SMG 1121.924

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

Northeast Medical Products Laboratory

Effective Date: December 14, 2018

1. Northeast Medical Products Laboratory (DCIFBD).

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

B. Maintains an effective internal quality assurance program (17025 accredited).

C. Conducts laboratory testing and analysis of samples for the Food and Drug Administration (FDA) field offices, as requested, to:

1. Assess their compliance with applicable laws and regulations enforced by the FDA;

2. Determine 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.

D. Provides evidence regarding analytical findings as requested.

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

F. Serves as an Office of Regulatory Science (ORS) 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, academia, and industry.

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

H. Serves as a national resource for drug analyses.

I. Performs laboratory analyses and examination of samples which are collected by field offices. They analyze the samples to assess each one's compliance with laws and regulations enforced by the FDA; and if applicable, to assess the extent to which reconditioning, reprocessing, and relabeling actions have brought violative commodities into compliance.

J. Tests, for purposes of violation, 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.

K. Conducts research and participate in collaborative studies to develop and refine methodology used in the analysis of drug samples and to explore new techniques and systems of analysis.

L. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated drug and medical device products.

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

N. Provides court testimony regarding analytical findings as requested.

O. Maintains liaison with scientists and scientific institutions, with interest pertinent to laboratory activities.

2. Authority and Effective Date.

The functional statements for the Northeast 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, Northeast Medical Products Laboratory organization structure depicting all the organizational structures reporting to the Director:

Northeast Medical Products Laboratory (DCIFBD)

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