

**SMG 1117A.645**

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of Operations**

**Office of Finance, Budget, Acquisitions, and Planning**

**Office of Planning, Evaluation, and Risk Management**

**Division of Enterprise Risk Management**

Effective: February 9, 2022

**1. Division of Enterprise Risk Management (DCNEDE).**

- A. Develops, , implement, and oversee the enterprise risk management program including the processes for identifying, assessing, prioritizing, mitigating, monitoring, and reporting on key risks that could impair the agency's ability to achieve its mission or goals.
- B. Collaborate with leadership of FDA components to promote effective governance of significant enterprise risks.
- C. Advise and inform FDA components, and leaders on risk management matters, as well as promote the consideration of risk management factors in budgetary, operational, and strategic decision-making.
- D. Oversee enterprise risks by FDA components in compliance with the Federal Managers Financial Integrity Act (FMFIA) and OMB Circular No. A-123 (Management's Responsibility for Enterprise Risk Management and Internal Controls).
- E. Monitor and report on progress FDA's progress in taking timely and appropriate corrective action to address recommendations identified on the FDA Risk Register/Profile.

**2. Authority and Effective Date.**

The functional statements for the Division of Enterprise Risk Management were approved by the Acting Commissioner of Food and Drugs on December 7, 2021, and effective on February 9, 2022.

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of Operations, Office of Finance, Budget, Acquisitions, and Planning, Office of Planning, Evaluation, and Risk Management, Division of Enterprise Risk Management organization structure depicting all the organizational structures reporting to the Director:

Division of Enterprise Risk Management (DCNEDE)