SMG 1280.20

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF PHARMACEUTICAL QUALITY

OFFICE OF BIOTECHNOLOGY PRODUCTS

Effective Date: September 26, 2014

1. OFFICE OF BIOTECHNOLOGY PRODUCTS (DKKNVA).

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. 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.

C. 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.

D. Participates in inspections of manufacturing facilities for compliance with applicable standards.

E. Administers applicable provisions of the FD&C Act as they pertain to certain devices and drugs that are under the jurisdiction of the office.

F. Provides risk-based quality assessments recommending denial of license applications or the withdrawal of approved licenses as specified in the Act.

G. 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.

H. 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.

I. 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.

J. Performs the investigational device exemption review process for devices related to biological therapeutic products regulated by the office, and develops related policy.

K. Tests and partners with other Center units in the testing of products submitted for release by manufacturers.

L. 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 this Office were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
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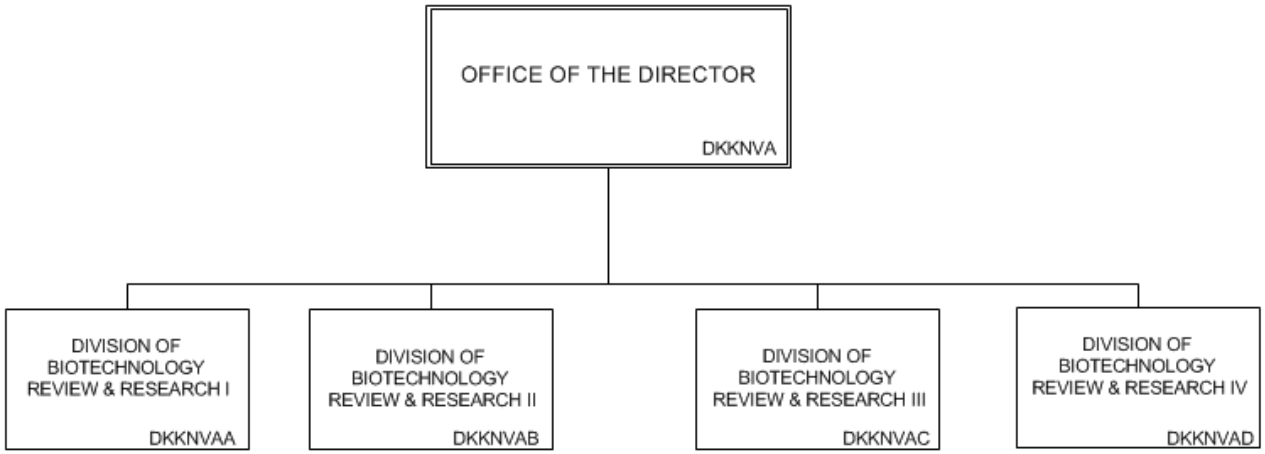

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Biotechnology Products organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNVA:

- DIVISION OF BIOTECHNOLOGY REVIEW & RESEARCH I - DKKNVAA
- DIVISION OF BIOTECHNOLOGY REVIEW & RESEARCH II - DKKNVAB
- DIVISION OF BIOTECHNOLOGY REVIEW & RESEARCH III - DKKNVAC
- DIVISION OF BIOTECHNOLOGY REVIEW & RESEARCH I V- DKKNVAD