

SMG 1114.10

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

OFFICE OF THE CHIEF SCIENTIST

OFFICE OF HEALTH INFORMATICS

Effective Date: July 22, 2015

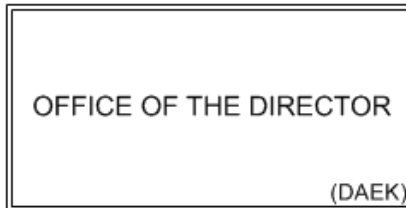
1. OFFICE OF HEALTH INFORMATICS (DAEK).

- A. Develops and implements health initiatives including: data harmonization and data exchange standards, data science and analytics, open data, knowledge management, research and development, and big data initiatives and activities.
- B. Captures, develops, coordinates, and effective uses of informatics-based organizational knowledge.
- C. Ensures a next generation open source informatics platform that allows collaboration of and fosters sharing of information and analytic tools pertaining to the Precision Medicine Initiative.
- D. Leads, researches and implements enterprise informatics solutions in support of the Agency regulatory mission.
- E. Ensures, coordinates and sponsors standards-based electronic data submission, brokering, storage, retrieval, analysis, and knowledge dissemination.
- F. Defines, advocates, and implements data exchange standards that are consistent with health information technology and the industry.
- G. Implements harmonized controlled vocabularies and data.
- H. Identifies and reviews electronic data sources (e.g. electronic medical records, data standards, novel data sources, etc.) for Agency's space in collaboration with Office of the National Coordinator (ONC), Centers for Medicare & Medicaid Services (CMS), other OPDIVs, and industry.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Acting Commissioner for Food and Drugs, and effective on July 22, 2015.

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The following is the Food and Drug Administration, Office of the Commissioner, Office of the Chief Scientist, Office of Health Informatics, organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DAEK)