SMG 1316.5

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 OPERATIONS

REGIONAL FIELD OFFICE, PACIFIC REGION – OAKLAND, CA

PACIFIC REGIONAL LABORATORY SOUTHWEST – IRVINE, CA

Effective Date: 08/07/2012

1. PACIFIC REGIONAL LABORATORY SOUTHWEST – IRVINE, CA (DLLRPD).

A. Plans, schedules, and controls laboratory operations; and formulates, implements, and coordinates domestic and import analytical laboratory work plans and schedules with district offices being serviced.

B. Conducts laboratory analysis of samples to:

1. Assess each sample's compliance with applicable laws and regulations enforced by the Agency;

2. Determines the extent to which findings provide evidence of violative conditions and practices; and

3. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.

C. Provides evidence regarding analytical findings as requested.

D. Conducts research to develop and refine methodology used in the analysis of samples and explore new techniques and systems of analysis.

E. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to products regulated by the Agency.

F. Serves as a resource in scientific knowledge and provides expert-advice and training regarding laboratory techniques and technological developments to other Federal agencies, State and local agencies, foreign counterpart agencies, and industry.

G. Provides assistance to districts, as requested, in the conduct of complex inspections requiring an in-depth knowledge of laboratory techniques and practices and potential causes of adulteration.

H. Serves as national resource for analyses requiring complex electronic spectrophotometric, mass spectroscopic and other instrumental analyses.

I. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

J. Implements an effective internal quality assurance program.

K. Provides management support for program and operational activities, including-all phases of personnel management, financial management, management of facilities, services, property, and supplies. ¬

L. Maintains working liaison with other Federal offices-providing support services to the Agency.

M. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.

2. FOOD CHEMISTRY BRANCH (DLLRPD1).

A. Performs laboratory analyses and examinations of samples of food, feed and ceramic-ware to assess each sample's compliance with applicable laws and regulations enforced by the Agency; and to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.

B. Conducts research to develop and refine methodology used in the analysis of samples and to explore new techniques and systems of analysis.

C. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to food chemistry analyses.

D. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, and to State, local and foreign counterpart agencies, and to industry.

E. Provides court testimony regarding analytical findings as requested.

F. Plans, schedules, and controls branch operations to formulate, implement, and coordinate work plans for districts serviced nationally and within the region when these operations relate to the branch.

G. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated food, feed and ceramic-ware.

H. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

I. Maintains an effective internal quality assurance program.

3. DRUG CHEMISTRY BRANCH (DLLRPD2).

A. Performs laboratory analyses and examinations of samples of human and veterinary drug, biological, and medical device products to assess each sample's compliance with applicable laws and regulations enforced by the Agency; and to assess the extent to which reconditioning, reprocessing, and re-labeling actions have brought violative commodities into compliance.

B. Conducts research to develop and refine methodology used in the analysis of samples and to explore new techniques and systems of analysis.

C. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to drug, .biological, and medical device analyses.

D. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, and to State, local and foreign counterpart agencies, and to industry.

E. Provides court testimony regarding analytical findings as requested.

F. Plans, schedules, and controls branch operations to formulate, implement, and coordinate work plans for districts serviced nationally and within the region when these operations relate to the branch.

G. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated food, feed and ceramic-ware.

H. Tests, for purposes of validation, methods submitted by industry as part of a New Drug Application or Abbreviated New Drug Application, and provides a report of evaluation and technical comments on any deficiencies found.

I. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

J. Maintains an effective internal quality assurance program.

4. MICROBIOLOGY BRANCH (DLLRPD3).

A. Performs laboratory analyses and examinations of samples in order to assess each sample's compliance with applicable laws and regulations enforced by the Agency.

B. Conducts research to develop and refine methodology used in the analysis of samples and to explore new techniques and systems of analysis.

C. Serves as a resource in scientific knowledge, laboratory methodology, and techniques applicable to solving field problems pertinent to microbiology analyses.

D. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, and to State, local and foreign counterpart agencies, and to industry:

E. Provides court testimony regarding analytical findings as requested

F. Plans, schedules, and controls branch operations to formulate, implement, and coordinate work plans for districts serviced nationally and within the region when these operations relate to the branch,

G. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

H. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated food, feed and ceramic-ware.

I. Maintains an effective internal quality assurance program.

5. AUTHORITY AND EFFECTIVE DATE

The functional statements for this District Office were approved by the Commissioner of Food and Drugs, effective August 7, 2012.

FOOD AND DRUG ADMINISTRATION
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY
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PACIFIC REGIONAL LABORATORY SOUTHWEST

PACIFIC REGIONAL
LABORATORY SOUTHWEST
IRVINE, CA
Food Chemistry Branch
Drug Chemistry Branch
Microbiology Branch

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The following is the Food and Drug Administration, Office of Regulatory Affairs, Regional Field Office, Pacific Region, Oakland, CA, Pacific Regional Laboratory Southwest, Irvine, CA organization structure depicting all the organizational structures reporting to the Office of the Director.

PACIFIC REGIONAL LABORATORY SOUTHWEST – IRVINE, CA:

- Food Chemistry Branch
- Drug Chemistry Branch
- Microbiology Branch