SMG 1213.3

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Biostatistics and Pharmacovigilance

Division of Pharmacovigilance

Effective Date: September 30, 2022

1. Division of Pharmacovigilance (DCBDB).

A. Monitors the post-market safety of Center for Biologics Evaluation and Research (CBER) regulated biological products to inform regulatory decisions.

B. Develops and implements systems for the acquisition of data concerning clinical experience and use trends of biological products.

C. Develops, maintains, monitors, and analyzes national safety surveillance databases of adverse events to biological products, including vaccines, cellular and gene therapies, blood and blood derived products, and tissue allografts. Coordinates the Center adverse event reporting systems.

D. Performs pharmacovigilance review to assess the adequacy of the pharmacovigilance plan based on the safety profile data submitted in an original Biological License Application (BLA) or BLA efficacy supplement as part of inter-office, interdisciplinary review teams, and provides recommendations for post-market safety monitoring, post-marketing requirement (PMR) studies, and Risk Evaluation and Mitigation Strategies (REMS) under the Food and Drug Administration Amendment Act (FDAAA). Reviews labeling supplements for safety-related label changes. Reviews the design, evaluates the implementation and clinical safety data from Phase IV post-marketing surveillance studies conducted by regulated industry.

E. Performs reviews of other safety data analyses submitted by regulated industry.

F. Performs comprehensive review of the post-marketing pediatric safety data to the Pediatric Advisory Committee (PAC).

G. Trains CBER reviewers in the analysis of observational epidemiological studies and the methods of post-marketing safety surveillance.

H. Serves as the Center's representative to national and international working groups on the reporting of adverse drug reactions and other activities to assess the risk of biological products.

I. Collaborates with other Center scientists on original research projects, providing epidemiological and pharmacovigilance input to Center programs.

2. Pharmacovigilance Branch 1 (DCBDB1)

A. Monitors the post-market safety of CBER-regulated biological products to inform regulatory decisions.

B. Develops, maintains, monitors, and analyzes national safety surveillance databases of adverse events to biological products, including vaccines, cellular and gene therapies, blood and blood derived products, and tissue allografts. Coordinates the Center adverse event reporting systems.

C. Performs pharmacovigilance review to assess the adequacy of the pharmacovigilance plan based on the safety profile data submitted in an original Biological License Application (BLA) or BLA efficacy supplement as part of inter-office, interdisciplinary review teams, and provides recommendations for post-market safety monitoring, post-marketing requirement (PMR) studies and Risk Evaluation and Mitigation Strategies (REMS) under FDAAA. Reviews labeling supplements for safety-related label changes. Reviews the design, evaluates the implementation and clinical safety data from Phase IV post-marketing surveillance studies conducted by regulated industry.

D. Performs reviews of other safety data analyses submitted by regulated industry.

3. Pharmacovigilance Branch 2 (DCBDB2)

A. Monitors the post-market safety of CBER-regulated biological products to inform regulatory decisions.

B. Develops, maintains, monitors, and analyzes national safety surveillance databases of adverse events to biological products, including vaccines, cellular and gene therapies, blood and blood derived products, and tissue allografts. Coordinates the Center adverse event reporting systems.

C. Performs pharmacovigilance review to assess the adequacy of the pharmacovigilance plan based on the safety profile data submitted in an original Biological License Application (BLA) or BLA efficacy supplement as part of inter-office, interdisciplinary review teams, and provides recommendations for post-market safety monitoring, post-marketing requirement (PMR) studies and Risk Evaluation and Mitigation Strategies (REMS) under FDAAA. Reviews labeling supplements for safety-related label changes. Reviews the design, evaluates the implementation and clinical safety data from Phase IV post-marketing surveillance studies conducted by regulated industry.

D. Performs reviews of other safety data analyses submitted by regulated industry.

4. Pharmacovigilance Branch 3 (DCBDB3)

A. Monitors the post-market safety of CBER-regulated biological products to inform regulatory decisions.

B. Develops, maintains, monitors, and analyzes national safety surveillance databases of adverse events to biological products, including vaccines, cellular and gene therapies, blood and blood derived products, and tissue allografts. Coordinates the Center adverse event reporting systems.

C. Performs pharmacovigilance review to assess the adequacy of the pharmacovigilance plan based on the safety profile data submitted in an original Biological License Application (BLA) or BLA efficacy supplement as part of inter-office, interdisciplinary review teams, and provides recommendations for post-market safety monitoring, post-marketing requirement (PMR) studies and Risk Evaluation and Mitigation Strategies (REMS) under FDAAA. Reviews labeling supplements for safety-related label changes. Reviews the design, evaluates the implementation and clinical safety data from Phase IV post-marketing surveillance studies conducted by regulated industry.

D. Performs reviews of other safety data analyses submitted by regulated industry.

5. Authority and Effective Date.

The functional statements for the Office of Biostatistics and Pharmacovigilance, Division of Pharmacovigilance were approved by the Commissioner of Food and Drugs and effective on September 30, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluations and Research
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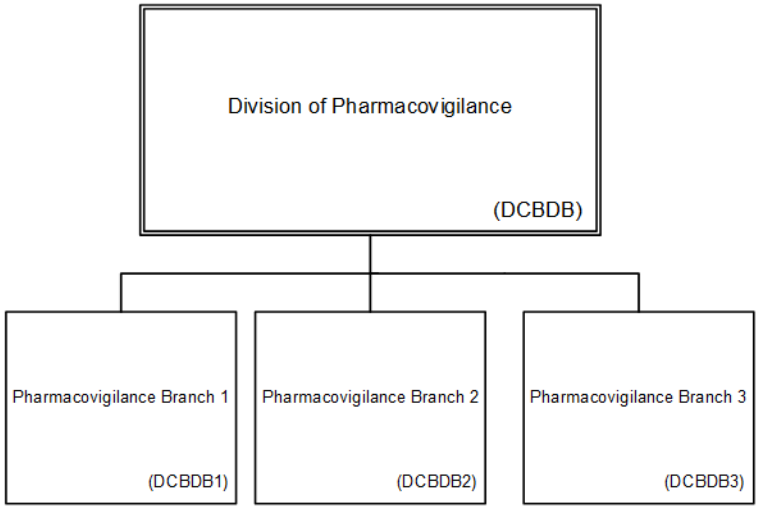

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Biostatistics and Pharmacovigilance, Division of Pharmacovigilance organization structure depicting all the organizational structures reporting to the Director:

Division of Pharmacovigilance (DCBDB)

These organizations report to the Division of Pharmacovigilance:

Pharmacovigilance Branch 1 (DCBDB1)

Pharmacovigilance Branch 2 (DCBDB2)

Pharmacovigilance Branch 3 (DCBDB3)