**SMG 1218.6**

**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 Tissues and Advanced Therapies**

**Division of Regulatory Project Management**

Effective Date: December 14, 2018

## 1. Division of Regulatory Project Management (DCBGE).

A. Conducts administrative and regulatory screening of all 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 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) reviews. 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 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 all 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 Project Management Branch I (DCBGE1).**

A. Conducts administrative and regulatory 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) reviews. 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 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 all formal meetings between sponsors/applicants/manufacturers and Office personnel.

G. Conducts, in coordination with other 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.

**3. Regulatory Project Management Branch 2 (DCBGE2).**

A. Engages in all Division of Regulatory Project Management activities in assigned areas of responsibility.

B. Coordinates processing and review of all INDs and IDEs. Serves as primary 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) reviews. 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 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/applicants/manufacturers.

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

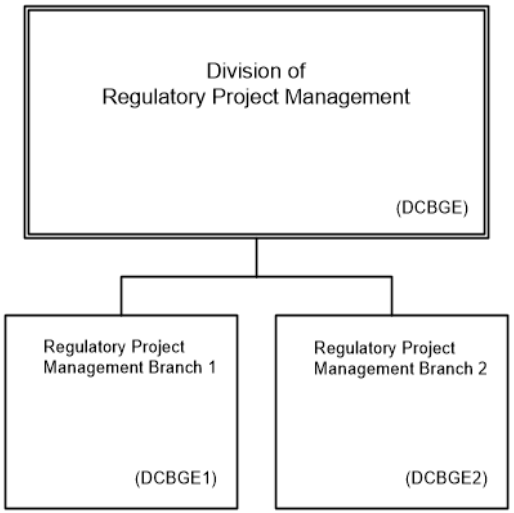
H. Contributes to databases on Office IND/IDE and marketing application review activities and provides information to Division, Office, Center and FDA management, manufacturers, and consumers.

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 as assigned.

**4. Authority and Effective Date.**

The functional statements for the Division of Regulatory Project Management were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services**
**Food and Drug Administration**
**Center for Biologics Evaluation and Research**
**Office of Tissues and Advances Therapies**
**Division of Regulatory Project Management**



STAFF MANUAL GUIDE 1218.6
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: December 14, 2018

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Biologics Evaluation and Research, Office of Tissues and Advanced Therapies, Division of Regulatory Project Management organization structure depicting all the organizational structures reporting to the Office Director.

Office of the Director (DCBGE)

- Regulatory Project Management Branch 1 (DCBGE1)

- Regulatory Project Management Branch 2 (DCBGE2)

Back to Organizations and Functions, Volume I (1000-1300)