SMG 1119A.1

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Chief Scientist

Effective Date: January 6, 2022

1. Office of the Chief Scientist (DCP).

A. Provides strategic leadership, coordination, and expertise to support scientific excellence, innovation and capacity to achieve the Food and Drug Administration's (FDA) public health mission.

B. Fostering development and use of innovative technologies to meet public health needs including health informatics.

C. Supporting scientific excellence and the professional development of FDA scientists in all areas (i.e. population/statistical, review, laboratory and manufacturing sciences), including through FDA-wide Fellowship and Traineeship Programs, continuing education, and scientific interactions with universities and others.

D. Providing strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and address important public health issues concerning FDA regulated products, including their evaluation, quality, safety and effectiveness.

E. Providing cross-agency scientific coordination (e.g., for emerging technologies, scientific issues involving multiple FDA components, standards coordination, the FDA Science Board, electronic data sources, and science communication).

F. Supporting scientific outreach, training, and collaboration, including research and development activities, that engage other Agencies, global regulatory partners, academia, innovators, and consumers.

G. Providing strategic leadership, coordination, and oversight for FDA's national and global health security and emerging threats portfolios including coordinating FDA's Medical Countermeasures Initiative (MCMi) to facilitate the development

and availability of safe and effective medical countermeasures against chemical, biological, radiological, and nuclear agents and emerging threats.

H. Providing core scientific leadership and technical expertise, and ensuring FDA capacity, for advanced bioinformatics activities needed to support FDA programs. Serve as an FDA and government resource for excellence, methods development, outreach and partnerships in advanced bioinformatics and health informatics science.

I. Leading FDA efforts to protect and enhance scientific integrity, and, where substantive scientific differences of opinion arise and require review at the FDA level, addressing them through appropriate processes intended to protect both FDA's mission and the integrity of its science.

J. Providing centralized oversight of all animal research activities and facilities under the FDA's purview.

K. Ensuring consistent operations of the FDA's advisory committee program.

L. Leading FDA in implementation of the Federal Technology Transfer Act and related legislation to foster scientific collaborations and partnerships that promote innovation and to translate FDA inventions into public health solutions through collaboration, patenting, and licensing.

2. Advisory Committee Oversight and Management Staff (DCP1)

A. Works in close collaboration with FDA Centers to ensure consistent operations within the FDA's advisory committee program.

B. Provides guidance and assistance on the establishment, staffing, and management of the FDA's advisory committees in order to obtain the best possible scientific advice to assist the FDA in meeting its public health mission.

C. Serves as the FDA liaison with the Office of the Secretary and the Department of Health and Human Services (DHHS) Committee Management Office on matters related to the FDA's advisory committees.

D. Ensures that all FDA advisory committee activities are consistent with the provisions of the Federal Advisory Committee Act, other applicable Federal laws, FDA and Departmental policies, and related guidances, regulations and statutes

3. FDA Technology Transfer Program Staff (DCP2)

A. Performs FDA-wide responsibility for managing, directing, and implementing the Stevenson-Wydler Technology Innovation Act of 1980 and its amendments, including the Federal Technology Transfer Act of 1986.

B. Using technology transfer authorities, establishes and maintains the frameworks and tools that FDA relies on to collaborate with external partners and enhance the regulatory science enterprise through innovation.

C. Provides for the best possible use of FDA inventions by translating these research outcomes into opportunities and products that improve public health.

D. Works in close collaboration with FDA Centers and Offices to ensure consistent application of HHS and FDA technology transfer policies and processes, in compliance with relevant laws and regulations.

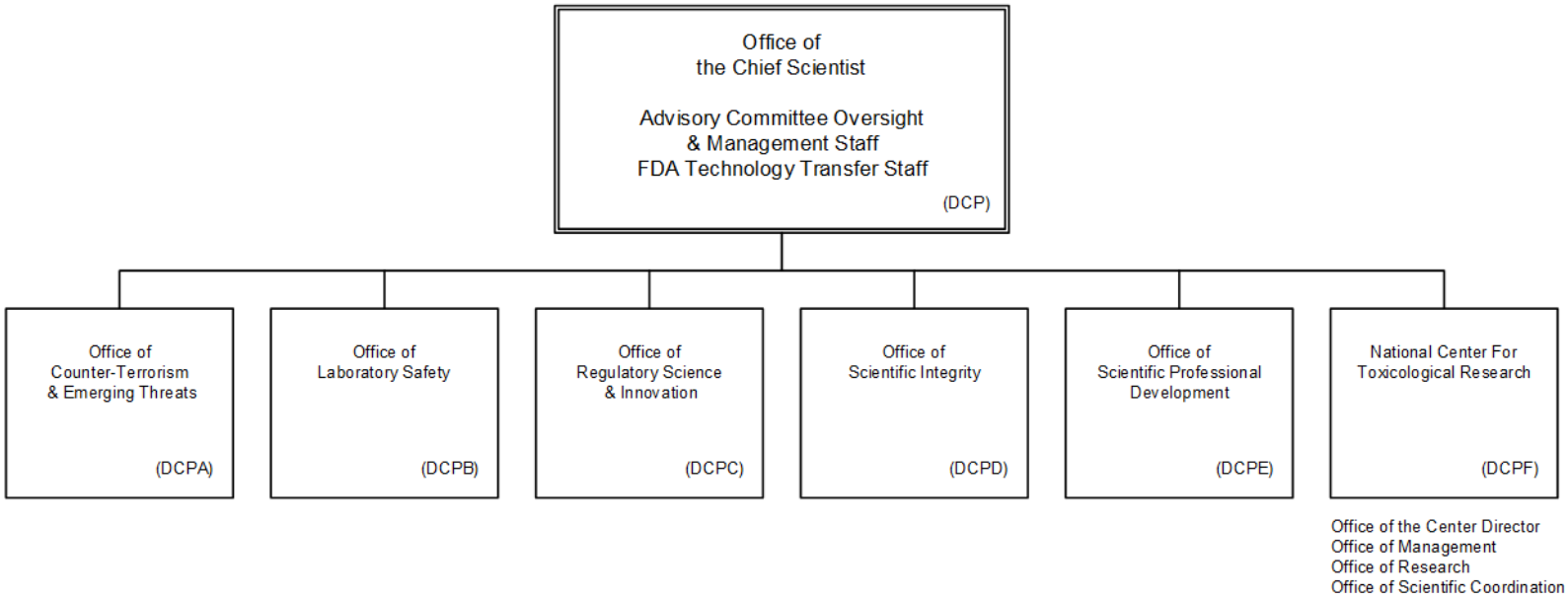
E. Provides intellectual property guidance for FDA; protects and manages the Agency's intellectual property portfolio.

F. Serves as FDA's liaison on technology transfer matters to HHS and its components, the Federal Laboratory Consortium, and the Interagency Working Group for Technology Transfer.

4. Authority and Effective Date.

The functional statements for the Office of the Chief Scientist were approved by the Deputy Secretary of Health and Human Services on October 22, 2022, and effective on January 6, 2022.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Scientist



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Scientist organization structure depicting all the organizational structures reporting to the Chief Scientist.

These organizations report to the Office of the Chief Scientist (DCP)

Advisory Committee Oversight & Management Staff

FDA Technology Transfer Staff

Office of Counter-Terrorism and Emerging Threats (DCPA)

Office of Laboratory Safety (DCPB)

Office of Regulatory Science and Innovation (DCPC)

Office of Scientific Integrity (DCPD)

Office of Scientific Professional Development (DCPE)

National Center for Toxicological Research (DCFE)

These organizations report to the National Center for Toxicological Research (DCFE)

Office of the Center Director

Office of Management

Office of Research

Office of Scientific Coordination