

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Center for Drug Evaluation and Research**

**Office of Pharmaceutical Quality**

**Office of Biotechnology Products**

Effective Date: December 14, 2018

**1. Office of Biotechnology Products (DCDLA).**

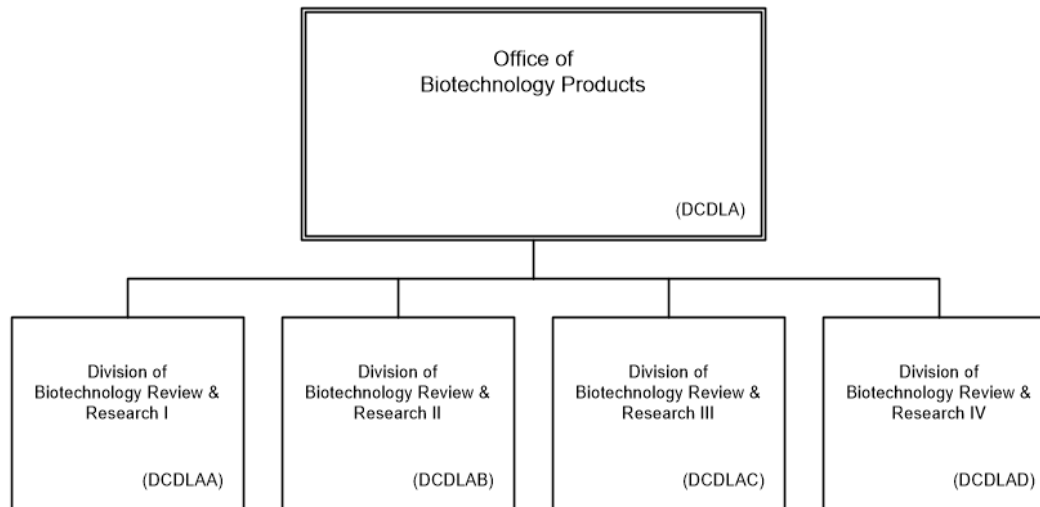
- A. Protects and advances the public health through review, regulation, and research of biological products and biosimilar biological products as specified by the Public Health Service (PHS) Act and applicable provisions of the Federal Food, Drug, & Cosmetic (FD&C) Act.
- B. Protects and advances the public health through knowledge management, innovation and technological tools that support that support review, regulation, and research of biological products and biosimilar biological products as specified by the PHS Act and applicable provisions of the FD&C Act.
- C. Provides risk-based product quality assessments of the manufacturer's assurance that the quality of a biologic product fully anticipates the clinical outcomes of the label claim and that, through characterization of both product and associated manufacturing processes, these products are not adulterated.
- D. Reviews, evaluates, and takes appropriate action on investigational new drug applications (related to therapeutic biological products and subsequent amendments. Actions may include approval or disapproval of research plans and phase appropriate lifecycle management of process control.
- E. Participates in inspections of manufacturing facilities for compliance with applicable standards.
- F. Administers applicable provisions of the FD&C Act as they pertain to certain devices and drugs that are under the jurisdiction of the office.
- G. Provides risk-based quality assessments recommending denial of license applications or the withdrawal of approved licenses as specified in the Act.

- H. Develops policies and procedures governing the pre-market approval review and evaluation of biological therapeutic products in keeping with the provisions of the PHS Act and applicable provisions of the FD&C Act.
- I. Provides subject matter expertise in the development of policies and procedures governing the quality evaluation of Center for Drug Evaluation and Research-regulated products supporting the policies of the Office of Pharmaceutical Quality, the PHS Act, and applicable provisions of the FD&C Act.
- J. Plans and conducts mission-related research on the development, manufacture, testing, and molecular actions of therapeutic biological products in order to assure a scientific basis for establishment standards for safety, purity, potency, and effectiveness of biological therapeutic products, anticipate emerging technologies, and enable the timely provision of biological products to meet patient needs.
- K. Performs the investigational device exemption review process for devices related to biological therapeutic products regulated by the office and develops related policy.
- L. Tests and partners with other Center units in the testing of products submitted for release by manufacturers.
- M. Assures compliance and responsible stewardship of federal assets and resources including providing a work atmosphere supporting respect for diversity in the workforce and continued professional development.

## **2. Authority and Effective Date.**

The functional statements for the Office of Biotechnology Products were approved by the Secretary of Health and Human Services on December 14, 2018.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Pharmaceutical Quality  
Office of Biotechnology Products**



Staff Manual Guide 1280.20  
Organizations and Functions  
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Biotechnology Products organizational structures depicting all the organizational structures reporting to the Director.

Office of Biotechnology Products (DCDLA).

These organizations report to the Office of Biotechnology Products:

Division of Biotechnology Review & Research I (DCDLAA)

Division of Biotechnology Review & Research II (DCDLAB)

Division of Biotechnology Review & Research III (DCDLAC)

Division of Biotechnology Review & Research IV (DCDLAD)