

**SMG 1121A.6**

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

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of Inspections and Investigations**

**Office of Business Informatics and Solutions Management**

Effective Date: May 13, 2024

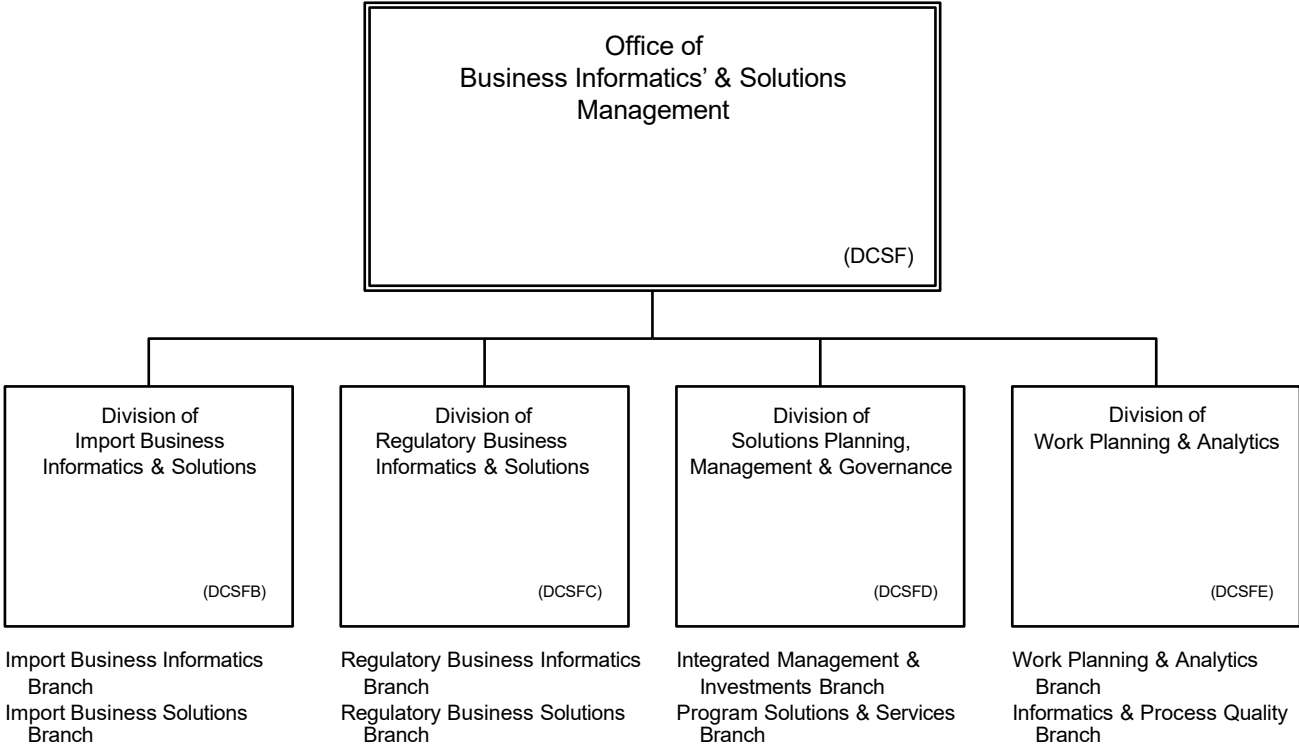
- 1. Office of Business Informatics and Solutions Management (DCSF).**
  - A. Provides advice and guidance to the Office of Inspections and Investigations (OII) leaders and other senior management officials on all matters related to the OII business informatics and solutions management needs and related budgetary needs.
  - B. Leads and coordinates business informatics and solutions management activities across OII. Partners with the Food and Drug Administration's (FDA's) Office of Digital Transformation (ODT) and the FDA organizations responsible for enterprise transformation to ensure alignment, coordination, and collaboration across the Centers and Offices.
  - C. Identifies, develops, evaluates, and prioritizes business needs in relation to current and planned business informatics and solutions, information technology (IT) systems, data models and standards, and reporting and visualization functions in partnership with internal clients in OII offices and programs, field organizations and laboratories, as well as partners external to OII including Centers and Offices.
  - D. Serves as the focal point for data requests and data calls associated with OII operational data emanating from OII mission critical systems.
  - E. Facilitates OII IT-related hardware and software requests and interactions with the ODT.
  - F. Translates business priorities into a single, organization-wide portfolio of business informatics and solutions initiatives that are delivered through strategic partnerships with ODT and FDA organizations responsible for enterprise transformation.

- G. Provides IT portfolio spend planning and budget support services for all acquisitions and discretionary spending accounts for OII Business Informatics and Solutions.
- H. Develops long-range strategic plans for OII's business informatics and solutions management, including coordinating with ODT, the FDA enterprise transformation organization, Centers and offices on technology infrastructure, equipment, data, and systems.
- I. Solicits internal and external feedback from OII and other FDA Centers and offices end-users to achieve efficiencies within business informatics and solutions and to ensure customer needs are met.
- J. Evaluates new policies and regulations for impacts to OII business informatics and solutions, and coordinates with ODT, and FDA organizations responsible for enterprise transformation, for technology infrastructure, equipment, data, and systems.
- K. Coordinates and manages OII's IT Investment Review Board (ITIRB) and Change Control Boards (CCBs). Manages OII's IT Investment Portfolio and provides Capital Planning and Investment Control (CPIC) functions to ensure that all business informatics and solutions initiatives are managed with sound life cycle management principles and practices consistent with FDA policies and procedures.

## **2. Authority and Effective Date.**

The functional statements for the Office of Business Informatics and Solutions Management were approved by the Secretary for Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services  
Food and Drug Administration  
Office of Inspections and Investigations  
Office of Business Informatics' and Solutions Management**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Business Informatics' and Solutions Management organization structure depicting all the organizational structures reporting to the Director:

Division of Import Business Informatics and Solutions (DCSFB)  
Division of Regulatory Business Informatics and Solutions (DCSFC)  
Division of Solutions Planning, Management and Governance (DCSFD)  
Division of Work Planning and Analytics (DCSFE)

These organizations report to the Division of Import Business Informatics and Solutions (DCSFB):

Import Business Informatics Branch  
Import Business Solutions Branch

These organizations report to the Division of Regulatory Business Informatics and Solutions (DCSFC):

Regulatory Business Informatics Branch  
Regulatory Business Solutions Branch

These organizations report to the Division of Solutions Planning, Management and Governance (DCSFD):

Integrated Management and Investments Branch  
Program Solutions and Services Branch

These organizations report to the Division of Work Planning and Analytics (DCSFE) :

Work Planning and Analytics Branch  
Informatics and Process Quality Branch