SMG 1217.6

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 Review Management and Regulatory Review

Effective Date: August 8, 2023

1. Division of Review Management and Regulatory Review (DCBFD).

A. Conducts administrative screening and regulatory review of all investigational regulatory applications and amendments (IRAs), biologics license applications (BLAs) and supplements, meeting requests, and other relevant submissions and correspondence for products regulated by the Office.

B. Coordinates the processing and review of all IRAs. Serves as the primary administrative and scientific point of contact between IRA sponsors and the Office. Drafts and issues all letters related to IRA review. Monitors and tracks all regulatory actions for Office IRAs and ensures consistency of actions with applicable regulations, policies, and procedures.

C. Coordinates the processing and review of BLAs and supplements for the Office. Serves as the primary administrative and scientific point of contact between BLA applicants and the Office. Drafts and issues all letters related to BLA and supplement review. Monitors and tracks all regulatory actions for Office BLAs and supplements and ensures consistency of actions with applicable regulations, policies, and procedures.

D. Reviews regulations and guidelines setting forth administrative and regulatory procedures for products assigned to the Office. Develops policies and procedures applicable to the review of regulatory submissions, in the absence of Center-level policies and procedures. Monitors and evaluates labeling of products assigned to the Office. Assists in evaluating the adequacy of product package inserts for products regulated by the Office.

E. Conducts or coordinates for the Office, written and oral communication with sponsors/applicants/manufacturers. Coordinates, schedules, and conducts

formal and informal meetings between sponsors/applicants/manufacturers and Office personnel.

F. Maintains databases and information on Office review activities and provides reports and relevant information to Office, Center, and Agency management.

G. Provides staff support and regulatory guidance and advice to Agency committees, other government agencies, manufacturers, and consumers on issues related to this Office.

2. Regulatory Review Branch 1 (DCBFD1).

A. Conducts regulatory review of investigational regulatory applications and amendments (IRAs), biologics license applications (BLAs) and supplements, meeting requests, and other relevant submissions and correspondence for products regulated by the Office.

B. Coordinates the processing and review of assigned IRAs. Serves as the primary administrative and scientific point of contact between IRA sponsors and the Office. Drafts letters related to IRA review. Monitors and tracks all regulatory actions for assigned IRAs and ensures consistency of actions with applicable regulations, policies, and procedures.

C. Coordinates the processing and review of assigned BLAs and supplements. Serves as the primary administrative and scientific point of contact between BLA applicants and the Office. Drafts letters related to BLA and supplement review. Monitors and tracks all regulatory actions for assigned BLAs and supplements and ensures consistency of actions with applicable regulations, policies, and procedures.

D. Reviews regulations and guidelines setting forth administrative and regulatory procedures for products assigned to the Office. Develops policies and procedures applicable to the review of regulatory submissions, in the absence of Center-level policies and procedures. Monitors and evaluates labeling of products assigned to the Office. Assists in evaluating the adequacy of product package inserts for products regulated by the Office.

E. Conducts or coordinates for the Office, written and oral communication with sponsors/applicants/manufacturers. Coordinates, schedules, and conducts formal and informal meetings between sponsors/applicants/manufacturers and Office personnel.

F. Provides staff support and regulatory guidance and advice to Agency committees, other government agencies, manufacturers, and consumers on issues related to this Office.

3. Regulatory Review Branch 2 (DCBFD2).

A. Conducts regulatory review of investigational regulatory applications and amendments (IRAs), biologics license applications (BLAs) and supplements, meeting requests, and other relevant submissions and correspondence for products regulated by the Office.

B. Coordinates the processing and review of assigned IRAs. Serves as the primary administrative and scientific point of contact between IRA sponsors and the Office. Drafts letters related to IRA review. Monitors and tracks all regulatory actions for assigned IRAs and ensures consistency of actions with applicable regulations, policies, and procedures.

C. Coordinates the processing and review of assigned BLAs and supplements. Serves as the primary administrative and scientific point of contact between BLA applicants and the Office. Drafts letters related to BLA and supplement review. Monitors and tracks all regulatory actions for assigned BLAs and supplements and ensures consistency of actions with applicable regulations, policies, and procedures.

D. Reviews regulations and guidelines setting forth administrative and regulatory procedures for products assigned to the Office. Develops policies and procedures applicable to the review of regulatory submissions, in the absence of Center-level policies and procedures. Monitors and evaluates labeling of products assigned to the Office. Assists in evaluating the adequacy of product package inserts for products regulated by the Office.

E. Conducts or coordinates for the Office, written and oral communication with sponsors/applicants/manufacturers. Coordinates, schedules, and conducts formal and informal meetings between sponsors/applicants/manufacturers and Office personnel.

F. Provides staff support, regulatory guidance, and advice to Agency committees, other government agencies, manufacturers, and consumers on issues related to this Office.

4. Regulatory Review Branch 3 (DCBFD3).

A. Conducts regulatory review of investigational regulatory applications and amendments (IRAs), biologics license applications (BLAs) and supplements, meeting requests, and other relevant submissions and correspondence for products regulated by the Office.

B. Coordinates the processing and review of assigned IRAs. Serves as the primary administrative and scientific point of contact between IRA sponsors and the Office. Drafts letters related to IRA review. Monitors and tracks regulatory actions for assigned IRAs and ensures consistency of actions with applicable regulations, policies, and procedures.

C. Coordinates the processing and review of assigned BLAs and supplements. Serves as the primary administrative and scientific point of contact between BLA applicants and the Office. Drafts letters related to BLA and supplement review. Monitors and tracks all regulatory actions for assigned BLAs and supplements, and ensures consistency of actions with applicable regulations, policies, and procedures.

D. Reviews regulations and guidelines setting forth administrative and regulatory procedures for products assigned to the Office. Develops policies and procedures applicable to the review of regulatory submissions, in the absence of Center-level policies and procedures. Monitors and evaluates labeling of products assigned to the Office. Assists in evaluating the adequacy of product package inserts for products regulated by the Office.

E. Conducts or coordinates for the Office, written and oral communication with sponsors/applicants/manufacturers. Coordinates, schedules, and conducts formal and informal meetings between sponsors/applicants/manufacturers and Office personnel.

F. Provides staff support and regulatory guidance and advice to Agency committees, other government agencies, manufacturers, and consumers on issues related to this Office.

5. Review Management Support Branch (DCBFD4).

A. Conducts administrative screening of all investigational regulatory applications and administrative amendments for IRAs, biologics license applications (BLAs) and supplements, meeting requests, and other relevant submissions and correspondence for products regulated by the Office.

B. Coordinates the processing and review of IRAs. Issues all letters related to IRA review. Monitors and tracks all regulatory actions for Office IRAs and ensures consistency of actions with applicable regulations, policies, and procedures.

C. Coordinates the processing and review of BLAs and supplements for the Office. Issues all letters related to BLA and supplement review. Monitors and tracks all regulatory actions for Office BLAs and supplements and ensures consistency of actions with applicable regulations, policies, and procedures.

D. Reviews regulations and guidelines setting forth administrative and regulatory procedures for products assigned to the Office. Develops policies and procedures applicable to the review of regulatory submissions, in the absence of Center-level policies and procedures. Monitors and evaluates labeling of products assigned to the Office. Assists in evaluating the adequacy of product package inserts for products regulated by the Office.

E. Conducts or coordinates for the Office, written and oral communication with sponsors/applicants/manufacturers. Coordinates and schedules formal meetings between sponsors/applicants/manufacturers and Office personnel.

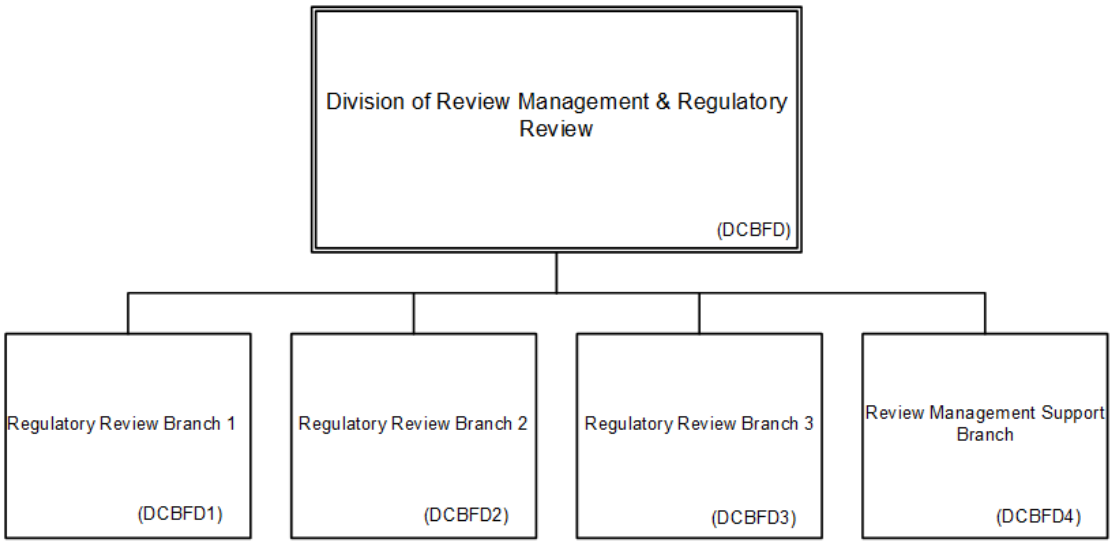
F. Maintains databases and information on Office review activities and provides reports and relevant information to Office, Center, and Agency management.

G. Provides staff support and regulatory guidance and advice to Agency committees, other government agencies, manufacturers, and consumers on issues related to this Office.

6. Authority and Effective Date.

The functional statements for the Office of Vaccines Research and Review, Division of Review Management and Regulatory 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 Evaluation and Research
Office of Vaccines Research and Review
Division of Review Management and Regulatory 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 Review Management and Regulatory Review organization structure depicting all the organizational structures reporting to the Office Director.

Division of Review Management and Regulatory Review (DCBFD):

- Regulatory Review Branch 1 (DCBFD1)
- Regulatory Review Branch 2 (DCBFD2)
- Regulatory Review Branch 3 (DCBFD3)
- Review Management Support Branch (DCBFD4)