

SMG 1270.223

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 STRATEGIC PROGRAMS

OFFICE OF BUSINESS INFORMATICS

DIVISION OF REGULATORY REVIEW SUPPORT

Effective Date: 04/24/2013

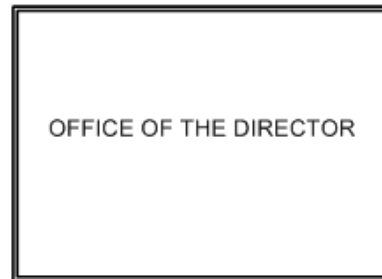
1. DIVISION OF REGULATORY REVIEW SUPPORT (DKKNTBC).

- A. Develops and conducts training programs for review and support personnel targeting the electronic submission and review process.
- B. Provides business-related training for IT systems.
- C. Interacts with applicants, sponsors and Center for Drug Evaluation and Research (CDER) personnel to provide accurate and timely guidance on electronic submission issues.
- D. Works with organizational units within the Center to help identify and address local computing requirements.
- E. Supports development of guidance and regulations associated with information management issues.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Drug Evaluation and Research on April 24, 2013.

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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 Strategic Programs, Office of Business Informatics, Division of Regulatory Review Support organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR