SMG 1218A.71

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 Therapeutic Products

Office of Review Management and Regulatory Review

Division of Review Management and Regulatory Review I

Effective Date: September 16, 2022

1. Division of Review Management and Regulatory Review I (DCBGKA).

A. Conducts administrative and regulatory screening of Investigational New Drug Applications (INDs), Investigational Device Exemptions (IDEs), Premarket Notifications (510(k)s), New Drug Applications (NDAs), Biologics License Applications (BLAs), Premarket Approvals (PMAs) for products regulated by the Office.

B. Coordinates processing and review of INDs and IDEs. Serves as primary point of contact between IND/IDE sponsors and the Office. Drafts and issues letters related to IND/IDE review. Monitors and tracks regulatory actions for Office INDs/IDEs and ensures consistency of actions with applicable regulations, policies, and procedures.

C. Coordinates processing and review of 510k premarket notifications. Serves as primary point of contact between 510k applicants and the Office. Drafts and issues letters related to 510(k) reviews. Monitors and tracks regulatory actions for Office 510(k)s and ensures consistency of actions with applicable regulations, policies, and procedures.

D. Coordinates processing and review of BLA/PMA/NDA marketing applications and supplements for the Office. Serves as primary point of contact between BLA/PMA/NDA applicants and the Office. Drafts and issues letters related to BLA/PMA/NDA review. Monitors and tracks regulatory actions for Office BLA/PMA/NDAs and ensures that actions are consistent with applicable regulations, policies, and procedures.

E. Reviews regulations and guidelines setting forth administrative and regulatory applications for procedures in the biological licensing area. Develops policies and procedures applicable to the review of INDs/IDEs and BLA/PMA/NDA marketing applications, in absence of Center-level policies and procedures. Monitors and evaluates labeling of biological products, drugs, and devices assigned to the Office. Assists in evaluating the adequacy of product package inserts for products regulated by the Office.

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

G. Conducts, in coordination with other Food and Drug Administration (FDA) components, continuing surveillance and medical evaluation of clinical experience reports submitted under the IND and IDE reporting requirements.

H. Maintains databases on Office IND/IDE and marketing application review activities and provides information to Office, Center and FDA management, manufacturers, and consumers.

I. Provides staff support and regulatory guidance and advice on biologics, drugs, and devices to FDA committees and provides advice and guidance to other government agencies, manufacturers, and consumers on issues related to this Office.

2. Regulatory Review Branch 1 (DCBGKA1).

A. Conducts regulatory screening of INDs, IDEs, premarket notifications (510(k)s), NDAs, BLAs, PMA for products regulated by the Office.

B. Coordinates processing and review of INDs and IDEs. Serves as primary point of contact between IND/IDE sponsors and the Office. Drafts and issues letters related to IND/IDE review. Monitors and tracks regulatory actions for Office INDs/IDEs and ensures consistency of actions with applicable regulations, policies, and procedures.

C. Coordinates processing and review of 510k premarket notifications. Serves as primary point of contact between 510k applicants and the Office. Drafts and issues letters related to 510(k) reviews. Monitors and tracks regulatory actions for Office 510(k)s and ensures consistency of actions with applicable regulations, policies, and procedures.

D. Coordinates processing and review of BLA/PMA/NDA marketing applications and supplements for the Office. Serves as primary point of contact between

BLA/PMA/NDA applicants and the Office. Drafts and issues letters related to BLA/PMA/NDA review. Monitors and tracks regulatory actions for Office BLA/PMA/NDAs and ensures that actions are consistent with applicable regulations, policies, and procedures.

E. Reviews regulations and guidelines setting forth regulatory applications for procedures in the biological licensing area. Develops policies and procedures applicable to the review of INDs/IDEs and BLA/PMA/NDA marketing applications, in absence of Center- or Office-level policies and procedures. Monitors and evaluates labeling of biological products, drugs, and devices assigned to the Office. Assists in evaluating the adequacy of product package inserts for products regulated by the Office.

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

G. Conducts, in coordination with other Office and FDA components, continuing surveillance and medical evaluation of clinical experience reports submitted under the IND and IDE reporting requirements.

H. Maintains databases on Office IND/IDE and marketing application review activities and provides information to Office, Center and FDA management, manufacturers, and consumers.

I. Provides support, regulatory guidance and advice on biologics, drugs, and devices to FDA committees and provides advice and guidance to other government agencies, manufacturers, and consumers on issues related to this Office.

3. Review Management Support Branch 1 (DCBGKA2).

A. Conducts administrative screening of all INDs, IDEs, premarket notifications (510(k)s), NDAs, BLAs, PMA for products regulated by the Office.

B. Coordinates processing and review of all INDs and IDEs. Serves as primary point of contact between IND/IDE sponsors and the Office. Drafts and issues all letters related to IND/IDE review. Monitors and tracks all regulatory actions for Office INDs/IDEs and ensures consistency of actions with applicable regulations, policies, and procedures.

C. Coordinates processing and review of 510K premarket notifications. Serves as primary point of contact between 510K applicants and the Office. Drafts and issues all letters related to 510(k) review. Monitors and tracks all regulatory

actions for Office 510(k)s and ensures consistency of actions with applicable regulations, policies, and procedures.

D. Coordinates processing and review of BLA/PMA/NDA marketing applications and supplements for the Office. Serves as primary point of contact between BLA/PMA/NDA applicants and the Office. Drafts and issues all letters related to BLA/PMA/NDA review. Monitors and tracks all regulatory actions for Office BLA/PMA/NDAs and ensures that actions are consistent with applicable regulations, policies, and procedures.

E. Reviews regulations and guidelines setting forth administrative applications for procedures in the biological licensing area. Develops policies and procedures applicable to the review of INDs/IDEs and BLA/PMA/NDA marketing applications, in absence of Center- or Office-level policies and procedures. Monitors and evaluates labeling of biological products, drugs, and devices assigned to the Branch. Assists in evaluating the adequacy of product package inserts for products regulated by the Office.

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

G. In coordination with other Office and Agency components, supports continuing surveillance and medical evaluation of clinical experience reports submitted under the IND and IDE reporting requirements.

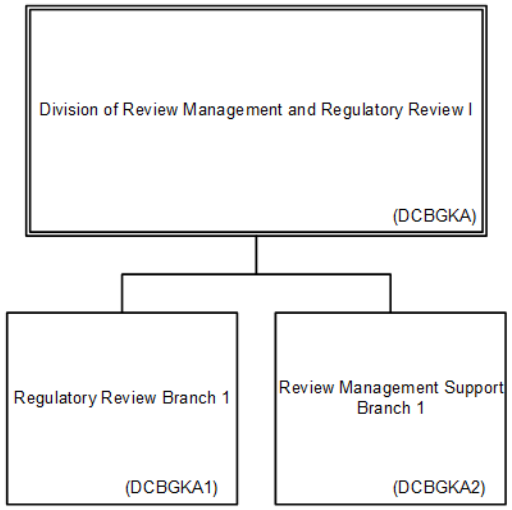
H. Maintains databases on Office IND/IDE and marketing application review activities and provides information to Office, Center and Agency management, manufacturers, and consumers.

I. Provides staff support on biologics, drugs, and devices to Agency committees and provides advice and guidance to other government agencies, manufacturers, and consumers on issues related to this Office.

4. Authority and Effective Date.

The functional statements for the Division of Review Management and Regulatory Review I were approved by the Secretary of Health and Human Services on August 8, 2022, and effective on September 16, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Therapeutic Products
Office of Review Management and Regulatory Review
Division of Review Management and Regulatory Review I



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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 Therapeutic Products, Office of Review Management and Regulatory Review, Division of Review Management and Regulatory Review I organization structure depicting all the organizational structures reporting to the Director.

Division of Review Management and Regulatory Review I (DCBGKA)