SMG 1217.7

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 Vaccines Research and Review

Division of Clinical and Toxicology Review

Effective Date: August 8, 2023

1. Division of Clinical and Toxicology Review (DCBFE).

A. Develops and maintains the Office's clinical and toxicology review programs.

B. Performs clinical and toxicology reviews and recommends appropriate actions on Investigational New Drug Applications (INDs) and IND amendments, Biologics License Applications (BLAs) and BLA supplements, product labeling, meeting packages, and other relevant submissions pertinent to products within the Office's purview.

C. Provides recommendations on clinical and toxicology programs intended to support IND and BLA submissions.

D. Contributes to interpretation of clinical and toxicology data submitted in support of INDs and amendments, and BLAs and supplements, including data submitted for post-marketing surveillance.

E. Develops regulatory policies and documents concerning clinical and toxicology information for products regulated by the Office.

F. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others regarding clinical and toxicology issues related to products regulated by the Office.

G. Performs clinical and toxicology consultative reviews in response to requests from other Agency components and serves as a source of clinical and toxicology information within the Center on products regulated by the Office.

H. Evaluates clinical experience and adverse reaction reports related to products regulated by the Office.

2. Toxicology Staff (DCBFE4).

A. Performs toxicology reviews and recommends appropriate actions on Investigational New Drug Applications (INDs) and IND amendments, Biologics License Applications (BLAs) and BLA supplements, product labeling, meeting packages, and other relevant submissions pertinent to products within the Staff's purview.

B. Provides recommendations on toxicology programs intended to support IND and BLA submissions.

C. Contributes to interpretation of toxicology data submitted in support of INDs and amendments, and BLAs and supplements.

D. Develops regulatory policies and documents concerning toxicology information for products regulated by the Office.

E. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, and others regarding toxicology issues related to products regulated by the Office.

F. Provides toxicology consultative reviews in response to requests from other Agency components and serves as a source of toxicology information within the Center on products regulated in the Office.

3. Clinical Review Branch 1 (DCBFE1).

A. Performs clinical reviews and recommends appropriate actions on Investigational New Drug Applications (INDs) and IND amendments, Biologics License Applications (BLAs) and BLA supplements, product labeling, meeting packages, and other relevant submissions pertinent to products within the branch's purview.

B. Provides recommendations on clinical programs intended to support IND and BLA submissions.

C. Contributes to interpretation of clinical data submitted in support of INDs and amendments, and BLAs and supplements, including data submitted for post-marketing surveillance.

D. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others regarding clinical issues related to products regulated by the Office.

E. Performs clinical consultative reviews in response to requests from other Agency components and serves as a source of clinical information within the Center on products regulated by the Office.

F. Evaluates clinical experience and adverse reaction reports related to products regulated by the Office.

4. Clinical Review Branch 2 (DCBFE2).

A. Performs clinical reviews and recommends appropriate actions on Investigational New Drug Applications (INDs) and IND amendments, Biologics License Applications (BLAs) and BLA supplements, product labeling, meeting packages, and other relevant submissions pertinent to products within the branch's purview.

B. Provides recommendations on clinical programs intended to support IND and BLA submissions.

C. Contributes to interpretation of clinical data submitted in support of INDs and amendments, and BLAs and supplements, including data submitted for post-marketing surveillance.

D. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others regarding clinical issues related to products regulated by the Office.

E. Performs clinical consultative reviews in response to requests from other Agency components and serves as a source of clinical information within the Center on products regulated by the Office.

F. Evaluates clinical experience and adverse reaction reports related to products regulated by the Office.

5. Clinical Review Branch 3 (DCBFE3).

A. Performs clinical reviews and recommends appropriate actions on Investigational New Drug Applications (INDs) and IND amendments, Biologics License Applications (BLAs) and BLA supplements, product labeling, meeting packages, and other relevant submissions pertinent to products within the branch's purview.

B. Provides recommendations on clinical programs intended to support IND and BLA submissions.

C. Contributes to interpretation of clinical data submitted in support of INDs and amendments, and BLAs and supplements, including data submitted for post-marketing surveillance.

D. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others regarding clinical issues related to products regulated by the Office.

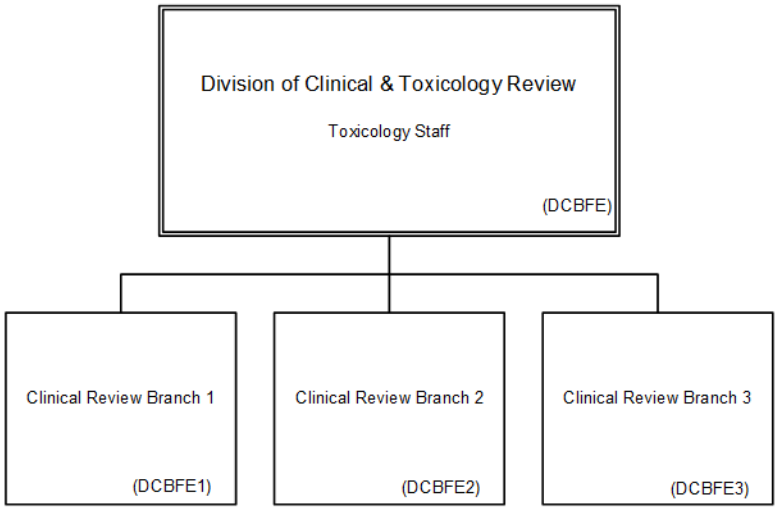
E. Performs clinical consultative reviews in response to requests from other Agency components and serves as a source of clinical information within the Center on products regulated by the Office.

F. Evaluates clinical experience and adverse reaction reports related to products regulated by the Office.

6. Authority and Effective Date.

The functional statements for the Office of Vaccines Research and Review, Division of Clinical and Toxicology Review, were approved by the Secretary of Health and Human Services and effective on August 8, 2023.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluations and Research
Office of Vaccines Research and Review
Division of Clinical and Toxicology Review



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The following is the Food and Drug Administration, Center for Center for Biologics Evaluation and Research, Office of Vaccines Research and Review, Division of Clinical and Toxicology Review organization structure depicting all the organizational structures reporting to the Office Director.

Division of Clinical and Toxicology Review (DCBFE):

- Clinical Review Branch 1 (DCBFE1)
- Clinical Review Branch 2 (DCBFE2)
- Clinical Review Branch 3 (DCBFE3)