SMG 1121.222

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 Medical Products and Tobacco Operations

Office of Pharmaceutical Quality Operations

Division of Foreign Pharmaceutical Quality Inspections

Effective Date: December 14, 2018

1. Division of Foreign Pharmaceutical Quality Inspections (DCIGBB).

A. Oversees all foreign Food and Drug Administration (FDA) field inspection operations related to pharmaceutical products, including all pharmaceutical and biopharmaceutical products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM).

B. Serves as subject matter experts on foreign operations relative to the pharmaceutical quality program on internal cross-FDA committees, workgroups and task forces.

C. Manages and evaluates resources to assure pharmaceutical program accomplishments.

D. Manages and evaluates foreign pharmaceutical program activities, measures accomplishments against annual pharmaceutical program objectives, and advises the Office Director regarding strategy changes needed to reach objectives.

E. Implements decisions relative to pharmaceutical product investigatory operations involving foreign facilities, including emergency response activities.

F. Provides management support for foreign pharmaceutical program and operational activities, including all phases of personnel management, financial management, property, and supplies.

G. Serves as operational liaison for pharmaceutical products foreign inspection programs to FDA's foreign and other offices.

2. Foreign Pharmaceutical Quality Inspections Branch 1 (DCIGBB1)

A. Coordinates and directs foreign pharmaceutical inspection activities.

B. Serves as operational liaison for foreign pharmaceutical products inspection programs to FDA's foreign and other offices.

C. Inspects foreign pharmaceutical establishments for which CDER and CVM have regulatory responsibility, collects samples for analysis, performs field examinations and prepares reports.

D. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow up.

E. Prepares and provides evidence of investigational findings as requested.

F. Provides dedicated inspectional and investigational support to the Headquarters and other divisions, as needed.

G. Advises the Office of Regulatory Affairs and the Office on emerging inspectional, scientific and regulatory issues related to pharmaceutical products.

H. Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.

3. Foreign Pharmaceutical Quality Inspections Branch 2 (DCIGBB2)

A. Coordinates and directs foreign pharmaceutical inspection activities.

B. Serves as operational liaison for foreign pharmaceutical products inspection programs to FDA's foreign and other offices.

C. Inspects foreign pharmaceutical establishments for which CDER and CVM have regulatory responsibility, collects samples for analysis, performs field examinations and prepares reports.

D. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow up.

E. Prepares and provides evidence of investigational findings as requested.

F. Provides dedicated inspectional and investigational support to the Headquarters and other divisions, as needed.

G. Advises ORA and the Office on emerging inspectional, scientific and regulatory issues related to pharmaceutical products.

H. Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.

4. Authority and Effective Date.

The functional statements for the Division of Foreign Pharmaceutical Quality Inspections were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
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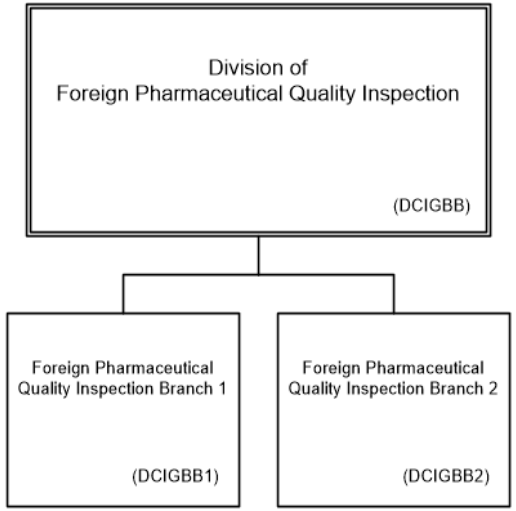

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Pharmaceutical Quality Operations, Division of Foreign Pharmaceutical Quality Inspection organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Division of Foreign Pharmaceutical Quality Inspection (DCIGBB):

Foreign Pharmaceutical Quality Inspection Branch 1 (DCIGBB1)

Foreign Pharmaceutical Quality Inspection Branch 2 (DCIGBB2)

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