SMG 1261.1

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of the Center Director

Effective Date: December 14, 2018

1. Office of the Center Director (DCDA).

A. Promulgates, plans, administers, coordinates, and evaluates overall Center scientific, management, and regulatory programs, plans, and policies.

B. Provides leadership and direction for all Center activities.

C. Coordinates and directs the Center management, planning, and evaluation systems, to assure optimum utilization of Center Manpower, financial resources, and facilities.

Drug Safety Operations

1. Provides overall leadership, direction, planning, and policy formulation for Safety First.

2. Identifies, tracks, and oversees the management of important drug safety issues.

3. Adjudicates organizational disputes concerning the management of drug safety issues.

4. Establishes policies regarding management of drug safety issues in Center for Drug Evaluation and Research (CDER).

5. Tracks important emerging safety issues and ensures that they are resolved in a timely manner.

6. Oversees the Drug Safety Oversight Board (DSB) for the Center. The DSB ensures that CDER decisions about a drug's safety benefit from the input and perspective of experts within and outside Food and Drug Administration (FDA)

who have not been directly involved in the ongoing premarket evaluation or postmarket surveillance activities with respect to that drug.

2. Controlled Substance Staff (DCDA1).

A. Provides overall leadership, direction, and planning for all domestic and international drug scheduling and drug abuse issues.

B. Performs, under the Food, Drug and Cosmetic Act, the scientific and medical abuse liability review of drugs (opioids, stimulants, depressants, hallucinogens, cannabinoids, anabolic steroids), Investigational New Drug Applications (INDs), New Drug Applications (NDAs), and petitions submitted to the Agency. Performs the labeling review and provides guidance to the review divisions and sponsors regarding studies and the drug abuse and dependence section of the Prescribing Information for drugs with abuse liability.

C. Conducts, under the Controlled Substances Act (CSA), a scientific and medical evaluation (eight factor analysis) as to whether the drug or substance should be controlled or removed from control, for the Assistant Secretary for Health of the Department of Health and Human Services. Collaborates with the National Institute on Drug Abuse (NIDA) regarding the conduct of the eight factor analysis and the recommendation for scheduling.

D. Conducts reviews of Schedule I protocols submitted by researchers to the Drug Enforcement Administration (DEA) seeking to obtain a Schedule I research license. Provides estimates of U.S. medical needs for Schedule I and II substances annually to the DEA.

E. Provides scientific and regulatory leadership and guidance within CDER for activities related to interventions which may be used in a public health emergency (e.g., scheduling of a drug which poses an immediate threat to the public health, etc). Provides CDER with guidance and assists with the design and implementation of the plan to address the public health emergency regarding drug scheduling or the misuse or abuse of the drug.

F. Collaborates and serves as the FDA and CDER Liaison with other Government Agencies including DEA, Office of National Drug Control Policy, Substance Abuse and Mental Health Services Administration, NIDA, Centers for Disease Control, and the Department of State regarding all matters of drug scheduling and identification of new trends in abuse and dependence.

3. Professional Affairs and Stakeholder Engagement Staff (DCDA2).

A. Provides leadership and direction for developing, communicating, implementing and assessing an advocacy and stakeholder relations strategy for CDER

B. Creates and facilitates public and private collaborations within the healthcare community by serving as a neutral convener and Liaison for external (private and public) stakeholders regarding initiatives that are of interest to CDER.

C. Conducts research to ensure that CDER has a thorough understanding of partner, stakeholder, and public opinion about issues of interest to CDER.

D. Engages, leverages, and supports the public and private sector in collaborative efforts to address issues of interest to CDER, including preventable medication harm and/or safe medication use issues.

E. Manages and coordinates preventable harm and/or safe medication use projects across the FDA, Federal Agencies and other private and public sector stakeholders.

4. Counter-Terrorism and Emergency Coordination Staff (DCDA3).

A. Provides scientific and regulatory leadership within the CDER for the drug development initiatives relating to terror and military counter-terrorism measures. Fosters and facilitates the special drug development issues relating to counter-terrorism (CT) and force protection, such as animal models, and the development and labeling of drugs for chemical, biological, radiological and nuclear threat agents.

B. Provides consultation for the evaluation for safety and effectiveness for the approval of NDAs or biological license applications (BLAs) for CT and military use indications regulated by other Offices of the Center, and the evaluation of supplements that propose changes in the conditions upon which NDA approvals or BLA licensures are based.

C. Facilitates development of policy and procedures governing the review and evaluation of drug investigations and NDAs and BLAs for CT and military use indications regulated by the Center.

D. Coordinates and performs consulting medical and scientific evaluations of submission of generic drugs, and over-the-counter drug products for CT and military use indications regulated by other Offices in the Center.

E. Consults with the relevant Offices or Centers, represents the Agency as Liaison with external Agencies, other Federal and State programs, advisory and professional groups, and academic institutions.

F. Provides scientific and regulatory leadership within CDER for activities related to interventions which may be used in a public health emergency (e.g., pandemic influenza, and disasters) or to counteract the effects of a terrorist event. Provides

CDER with Emergency Preparedness Training Tools and assists in the design, education and implementation of an emergency plan for responding to terrorism or a public health emergency.

G. Interacts with organizations within CDER, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Veterinary Medicine, and the Office of the Commissioner; coordinates drug issues with external government agencies, such as Center for Disease Control and Prevention (CDC) the Department of Defense (DOD), the Department of Homeland Security, National Institutes of Health, and Health and Human Services' Office of Public Health Preparedness. Provides scientific and educational resources for counter-terrorism and emergency risk communication involving other Food and Drug Administration (FDA) scientists, the CDC, DOD, and other health care Agencies.

H. Identifies areas of unmet medical need related to medical countermeasures (i.e., whether drugs are approved and/or labeled for the specific intended use).

I. Collaborates with CDER's Drug Shortage Staff, assists in assuring the availability of vitally important drugs used to counteract/treat the effects of chemical, biological, radiological or nuclear threat agents or public health emergencies (e.g., pandemic influenza, and disasters).

J. Serves as CDER's point of contact (POC) for all interactions with the Strategic National Stockpile, as well as state, local, and other stockpiles.

K. Serves as initial POC for CDER for all incidents involving CDER-regulated products conveyed through FDA's Office of Emergency Operations. Serves as coordinator for inter-office meetings intended to identify, address, and mitigate the emergency safety issue(s) associated with CDER-regulated products.

I. Oversees the CDER Situation Room (CSR), including appropriate and adequate staffing when the CSR has been activated in response to an incident of national significance affecting CDER-regulated products, at the request of the Center Director or the Commissioner. Provides leadership in support of CDER's role in emergency response exercises (e.g., TOPOFF).

M. Assigns an Incident Commander from the Counter-Terrorism and Emergency Coordination Staff (CTECS) to coordinate Center responses for any incident of national significance requiring activation of the CSR, or of sufficient complexity so as to justify coordination by CTECS.

5. Drug Shortages Staff (DCDA4).

A. Receives reports of potential and actual shortages and shortage issues from outside stakeholders including industry, healthcare professionals, professional

organizations and patients as well as from other offices within FDA and evaluates whether a shortage or potential shortage exists based on historical market sales data and manufacturer data effective.

B. Utilizes all available FDA tools and coordinates efforts of FDA designated staff to address and prevent all shortages while prioritizing those that involve medically necessary drugs.

C. Develops policy and procedures governing the management and prevention of drug shortages.

D. Provides public communication regarding drug shortage issues, including maintaining an updated drug shortage list on the FDA website, developing communications and press pieces regarding shortages, providing targeted communications to stakeholders including professional associations and patient groups, responding to press and Congressional inquiries, and presenting at multiple national meetings.

E. Provides advice and information to other components of the Center, Agency, Department and other relevant parties on issues related to drug shortages.

F. Coordinates activities within the Center related to drug shortages. Provides advice to other components of the Agency, Department and other relevant parties on issues related to drug shortages.

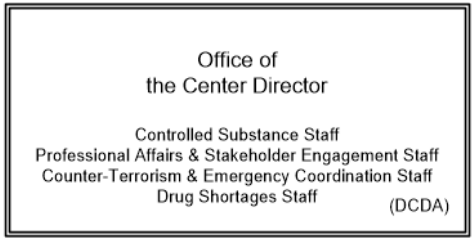
G. Coordinates activities, provides advice and information related to drug shortage activities to other components of the Center, Agency and the Department.

H. Develops, in coordination with other Agency components, guidance for staff, sponsors and the public that describes the Agency's interpretation of or policy on regulatory issues that involve drug shortages. Promulgates, plans, administers, coordinates, and evaluates overall Center scientific, management, and regulatory programs, plans, and policies.

6. Authority and Effective Date.

The functional statements for the Office of the Center Director were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of the Center Director



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of the Center Director organization structure depicting all the organizational structures reporting to the Director:

Office of the Center Director (DCDA).

These organizations report to the Office of the Center Director:
Controlled Substance Staff
Professional Affairs & Stakeholder Engagement Staff
Counter-Terrorism & Emergency Coordination Staff
Drug Shortages Staff

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