SMG 2350.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FINANCIAL MANAGEMENT

FINANCIAL INTEGRITY

GUIDANCE FOR THE IMPLEMENTATION OF THE FEDERAL MANAGERS' FINANCIAL INTEGRITY ACT (FMFIA)

Effective Date: 03/09/2015

1. PURPOSE.

This Guide sets forth FDA policy, responsibilities and guidelines for complying with Section 2 and Section 4 of the Federal Managers' Financial Integrity Act (FMFIA) of 1982 and Office of Management and Budget (OMB) Circular A-123, dated December 21, 2004.

2. POLICY.

Through FDA's FMFIA Program, FDA seeks to establish, maintain, and report on internal controls for the purpose of:

- Reducing the risk of fraud, waste, mismanagement of assets and resources, and misappropriation of funds
- Assuring compliance with applicable laws and regulations
- Promoting effective and efficient operations

FDA managers should incorporate the requirements, standards, and timelines contained within the Authorities and References section of this document for compliance with FMFIA.

3. RESPONSIBILITIES.

The Office of Financial Management (OFM) is responsible for leading FDA's overall internal controls program, including the day-to-day activities of the FDA FMFIA program and of the FDA A-123 Senior Assessment Team (SAT).

NOTE: The SAT is responsible for overseeing internal controls over financial reporting and for coordinating with the (Department of Health and Human Services) (HHS) SAT in order to comply with FMFIA, OMB Circular A-123, and HHS internal control requirements specifically pertaining to financial reporting. The SAT Charter can be found in the reference section. Questions related to FDA's internal controls program should be directed to OFM's Director of the Division of Controls, Compliance, and Oversight.

1. FDA Program Management.

a. The Commissioner is responsible for signing the Annual Statement of Assurance, which certifies that FDA is meeting its requirements under FMFIA. This statement and accompanying FMFIA report must include a summary of identified material weaknesses and non-conformances, and a plan for corrective action.

Deficiencies identified in the Center or Office of the Commissioner (OC) Office Individual Statements of Assurance that the Commissioner or other senior-level managers determine significant enough to be reported outside the agency (i.e., included in the agency's Annual Statement of Assurance) are considered a "**material weakness**" or, if the deficiency is directly related to the agency's financial systems, it is considered a "**material non-conformance**." A material weakness or material non-conformance is defined as a weakness that would significantly impair the fulfillment of the FDA's mission; deprive the public of needed services; violate statutory or regulatory requirements; significantly weaken safeguards against waste, loss, unauthorized use or misappropriation of funds, property or other assets; or result in a conflict of interest.

The designation of "material weakness" requires a judgment by the Commissioner or other senior-level managers that the relative risk and significance of the deficiency merits the attention of the HHS Secretary.

Likewise, the designation of "material non-conformance" requires a judgment by the Commissioner or other senior-level managers that the relative risk and significance of financial systems deficiencies merit the attention of the HHS Secretary.

Additionally, the Government Accountability Office (GAO) and the HHS Office of Inspector General (OIG) can make material weakness and/or

material non-conformance recommendations based on results of audits they conduct of agency programs and activities.

All **nonmaterial weaknesses** (i.e., less significant deficiencies) are to be reported internally and should be corrected and monitored at the Center or OC Office program level.

b. The **FDA FMFIA Coordinator** is responsible for overall FMFIA program management and administration. Specific duties of the FDA FMFIA Coordinator include:

(1) managing, coordinating, and developing FDA's FMFIA Annual Statements of Assurance

(2) developing and issuing FMFIA-related guidance to agency components, and working directly with all Centers and OC Offices to promote improved FMFIA processes and operations

(3) working with Centers and OC Offices in the development and monitoring of corrective action plans for the tracking of deficiencies, including material weaknesses

(4) serving as a standing member of the SAT

(5) collaborating and sharing FMFIA program information with the SAT

(6) maintaining and updating FDA's FMFIA web page

(7) providing training and orientation as needed to Center or OC Offices FMFIA liaisons and to FDA program managers

(8) reviewing and providing comment on guidance issued by organizations including HHS and OMB

(9) assisting Centers and OC Offices in developing, facilitating, reviewing, and revising Risk Assessments

(10) performing administrative or programmatic reviews as requested by the SAT.

2. Financial Systems Management.

Director, OFM. Responsible for submitting (through the FDA FMFIA Coordinator) an Annual Statement of Assurance under Section 4 of FMFIA on whether FDA's financial systems comply with the Federal Financial Management Improvement Act of 1996 (FFMIA) and meet OMB requirements

as stated in Appendix D Circular A-123. If the FDA systems do not conform, the statement must discuss plans for bringing the systems into compliance.

The FFMIA requires agencies to have financial management systems that substantially comply with federal financial management systems requirements, standards promulgated by the Federal Accounting Standards Advisory Board (FASAB), and the United States Standard General Ledger (USSGL) at the transaction level. FFMIA requires that agency's financial management systems have general and application controls in place in order to support management decisions by providing timely and reliable data. The agency head must make a determination annually about whether the agency's financial management systems substantially comply with the FFMIA. If the systems are found not to be compliant, management is required to develop a remediation plan to bring those systems into substantial compliance. Management must determine whether non-compliances with FFMIA should also be reported as non-conformances under Section 4 of FMFIA.

3. Component Organization Program Management.

a. Center Directors, Associate Commissioner for Regulatory Affairs, and designated OC Office Directors.

Responsible for:

(1) planning, managing and coordinating internal control activities for their respective organizations

(2) submitting to the FDA FMFIA Coordinator, an Annual Statement of Assurance to provide reasonable assurance that resources are protected from waste, fraud, and mismanagement, programs have been evaluated periodically to assure compliance with applicable laws and regulations, and Center or OC Office activities are being managed in an effective and efficient manner

(3) reporting any deficiencies to the FDA FMFIA Coordinator as soon as identified, submitting a corrective action plan to the FDA FMFIA Coordinator for approval, and preparing status reports for inclusion in the Annual Statement of Assurance

(4) developing and submitting the Center or OC Office Risk Assessment which ties to the Individual Statement of Assurance

(5) assisting in administrative and programmatic reviews as required by the SAT.

b. FDA Managers (at all levels). Responsible for:

(1) providing quality and timeliness of program performance

(2) tracking effectiveness and efficiency of program and administrative activities

(3) controlling costs and mitigating adverse aspects of agency operations

(4) assuring that programs are managed with integrity and in compliance with applicable laws and regulations

(5) establishing and maintaining adequate controls over resources entrusted to them

(6) monitoring and improving the effectiveness of internal controls associated with their programs and operations.

c. FMFIA Liaisons. Responsible for:

(1) providing internal direction and guidance to their respective Center or OC Office component on FMFIA policies and procedures

(2) coordinating the Individual Statement of Assurance and Risk Assessment process within their respective Center or OC Office component

(3) directing or conducting FMFIA activities within their components

(4) submitting information regarding FMFIA activities to the FDA FMFIA Coordinator, as requested

(5) monitoring and tracking corrective actions to ensure that deficiencies are corrected

(6) maintaining communication with the FDA FMFIA Coordinator on all matters relating to FMFIA.

4. AUTHORITIES AND REFERENCES.

A. Attachment A:

Federal Managers' Financial Integrity Act of 1982 (P.L. 97-255) as codified in 31 U.S.C. 3512 identifies the internal accounting and administrative requirements for each Federal agency as directed by the Comptroller General.

http://www.whitehouse.gov/omb/financial/fmfia1982.html

B. Attachment B:

Revised OMB Circular A-123, dated December 21, 2004 identifies requirements to improve accountability and effectiveness of the Federal Government's programs and operations by establishing, assessing, correcting and reporting on internal controls.

http://www.whitehouse.gov/omb/circulars/a123/a123_rev.html

C. Attachment C:

OMB Circular A-123, Appendix B provides requirements for agencies to reduce the risk of fraud, waste, and error in government charge card programs.

http://www.whitehouse.gov/sites/default/files/omb/assets/agencyinformation_circulars_pdf/a123_appendix_b.pdf

D. Attachment D:

OMB Circular A-123, Appendix C provides clarification and requirements to agencies for effective measurement and remediation of improper payments.

http://www.whitehouse.gov/sites/default/files/omb/assets/a123/a123_appx-c.pdf

E. Attachment E:

OMB Circular A-123, Appendix D provides requirements for agencies to comply with the Federal Financial Management Improvement Act of 1996.

http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-23.pdf

F. Attachment F:

HHS A-123 Assessment Guidance outlines the guidance and activities required by FDA in order to comply with OMB Circular A-123.

http://www.whitehouse.gov/sites/default/files/omb/assets/OMB/circulars/a123/a123_appx_a_implementation_guide.pdf

G. Attachment G:

GAO Standards for Internal Control in the Federal Government outlines the FMFIA requirements for the GAO to issue standards for internal control in government. The standards provide the overall framework for establishing and

maintaining internal control. They also establish a framework for identifying and addressing major performance and management challenges and the areas at greatest risk of fraud, waste, abuse, or mismanagement.

http://www.gao.gov/assets/670/665712.pdf

H. Attachment H:

GAO Internal Control Management and Evaluation Tool is intended to help management and evaluators determine how well an agency's internal control is designed. It may be helpful in the assessment of risk, as well as to determine what, where, and how internal control improvements, may be implemented.

http://www.gao.gov/new.items/d011008g.pdf

I. Attachment I:

SAT Charter

http://sharepoint.fda.gov/orgs/OC-OO-OFBA/OFM/A-123OFM/Shared%20Documents/A-123%20OFM%20Documentation%20Library/FY%202014/A-123%20SAT%20Materials/FDA%20A-123%20SAT%20Charter.pdf

5. EFFECTIVE DATE.

This policy is effective as of March 9, 2015.

6. DOCUMENT HISTORY. SMG 2350.1, Guidance for the Implementation of the Federal Managers' Financial Integrity Act (FMFIA)

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/16/2009	N/a	OC/OO/ OM/OFM	William C. Collison, Acting Director, OFM
Revision	07/03/2014	N/a	OFBA/OFO/ OFM	William Collinson, Director, Office of Financial Management
Revision	12/22/2014	N/a	OC/OO/ OFBA/OFM	William C. Collison, Director, OFM