SMG 1121.925

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Regulatory Science

Office of Medical Products, Tobacco and Specialty Laboratory Operations

Pacific Southwest Medical Products Laboratory

Effective Date: December 14, 2018

1. Pacific Southwest Medical Products Laboratory (DCIFBE).

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:

C. Assess each sample's compliance with applicable laws and regulations enforced by the Food and Drug Administration (FDA);

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

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

D. Provides evidence regarding analytical findings as requested.

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

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

G. 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.

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

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

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

K. Conducts reviews of data provided from contract, state, and private laboratories in support of Office of Regulatory Affairs (ORA's) regulatory mission.

L. Implements an effective internal quality assurance program.

M. Maintains working liaison with other Federal offices-providing support services to the FDA.

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

2. Authority and Effective Date.

The functional statements for the Pacific Southwest Medical Products Laboratory were approved by the Secretary for Health and Human Services and effective on December 14, 2018.

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Science, Office of Medical Products, Tobacco and Specialty Laboratory Operations, Pacific Southwest Medical Products Laboratory organization structure depicting all the organizational structures reporting to the Director:

Pacific Southwest Medical Products Laboratory (DCIFBE)

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