SMG 1280.21

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

DIVISION OF BIOTECHNOLOGY REVIEW AND RESEARCH I

Effective Date: September 26, 2014

1. DIVISION OF BIOTECHNOLOGY REVIEW AND RESEARCH I (DKKNVAA).

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 analyses which evaluate the manufacturer's claims that the quality of a biological product assures 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 (INDs) 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. Provides risk-based quality assessments recommending denial of license applications or the withdrawal of approved licenses as specified in the PHS Act.

E. Conforms with office procedures governing the evaluation of biological therapeutic products.

F. Provides subject matter expertise in the development of policies and procedures governing the quality assessment of Center for Drug Evaluation and Research (CDER)-regulated products supporting the policies of the Office of Pharmaceutical Quality, the PHS Act and applicable provisions of the FD&C Act.

G. Plans and conducts mission-critical research within the Division 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.

H. Enables collaborative research and management of contract-supported activities in the areas of immunology, biochemistry, and chemistry, required for regulation of therapeutic biological products.

I. Participates in inspections and investigations of manufacturing facilities as directed by the office.

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

K. Cooperates with other Agency components and outside organizations on a variety of issues related to products assigned to the division, including evaluation of adverse reactions, adequacy of directions for use and warnings, and other information in proposed labeling for products regulated by the division.

L. Assures compliance and responsible stewardship of federal assets and resources.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division 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
OFFICE OF PHARMACEUTICAL QUALITY
OFFICE OF BIOTECHNOLOGY PRODUCTS
DIVISION OF BIOTECHNOLOGY REVIEW AND RESEARCH I

OFFICE OF THE DIRECTOR

DKKNVAA

STAFF MANUAL GUIDE 1280.21
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

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, Division of Biotechnology Review and Research I organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR - DKKNVAA