

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Information Systems Management

Division Import Systems Solutions

Effective Date: February 9, 2022

1. Division of Import Systems Solutions (DCIKB).

- A. Manages operational Information Technology (IT) systems supporting the Import Program of the Office of the Regulatory Affairs (ORA).
- B. Partners with the Office of Information Management and Technology (OIMT) to plan, implement, operate, and maintain systems that support the Imports Program for ORA as well as integrate such systems with other Food and Drug Administration (FDA) Centers and state regulatory and public health agency systems.
- C. Serves as a liaison to the Office of Information Management and Technology (OIMT) and the Department of Health and Human Services (DHHS) for the design, development, application, and implementation of operational business IT systems supporting the Import Program; analyzes, reviews and makes recommendations for modifications to existing systems; and proposes new business systems to meet ORA and its customers' requirements.
- D. Provides a customer-oriented IT support center, technical assistance and business process re-engineering activities for ORA business systems supporting Import operations.
- E. Develops scope of work and contractual mechanisms for execution of ORA IT projects supporting the Import Program working in conjunction with business sponsors, the Office of Acquisition and Grants (OAGS) and OIMT.

2. Import Data Management Branch (DCIKB1).

- A. Provides official data responses and ad hoc reports in response to data requests associated with data stored in ORA systems supporting the Import Program.
- B. Provides technical assistance and training to ORA staff associated with the generation of data and creation of reports associated with data stored in systems supporting the Import Program.
- C. Assists business in managing data stored in ORA systems natively or received from other systems through analysis of data quality and recommending solutions to resolve or to improve data quality of data stored in systems supporting the Import Program.
- D. Engages with the development and enhancement of systems to be aware of policies that drive data collection, data exchange implementations, changes to data content, and changes to data modeling, and to advise on and have awareness of development to conduct data reporting and analysis.
- E. Facilitates implementation of best practices for data collection, data exchange, querying, and governance of data structures in ORA systems supporting the Import Program.

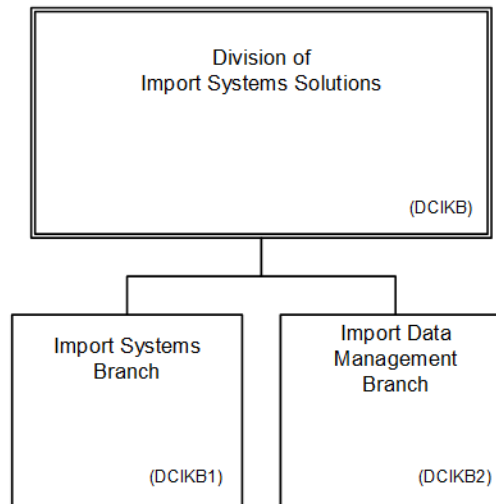
3. Import Systems Branch (DCIKB2).

- A. Serves as business leads and subject matter experts for ORA IT systems supporting import activities and processes.
- B. Conducts joint business planning with ORA and Center stakeholders to systematically assess and prioritize business needs for new functionality associated with import activities.
- C. Ensures processes and resources are in place to build, deploy, and support solutions supporting import activities.
- D. Supports adherence to policies and procedures for import operations through IT processes and development activities.

4. Authority and Effective Date.

The functional statements for the Division of Import Systems Solutions were approved by the Deputy Secretary for Health and Human Services on December 22, 2021, and effective on February 9, 2022.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Information Systems Management
Division of Import Systems Solutions**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Information Systems Management, Division of Import Systems Solutions organization structure depicting all the organizational structures reporting to the Director:

Import Systems Branch (DCIKB1)

Import Data Branch (DCIKB2)