

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office of Ethics and Integrity

Effective Date: December 14, 2018

1. Office of Ethics and Integrity (DCNB).

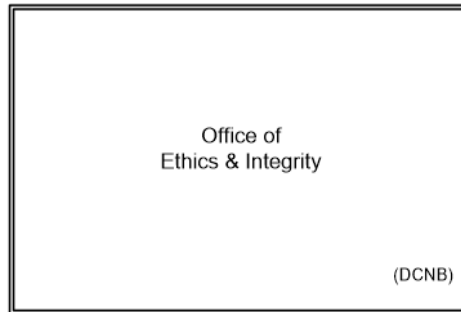
- A. Develops Food and Drug Administration (FDA) policy and procedures implementing the “Standards of Ethical Conduct for Employees of the Executive Branch” (5 C.F.R., Part 2635) including the Department of Health and Human Services (DHHS) supplemental regulations (5 C.F.R., Part 5501).
- B. Ensures employee compliance with Federal regulations relating to ethical conduct. Reviews, prepares, evaluates and secures appropriate approvals for waivers and other determinations regarding financial interest, conflict of interest and other ethical issues.
- C. Develops and conducts training for supervisors, managers, administrative staff, special government employees and other FDA employees.
- D. Provides oversight and direction to the FDA’s Advisory Committee program as it relates to special government employees.
- E. Assures that Conflict of Interest (COI) waivers are consistent, legally supportable, well-documented and timely. Evaluates cooperative agreements developed by FDA components under the Federal Technology Transfer Act and provides technical advice on any related conflict of interest matters.
- F. Provides advice to employees to ensure compliance with applicable regulations and statutes on the following: (1) “Standards of Ethical Conduct for Employees of the Executive Branch” (5 C.F.R., Part 2635); (2) “Supplemental Standards of Conduct for Employees of the Department of Health and Human Services” (5 C.F.R., Part 5501); (3) “Executive Branch Financial Disclosure, Qualified Trusts, Certificates of Divestiture” (5 C.F.R., Part 2634); and (4) Criminal Conflict of Interest Statutes – Chapter 11 – Bribery, Graft, and Conflicts of Interest (Chapter 11 of Title 18 U.S.C.).

- G. Serves as Liaison with other FDA components and the DHHS Office of General Counsel/Ethics Division to develop co-sponsorship agreements.
- H. Provides executive and administrative support to the Conflict of Interest Review Board. Coordinates activities, makes recommendations, and implements decisions including advising affected employees of Boards final determinations.

2. Authority and Effective Date.

The functional statements for the Office of Ethics and Integrity 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
Office of Operations
Office of Ethics and Integrity**



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

Office of Ethics and Integrity (DCNB)