SMG 1263.67

FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of New Drugs

Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine

Division of Pediatric & Maternal Health

Effective Date: September 25, 2019

1. Division of Pediatric & Maternal Health (DCDGEC).

A. Provides scientific and regulatory leadership and consultation with Center for Drug Evaluation and Research (CDER) for the pediatric product development process and risk characterization and product development for use of medications during pregnancy and lactation.

B. Provides scientific and regulatory consultation for issues relating to the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act in the pediatric product development process. Administers the Pediatric Exclusivity Board and the Pediatric Review Committee.

C. Provides scientific and regulatory consultation for issues relating to maternal and fetal health and lactation during all phases of product development.

D. Fosters and facilitates development of expertise within the Food and Drug Administration and/or in conjunction with external entities in all phases of pediatric product development, pediatric clinical trials, product labeling (including pediatric use, pregnancy and lactation labeling), pregnancy registries, and other maternal and fetal health issues in all phases of drug development .

E. Defines, develops and maintains data collection and reporting systems capturing pediatric and maternal health information.

F. Administers the Pediatric Review Committee and interacts with other centers and represents CDER’s Pediatric program and CDER’s Maternal and Fetal Health

Program at external activities with other Federal and State Agencies, professional and advisory groups, and academic institutions.

G. Reviews Investigational New Drugs and requests for claimed investigational exemption regulated by this Division 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.

H. Evaluates New Drug Applications (NDAs) and Biologics License Applications (BLAs) for safety and effectiveness and formulates decisions or recommendations regarding approvability in accord with applicable delegations of authority. Also evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based. Develops policies and procedures applicable to the review and evaluation of drugs and biologics regulated by the Division.

I. Performs medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and Over-the-Counter drug products regulated by other offices in the Center, as applicable.

2. Authority and Effective Date.

The functional statements for the Division of Pediatric & Maternal Health were approved by the Secretary of Health and Human Services on September 25, 2019.

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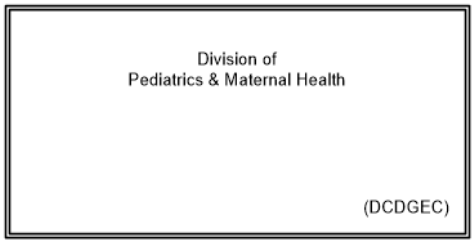

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine, Division of Pediatrics & Maternal Health organization structure depicting all the organizational structures reporting to the Director.

Division of Pediatrics & Maternal Health (DCDGEC).

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