

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

FOOD AND DRUG ADMINISTRATION

OFFICE OF FOODS AND VETERINARY MEDICINE

**OFFICE OF COORDINATED OUTBREAK RESPONSE AND EVALUATION
NETWORK**

Effective Date: October 1, 2012

**1. OFFICE OF COORDINATED OUTBREAK RESPONSE AND EVALUATION
NETWORK (DJJB).**

- A. Provides leadership and direction for FDA outbreak activities including preparedness, response, environmental assessments and post response activities associated with FDA-regulated human and animal food, dietary supplements, and cosmetics.
- B. In conjunction with other Agency components, prioritizes efforts, directs resources and provides guidance to the field on investigational activities associated with outbreaks related to FDA-regulated human and animal food, dietary supplements, and cosmetics.
- C. Reviews and analyzes information for the early recognition of outbreaks associated with FDA-regulated human and animal food, dietary supplements, and cosmetics. Ensures findings, pertinent data and recommendations are incorporated into prevention-based regulatory efforts.
- D. Collaborates with federal, state, local, and tribal partners and non-governmental stakeholders to support outbreak preparedness, response, environmental assessments and post response activities as part of an integrated food safety system.
- E. Develops and coordinates communication materials and outreach activities related to outbreak preparedness, response, environmental assessments and post response activities with federal, state, local tribal partners, non-governmental stakeholders, and the public.

2. PREVENTION STAFF (DJJB1).

- A. Gathers historical data on forborne pathogens/outbreaks.

- B. Provide all needed data and background information required to initiate response activities and propose appropriate response strategies.
- C. Directs other FDA units in surveillance and trending activities for both human and animal foods and seek to leverage assistance from other FDA units.
- D. Partners with CVM to evaluate incoming information to determine whether there are incidents on which CORE should focus.
- E. Partner with CDC for data gathering needs/requests and trends analysis from the PFGE databases and other databases.
- F. Makes determination whether environmental assessments (EAs), root cause analyses and other activities will be conducted during or after an outbreak.
- G. Prepares and communicates findings from select outbreaks and incident summary closeout reports for each incident handled by CORE.

3. RESPONSE STAFF (DJJB2).

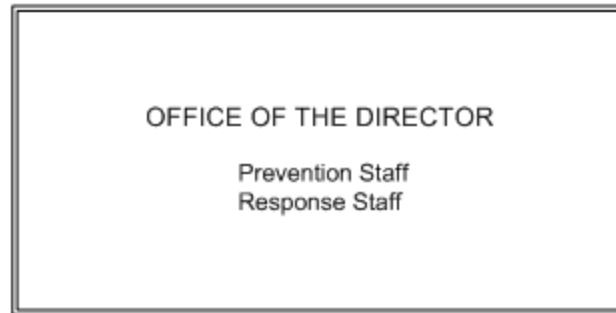
- A. Coordinates outbreak actions with the Centers and the Districts. Provides leadership and direction for all outbreaks within its responsibilities.
- B. Coordinates information flow across organizations during response efforts.
- C. Manages communication with the field and initiates assignments in relation to outbreak response, unless OEO/IMG is managing the outbreak.
- D. Responsible for preparing strategic incident plans in consultation with regulatory stakeholders.
- E. Coordinates with Prevention Staff, the selection of outbreaks for environmental assessments and other activities.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary for Health and Human Services, effective October 1, 2012.

Staff Manual Guide 1160.20
Organizations and Functions
Effective Date: October 1, 2012

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The following is the Food and Drug Administration, Office of Foods and Veterinary Medicine, Office of Coordinated Outbreak Response and Evaluation Network, organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Prevention Staff
- Response Staff