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FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of the Chief Scientist

Office of Analytical Regulatory Laboratories

Irvine Medical Products Laboratory

Effective Date: May 13, 2024

1. Irvine Medical Products Laboratory (DCPJB).

A. Manages and evaluates program activities, measures accomplishments against annual work-plan objectives, initiates management and program analyses, manages a quality assurance program, and advises the Office of Analytical Regulatory Laboratories regarding strategy changes needed to reach existing or modified objectives.

B. Coordinates emergency activities by maintaining liaison with other federal agencies and by providing assistance to States and localities in the event of a national disaster or other emergency.

C. Plans, schedules, and controls laboratory operations; and formulates, implements, and coordinates analytical workplans with the Food and Drug Administration (FDA) Centers and Offices being supported.

D. Conducts laboratory analysis of samples to:

   a. Assess compliance of each sample with laws and regulations enforced by FDA.

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

E. Provides evidence regarding analytical findings as requested.

F. Conducts research and participates in collaborative studies to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.

G. Serves as a resource in scientific knowledge and provides expert advice and training regarding laboratory techniques and technological developments to FDA Centers and Offices, other federal agencies, state and local agencies, foreign counterpart agencies, industry, and academic institutions.

H. Provides assistance to FDA Centers and 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. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

J. Provides analytical support to other FDA Centers and Offices as needed.

K. Coordinates the Equal Employment Opportunity, internal security, safety, and emergency preparedness programs.

L. Implements an effective internal quality assurance program to assure the reliability of analytical results.

2. Authority and Effective Date.

The functional statements for the Irvine Medical Products Laboratory were approved by the Secretary of Health and Human Services on March 5, 2024 and effective on May 13, 2024.

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of the Chief Scientist, Office of Analytical and Regulatory Laboratories, Irvine Medical Products Laboratory organization structure depicting all the organizational structures reporting to the Director: