

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

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

OFFICE OF EXTERNAL AFFAIRS

OFFICE OF HEALTH AND CONSTITUENT AFFAIRS

Effective Date: 02/27/2013

1. OFFICE OF HEALTH AND CONSTITUENT AFFAIRS (DAUC).

- A. Advises the Commissioner and other key FDA officials on matters related to patients, patient advocacy, health professionals, consumers, State and Federal activities and industry issues.
- B. Assists in the planning, administration, development, and evaluation of Food and Drug Administration (FDA) policies related to patient advocacy and health professional organizations, consumers, States, industry on serious and life-threatening issues.
- C. Serves as a Liaison between FDA and stakeholder organizations to educate various constituents on FDA related issues and activities.
- D. Provides internal coordination on FDA activities related to patient advocacy, health professional organizations, consumer groups, State organizations and industry groups on high-priority topics such as serious and life-threatening diseases, imminent public health needs and other special health issues.
- E. Serves as a focal point to coordinate contacts and activities between FDA and other Federal Agencies to ensure effective coordination and communication regarding issues related to FDA public health priorities such as serious and life-threatening diseases and other special health issues.
- F. Coordinates and implements policies, programs, and initiatives related to MedWatch including the MedWatch web pages, E-list, Rich Summary Site (RSS) feed, and Twitter account.
- G. Informs patients, patient advocates and health professional organizations

of upcoming public meetings and policy issues of importance to them and allows them opportunity to comment on proposed rules.

- H. Assures that patient perspectives are taken into consideration during drug development and policy issues through the patient representative and patient consultant programs. Supports active participation of these groups in forming FDA regulatory policy to assure the Agency's decisions are based upon a full range of perspectives.
- I. Administers MedWatch, the FDA safety information and adverse event reporting program, also provides education and information on FDA's key responsibilities particularly, the drug approval process, clinical trial design, and expanded access to investigational therapeutic products.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner of Food and Drugs on February 27, 2013.

**FOOD AND DRUG ADMINISTRATION
OFFICE OF THE COMMISSIONER
OFFICE OF EXTERNAL AFFAIRS
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OFFICE OF THE DIRECTOR

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The following is the Food and Drug Administration, Office of the Commissioner, Office of External Affairs, Office of Health and Constituent Affairs organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR