D. Moncarz -S
Date: 2022.12.09 16:38:10 -05'00'

In accordance with the requirements of the Office of National Drug Control Policy (ONDCP) *National Drug Control Program Agency Compliance Reviews*, dated September 9, 2021, the Food and Drug Administration (FDA) is providing this memorandum.

Summer Budget Formulation Information

FDA provided the FY 2024 summer budget submission to ONDCP on June 3, 2022. A copy of the submission is provided as an attachment to this memorandum.

Timeliness of Summer Budget Submission

I assert that FDA provided the FY 2024 summer budget submission to ONDCP at the same time as HHS.

Funding Levels Represent Bureau-Level Request

I assert that the information provided in FDA's FY 2024 summer budget submission was the same as what was provided to the Department of Health and Human Services (HHS) and was provided to ONDCP without alteration or adjustment by HHS.

Attachment:
FDA FY 2024 Summer Budget Submission to ONDCP