

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

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

OFFICE OF REGULATORY SCIENCE

OFFICE OF FOOD AND FEED LABORATORY OPERATIONS

Effective: June 6, 2016

A. OFFICE OF FOOD AND FEED LABORATORY OPERATIONS (DLLRKC).

- A. Advises the Director on scientific issues related to food and feed laboratory operations.
- B. Provides strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and address important public health issues concerning FDA regulated products, including their evaluation, quality, safety and effectiveness.
- C. Fosters development and use of innovative technologies to meet public health needs.
- D. Advises the Director concerning the management of the ORA's field scientific resources (including national experts) to assure their coordinated, efficient, and effective use.
- E. Collaborates with other international, Federal, State and local partners in the development of policies and procedures to assure capacity for analytical testing of foods and feed in emergency situations, i.e., FERN.

2. FOOD AND FEED SCIENTIFIC STAFF (DLLRKC1).

- A. Works with appropriate Centers and other stakeholders to establish and execute strategic and tactical plans for the effective use of ORA science resources relative to foods and feed.
- B. Provides day to day subject matter expertise and technical support and service to ORA laboratories relative to foods and feed.

- C. Serves as subject matter experts in the development of new or modified scientific and analytical compliance policies and regulatory procedures for all foods and feed regulated by the Agency.
- D. Participates in the development and maintenance of and/or oversees global laboratory networks and sample surveillance and data collection programs.
- E. Serves as subject matter experts for the development and delivery of foods program related laboratory training.
- F. Leads in the development, implementation and maintenance of laboratory accreditation standards and oversight programs.
- G. Reviews and clears appropriate sections in food program compliance programs and assignments.
- H. Represents ORA on internal and external working groups, committees, task forces etc in area of program and product responsibility.

3. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Secretary for Health and Human Services and effective on June 6, 2016.

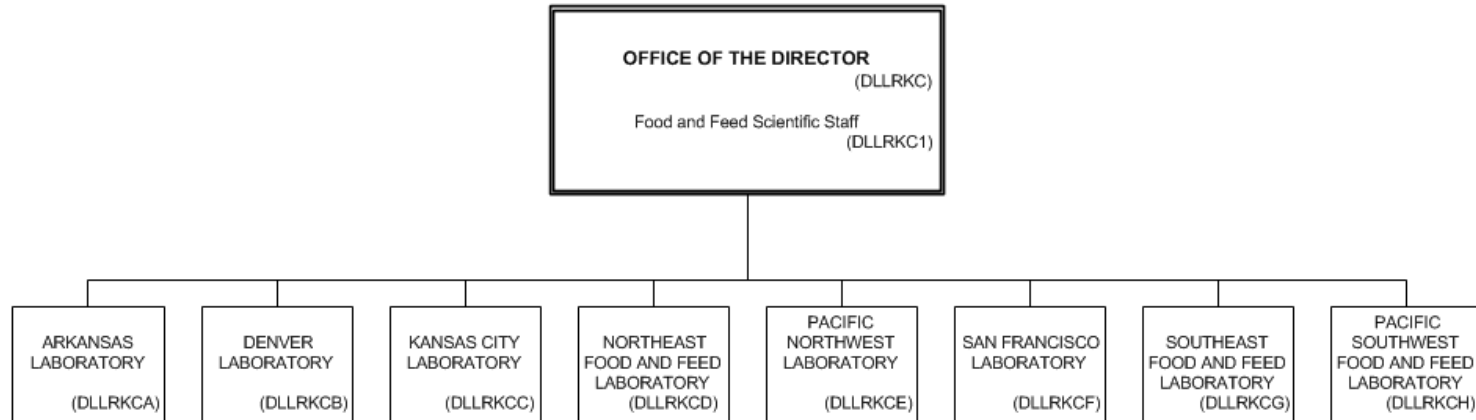
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ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: June 6, 2016

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Regulatory Science, Office of Food and Feed Laboratory Operations organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DLLRKC):

- Food and Feed Scientific Staff (DLLRKC1)
- ARKANSAS LABORATORY (DLLRKCA)
 - Chemistry Branch I (DLLRKCA1)
 - Chemistry Branch II (DLLRKCA2)
 - Microbiology Branch (DLLRKCA3)
- DENVER LABORATORY (DLLRKCB)
 - Chemistry Branch (DLLRKCB1)
 - Microbiology Branch (DLLRKCB2)
- KANSAS CITY LABORATORY (DLLRKCC)
 - Chemistry Branch I (DLLRKCC1)
 - Chemistry Branch II (DLLRKCC2)
- NORTHEAST FOOD AND FEED LABORATORY (DLLRKCD)
 - Chemistry Branch I (DLLRKCD1)
 - Chemistry Branch II (DLLRKCD2)
 - Microbiology Sciences Branch (DLLRKCD3)
- PACIFIC NORTHWEST LABORATORY (DLLRKCE)
 - Chemistry Branch (DLLRKCE1)
 - Microbiology Branch (DLLRKCE2)

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- Applied Technology Branch (DLLRKCE3)
- SAN FRANCISCO LABORATORY (DLLRKCF)
 - Chemistry Branch (DLLRKCF1)
 - Microbiology Branch (DLLRKCF2)
- SOUTHEAST FOOD AND FEED LABORATORY (DLLRKCG)
 - Microbiology Branch (DLLRKCG1)
 - Nutrient Analysis Branch (DLLRKCG2)
 - Chemistry Branch (DLLRKCG3)
- PACIFIC SOUTHWEST FOOD AND FEED LABORATORY (DLLRKCH)
 - Chemistry Branch (DLLRKCH1)
 - Microbiology Branch (DLLRKCH2)