SMG 1263.44

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 NEW DRUGS

OFFICE OF DRUG EVALUATION III

DIVISION OF BONE, REPRODUCTIVE AND UROLOGIC PRODUCTS

Effective Date: 04/16/2013

1. DIVISION OF BONE, REPRODUCTIVE AND UROLOGIC PRODUCTS (DKKNRCD).

A. Reviews Investigational New Drugs (INDs) and decides on appropriate action, including approval or disapproval of research plans and protocols, modifications, and restrictions. Develops policies and procedures pertinent to particular aspects of investigation of drugs and biologics.

B. Evaluates New Drug Applications (NDAs) and Biologic License Applications (BLAs) for safety and effectiveness and formulates decisions or recommendations regarding approvability in accord with applicable delegations of authority. Develops policies and procedures applicable to the review and evaluation of drugs and biologics regulated by the division.

C. Evaluates adequacy of directions for use, warning, and other information in proposed labeling for products regulated by the division.

D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs and BLAs for products regulated by the division.

E. Works collaboratively with the Office of Surveillance and Epidemiology (OSE) to conduct continuing surveillance and medical evaluation of the labeling, clinical experience, and reports submitted by IND sponsors, by NDA and BLA applicants, and from other sources.

F. Provides advice and information to other components of the Center and to

the Agency on bone, obstetric, gynecologic, urologic, infertility, and sexual dysfunction drug products with regard to medical and scientific issues, status of processing of drug and biologics applications, appropriate policy, and proposed regulatory actions.

G. Utilizes the advisory committee process to obtain advice on product safety and effectiveness.

H. Develops, in coordination with other Agency components, guidance for staff, sponsors and the public that describes the Agency's interpretation of or policy on regulatory issues that involve the Division.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by Director, Center for Drug Evaluation and Research on April 16, 2013.

Staff Manual Guide 1263.44
Organizations and Functions
Effective Date: April 16, 2013

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STAFF MANUAL GUIDE 1263.44
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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 New Drugs, Office of Drug Evaluation III, Division of Bone, Reproductive and Urologic Products organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR