

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

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

OFFICE OF THE CHIEF SCIENTIST

OFFICE OF SCIENTIFIC INTEGRITY

Effective Date: 07/08/2011

1. OFFICE OF SCIENTIFIC INTEGRITY (DAEH)

- A. Develops and implements policies to promote and protect scientific integrity throughout all of FDA's activities and organizational components.
- B. Helps ensure consistent understanding, application and implementation of regulatory standards throughout FDA to ensure integrity and accountability of FDA functions and processes.
- C. Advises and assists senior FDA leadership in coordinating responses to allegations of patterns of deviations by FDA or its components from appropriate standards of conduct and performance. Also advises and assists senior FDA leadership in preventing such deviations.
- D. Investigates and facilitates resolution of informal complaints and disagreements, whether generated internally or externally, with respect to the administrative processing of various applications for products regulated by the Agency as well as regarding the fair and even-handed application of Agency policy and procedures in this process.
- E. Processes all formal appeals, or requests for review, that are submitted to the Office of the Commissioner, whether generated internally or externally, including requests for hearings, appeals from administrative actions, and requests to review decisions at a lower level of the agency. Examples include, but are not limited to, requests to review decisions by the Centers, the Office of Regulatory Affairs, and elsewhere in the Office of the Commissioner under 21 CFR 10.75, appeals of formal or informal hearings, and agency-level scientific dispute resolution matters.
- F. Advises and assists the Chief Scientist and senior leadership in evaluating and resolving all formal appeals, requests for review, and requests for

hearings submitted to the Office of the Commissioner and coordinates responses to such appeals and requests.

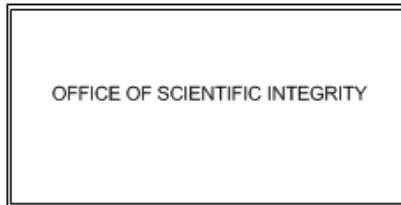
- G. Develops regulations and procedures to promote an efficient and effective process for addressing and resolving formal appeals, requests for review, and requests for hearings, as well as any other types of disputes suitable for formal resolution in the Office of the Commissioner.
- H. Determines whether an informal complaint should be construed and treated as a request for formal review by the Office of the Commissioner under established regulations or procedures.
- I. Oversees and directs the Agency's ombudsman and appeals to ensure coherence in decision making and the efficient operation of these functions internally and across Agency.

2. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Secretary of Health and Human Services, effective July 8, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	08/07/2009	N/a	OC/OA/OM/ OBOHCP/OMP	Secretary of the Department of Health and Human Services
Revision	07/08/2011	N/a	OO/OM	Secretary of the Department of Health and Human Services

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

OFFICE OF SCIENTIFIC INTEGRITY