



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



January 28, 2022

TO: James Tyler
Chief Financial Officer
Food and Drug Administration

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

SUBJECT: Independent Attestation Report: *Food and Drug Administration Budget Formulation Compliance Report and Detailed Accounting Submission for Fiscal Year 2021 National Drug Control Activities, and Accompanying Required Assertions*, A-03-22-00352

This report provides the results of our review of the Food and Drug Administration (FDA) Office of National Drug Control Policy (ONDCP) Budget Formulation Compliance Report, which includes budget formulation information for the fiscal year ending September 30, 2023, and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information. FDA's management is responsible for preparing and submitting the Budget Formulation Compliance Report in accordance with the ONDCP Circular National Drug Control Program Agency Compliance Reviews, dated September 9, 2021 (ONDCP Compliance Reviews Circular). It is our responsibility to express a conclusion about the reliability of management's assertions based on our review.

We performed this review as required by 21 U.S.C. § 1704(d)(1) and as authorized by 21 U.S.C. § 1703(d)(7) and in compliance with the ONDCP Compliance Reviews Circular.

We also received FDA's ONDCP Detailed Accounting Report and management's assertions for the fiscal year ended September 30, 2021. FDA did not provide this report in sufficient time for the Office of Inspector General to review and authenticate the report. Accordingly, we do not express a conclusion about the reliability of management's assertions.

Budget Formulation Compliance Report

We conducted our review of FDA's Budget Formulation Compliance Report for fiscal year 2023 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 management's assertions to be in accordance with the criteria. A review is substantially less in scope than an examination, the objective of which is to obtain reasonable assurance and express an opinion about whether management's assertions are in accordance with the criteria in all material respects. Accordingly, we do not express such an opinion. We believe that our review provides a reasonable basis for our conclusion.

Based on our review, we are not aware of any material modifications that should be made to FDA's Budget Formulation Compliance Report for fiscal year 2023 for it to be in accordance with the ONDCP Compliance Reviews Circular.

Detailed Accounting Report

FDA is required to submit its ONDCP Detailed Accounting Report along with the Office of Inspector General's authentication of that report to ONDCP by February 1, 2022. As stated in the ONDCP Compliance Reviews Circular, section 9, FDA's management must submit the ONDCP reports to the Office of Inspector General in sufficient time to allow for review and authentication.

We requested that FDA provide its reports to us by November 22, 2021. We did not receive FDA's ONDCP Detailed Accounting Report, which included an Accounting of Drug Control Funds, Fiscal Year 2021 FDA Operating Plan, and management's assertions for the fiscal year ended September 30, 2021, until January 10, 2022. FDA did not submit its ONDCP Detailed Accounting Report in a reasonable time for the Office of Inspector General to complete its authentication and ensure that its professional standards are not compromised. Consequently, the Office of Inspector General did not have sufficient time to complete its review and enable FDA to meet its statutory deadline by reporting to ONDCP by February 1, 2022.

Conclusion

Based on our review, FDA did not conform in all material respects to the ONDCP Compliance Reviews Circular. Specifically, FDA did not provide a timely ONDCP Detailed Accounting Report for the fiscal year ended September 30, 2021. Except for this deficiency, we are not aware of any material modifications that FDA should make to be in accordance with the ONDCP Compliance Reviews Circular.

FDA's Budget Formulation Compliance Report assertions are included as Attachment A.¹

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

¹ Only the Budget Formulation report assertions are included in Attachment A since the report contains prospective information.

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) 205-9125 or at Carla.Lewis@oig.hhs.gov. Please refer to report number A-03-22-00352 in all correspondence.

Attachment



Memorandum

Date: December 15, 2021

To: Director
Office of National Drug Control Policy

From: James Tyler, Chief Financial Officer
U.S. Food & Drug Administration

Subject: Assertions Concerning FY 2023 Budget Formulation Summer Submission

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 2023 summer budget submission to ONDCP on July 14, 2021. 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 2023 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 2023 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.

James E. Tyler Jr -S
James Tyler
Chief Financial Officer

Digitally signed by
James E. Tyler Jr -S
Date: 2021.12.15
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Attachment:
FDA FY 2023 Summer Budget Submission to ONDCP