

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 IV

DIVISION OF PEDIATRICS AND MATERNAL HEALTH

Effective Date: August 26, 2014

1. DIVISION OF PEDIATRICS AND MATERNAL HEALTH (DKKNREG).

- A. Provides scientific and regulatory leadership and consultation with Center for Drug Evaluation and Research (CDER) for the pediatric product development process.
- B. Provides scientific and regulatory leadership and consultation with CDER for risk characterization and product development for use of medications during pregnancy and lactation.
- C. Provides scientific and regulatory consultation for issues relating to the Best Pharmaceuticals for Children Act (BPCA) in the pediatric product development process. Administers the Pediatric Exclusivity Board.
- D. Provides scientific and regulatory consultation for issues relating to the Pediatric Research Equity Act (PREA) in the pediatric product development process.
- E. Provides scientific and regulatory consultation for issues relating to maternal and fetal health and lactation during all phases of product development.
- F. Administers the Pediatric Review Committee.
- G. Fosters and facilitates development of expertise within the Agency and/or in conjunction with external entities in all phases of pediatric product development, pediatric clinical trials, and pediatric product labeling.
- H. Fosters and facilitates development of expertise within the Agency and/or in conjunction with external entities relating to pregnancy and lactation labeling,

pregnancy registries, and other maternal and fetal health issues in all phases of drug development.

- I. Defines, develops and maintains data collection and reporting systems capturing pediatric information.
- J. Interacts with other centers and represents CDER's Pediatric program at external activities with other Federal and State Agencies, professional and advisory groups, and academic institutions.
- K. Interacts with other centers and represents CDER's Maternal and Fetal Health program at external activities with other Federal and State Agencies, professional and advisory groups, and academic institutions.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Drug Evaluation and Research and effective on August 26, 2014.

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OFFICE OF THE DIRECTOR
(DKKNREG)

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ORGANIZATION AND FUNCTIONS
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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 Evaluations IV, Division of Pediatric and Maternal Health organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR