

SMG 1118A.3

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of Policy, Legislation and International Affairs

Office of Economics and Analysis

Effective Date: December 14, 2018

1. Office of Economics and Analysis (DCOB).

- A. Advises and assists the Commissioner and other key Food and Drug Administration (FDA) officials concerning the performance of the FDA economic analysis activities.
- B. Conducts operations research, economic, social science, and special studies as a basis for forecasting trends, needs, and major problems requiring solutions, and provides assistance and consultation in these areas to operating units.
- C. Evaluates impact of external factors on FDA programs, including industry economics, consumer expectations, and prospective legislation. As necessary, recommends new programs or changes in existing programs and program priorities.

2. Economics Staff (DCOB1)

- A. Performs economic analyses and special studies for use by FDA officials in decisions regarding FDA policies.
- B. Serves as the FDA's chief resource for economic information.
- C. Collects and interprets economic data relevant to the FDA's public- health mission.
- D. Performs and reviews benefit-cost and cost-effectiveness analyses of FDA regulations.

- E. Advises and assists the Commissioner and other key FDA officials on a day to day basis concerning economic factors relating to current and proposed FDA activities.
- F. Provides economic research material for use by FDA officials in preparing testimony before congressional committees and in developing replies to inquiries directed to the FDA.
- G. Conducts economic studies of FDA related industries as a basis for forecasting trends, needs, and major problems affecting the FDA.
- H. Provides FDA representation to Congress, Office of Management and Budget (OMB), Department of Health and Human Services (DHHS), and others, as appropriate, on economic issues relating to FDA regulations and other current and proposed actions.

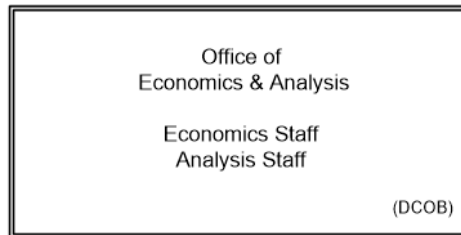
3. Analysis Staff (DCOB2)

- A. Acts as Office of the Commissioner and FDA resource for quantitative research and analysis on emerging issues, including helping to develop policy options and understanding the expected impact of those options on public health outcomes.
- B. Advances and informs work on priority public health and policy initiatives and issues at the request of the Commissioner or Deputy Commissioner.
- C. Works with the appropriate FDA experts to provide strategic thinking and leadership with respect to management of Government Accountability Office (GAO) and Office of the Inspector General (OIG) studies, and ensures that GAO and OIG engage with the appropriate FDA experts and receive accurate and timely information in response to their requests.
- D. Provides study teams with strategic advice on how to articulate FDA's message in response to GAO and OIG reports most effectively.
- E. Updates the status of the FDA's implementation of GAO/OIG recommendations.

4. Authority and Effective Date.

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

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Food and Drug Administration
Office of the Commissioner
Office of the Policy, Legislation and International Affairs
Office of Economics and Analysis**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Policy, Legislation and International Affairs, Office of Economics and Analysis organization structure depicting all the organizational structures reporting to the Director.

These Organizations report to the Office of Economics and Analysis (DCOB):

- Economics Staff
- Analysis Staff