SMG 1122A.13

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Human and Animal Drug Inspectorate

Division of Human and Animal Drug Inspectorate I

Effective Date: May 13, 2024

1. Division of Human and Animal Drug Inspectorate I (DCSJC).

A. Manages field inspection operations within the associated division for pharmaceutical products, including all pharmaceutical and biopharmaceutical products regulated by the Food and Drug Administration (FDA) Center for Drug Evaluation (CDER) and Center for Veterinary Medicine (CVM).

B. Manages and evaluates resource use in support of the pharmaceutical quality program.

C. Conducts investigations and inspections related to pharmaceutical products.

D. Manages and evaluates pharmaceutical program activities and manages a Quality Assurance Program.

E. Develops short and long-term work plans, staffing needs, and budgetary proposals for the Division's assigned portion of the nationwide program.

F. Advises the Office of Human and Animal Drug Inspectorate Director of emerging problems, trends, program needs, and any State or local issues.

G. Manages program and operational activities, including all phases of personnel management, financial management, and supplies for the Division.

2. Human and Animal Drug Investigations Branch 1 (DCSJC1).

A. Inspects pharmaceutical establishments, collects samples for analysis, performs field examinations, and prepares reports.

B. Refers inspections and investigations with 483 observations to Centers for consideration of appropriate follow-up.

C. Evaluates corrective actions taken by pharmaceutical establishments and provides feedback.

D. Prepares and provides evidence of investigational findings.

E. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience with any FDA-regulated pharmaceutical products; and performs pre-market clearance activities of pharmaceutical products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrence.

G. Provides inspectional and investigational support to Office of Inspections and Investigations (OII) headquarters, CDER, CVM, and other divisions, as needed.

H. Plans, schedules, and conducts pharmaceutical inspectional operations.

I. Supports the development and implementation of domestic and foreign inspectional work plans.

J. Provides guidance and training regarding inspectional techniques and technical developments to other Federal, State, and local agencies, foreign counterpart agencies, and to industry as appropriate.

K. Assists in managing, evaluating, and auditing the program aspects of Federal-State contracts.

L. Detains pharmaceutical products after appropriate clearance has been obtained.

M. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

N. Liaises with the United States (U.S.) Attorneys and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.

O. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or investigation. Presents public education and information programs to various external stakeholders and organizations.

3. Human and Animal Drug Investigations Branch 2 (DCSJC2)

A. Inspects pharmaceutical establishments, collects samples for analysis, performs field examinations, and prepares reports.

B. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.

C. Evaluates corrective actions taken by pharmaceutical establishments and provides feedback.

D. Prepares and provides evidence of investigational findings.

E. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience with any FDA-regulated pharmaceutical products; and performs pre-market clearance activities of pharmaceutical products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrence.

G. Provides inspectional and investigational support to OII headquarters, CDER, CVM and other divisions, as needed.

H. Plans, schedules, and conducts pharmaceutical inspectional operations.

I. Supports the development and implementation of domestic and foreign inspectional work plans.

J. Provides guidance and training regarding inspectional techniques and technical developments to other Federal, State, and local agencies, foreign counterpart agencies, and to industry as appropriate.

K. Assists in managing, evaluating, and auditing the program aspects of Federal-State contracts.

L. Detains pharmaceutical products after appropriate clearance has been obtained.

M. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

N. Liaises with the U.S. Attorneys and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.

O. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or

investigation. Presents public education and information programs to various external stakeholders and organizations.

4. Human and Animal Drug Investigations Branch 3 (DCSJC3).

A. Inspects pharmaceutical establishments, collects samples for analysis, performs field examinations, and prepares reports.

B. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.

C. Evaluates corrective actions taken by pharmaceutical establishments and provides feedback.

D. Prepares and provides evidence of investigational findings.

E. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience with any FDA-regulated pharmaceutical products; and performs pre-market clearance activities of pharmaceutical products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrence.

G. Provides inspectional and investigational support to OII headquarters, CDER, CVM and other divisions, as needed.

H. Plans, schedules, and conducts pharmaceutical inspectional operations.

I. Supports the development and implementation of domestic and foreign inspectional work plans.

J. Provides guidance and training regarding inspectional techniques and technical developments to other Federal, State, and local agencies, foreign counterpart agencies, and to industry as appropriate.

K. Assists in managing, evaluating, and auditing the program aspects of Federal – State contracts.

L. Detains pharmaceutical products after appropriate clearance has been obtained.

M. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

N. Liaises with the U.S. Attorneys and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.

O. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or investigation. Presents public education and information programs to various external stakeholders and organizations.

5. Human and Animal Drug Investigations Branch 4 (DCSJC4).

A. Inspects pharmaceutical establishments, collects samples for analysis, performs field examinations, and prepares reports.

B. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.

C. Evaluates corrective actions taken by pharmaceutical establishments and provides feedback.

D. Prepares and provides evidence of investigational findings.

E. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience with any FDA-regulated pharmaceutical products; and performs pre-market clearance activities of pharmaceutical products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrence.

G. Provides inspectional and investigational support to OII headquarters, CDER, CVM and other divisions, as needed.

H. Plans, schedules, and conducts pharmaceutical inspectional operations.

I. Supports the development and implementation of domestic and foreign inspectional work plans.

J. Provides guidance and training regarding inspectional techniques and technical developments to other Federal, State, and local agencies, foreign counterpart agencies, and to industry as appropriate.

K. Assists in managing, evaluating, and auditing the program aspects of Federal – State contracts.

L. Detains pharmaceutical products after appropriate clearance has been obtained.

M. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

N. Liaises with the U.S. Attorneys and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.

O. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or investigation. Presents public education and information programs to various external stakeholders and organizations.

6. Human and Animal Drug Investigations Branch 5 (DCSJC5).

A. Inspects pharmaceutical establishments, collects samples for analysis, performs field examinations, and prepares reports.

B. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.

C. Evaluates corrective actions taken by pharmaceutical establishments and provides feedback.

D. Prepares and provides evidence of investigational findings.

E. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience with any FDA-regulated pharmaceutical products; and performs pre-market clearance activities of pharmaceutical products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrence.

G. Provides inspectional and investigational support to OII headquarters, CDER, CVM and other divisions, as needed.

H. Plans, schedules, and conducts pharmaceutical inspectional operations.

I. Supports the development and implementation of domestic and foreign inspectional work plans.

J. Provides guidance and training regarding inspectional techniques and technical developments to other Federal, State, and local agencies, foreign counterpart agencies, and to industry as appropriate.

K. Assists in managing, evaluating, and auditing the program aspects of Federal – State contracts.

L. Detains pharmaceutical products after appropriate clearance has been obtained.

M. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

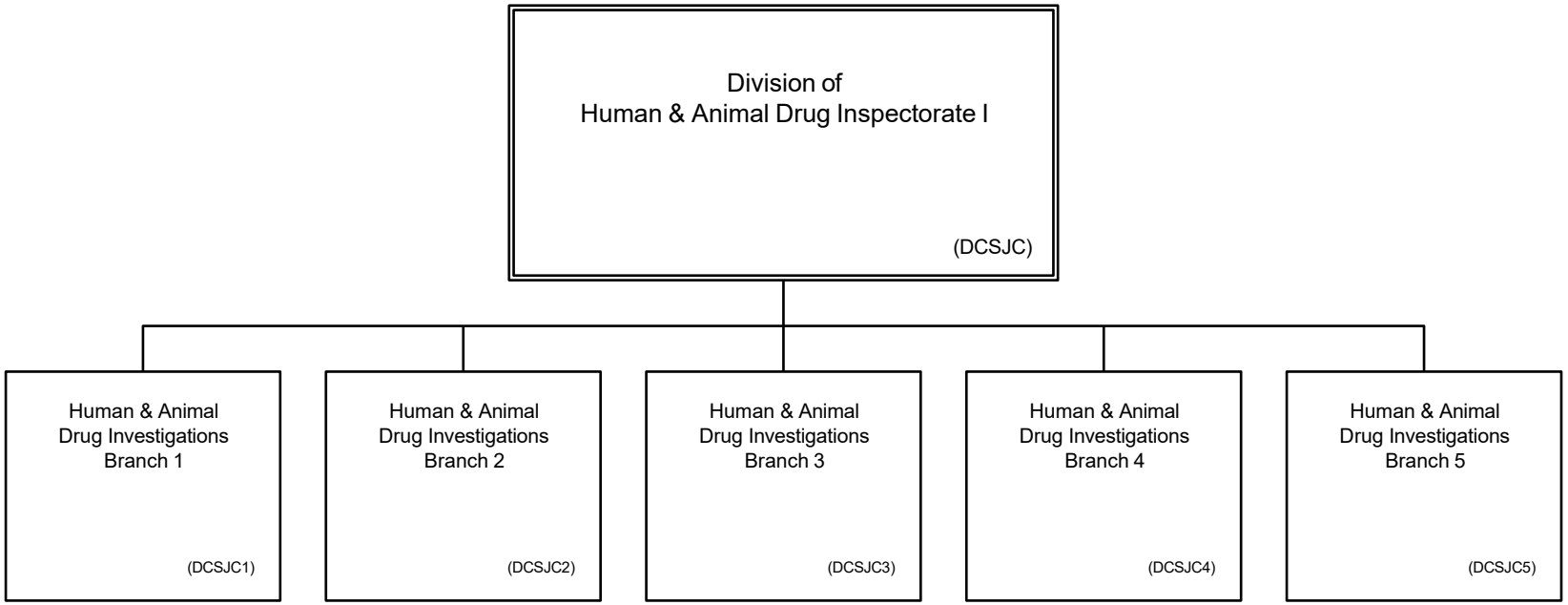
N. Liaises with the U.S. Attorneys and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.

O. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or investigation. Presents public education and information programs to various external stakeholders and organizations.

7. Authority and Effective Date.

The functional statements for the Division of Human and Animal Drug Inspectorate I were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

Department of Health and Human Services
Food and Drug Administration
Office of Inspections & Investigations
Office of Human and Animal Drugs Inspectorate
Division of Human and Animal Drug Inspectorate I



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Human and Animal Drugs Inspectorate, Division of Human and Animal Drug Inspectorate I organization structure depicting all the organizational structures reporting to the Director:

Human and Animal Drug Investigations Branch 1 (DCSJC1)
Human and Animal Drug Investigations Branch 2 (DCSJC2)
Human and Animal Drug Investigations Branch 3 (DCSJC3)
Human and Animal Drug Investigations Branch 4 (DCSJC4)
Human and Animal Drug Investigations Branch 5 (DCSJC5)