

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 Pharmacology Toxicology for Rare Diseases, Pediatrics, Urology & Reproductive Medicine

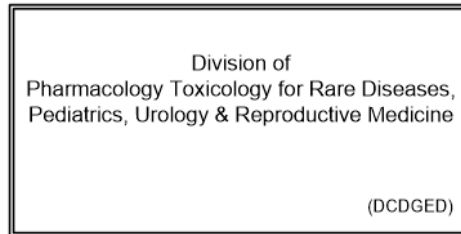
Effective Date: September 25, 2019

- 1. Division of Pharmacology Toxicology for Rare Diseases, Pediatrics, Urology & Reproductive Medicine (DCDGED).**
 - A. Reviews and evaluates non-clinical pharmacology and toxicology data in Investigational New Drug applications and formulates appropriate action, and provides recommendations for approval or disapproval of research plans and protocols, modifications, and restrictions as needed.
 - B. Reviews and evaluates New Drug Applications and Biological License Applications and formulates recommendations regarding approvability in accord with applicable delegations of authority. Develops policies and procedures applicable to the review and evaluation of drugs and biologics related to rare disease, pediatrics, men's and women's health, medical imaging, radioactive medicine, and ophthalmic conditions that are consistent with approaches across the pharmacology and toxicology discipline.
 - C. Evaluates adequacy of information (e.g., Nonclinical Toxicology section) in proposed labeling and provides recommendations for modifications for drug products used for the treatment of rare disease, pediatrics, men's and women's health, ophthalmic conditions, as radioactive medicine, and for medical imaging purposes.
 - D. Develops, in coordination with other Food and Drug Administration (FDA) components, guidance for staff, sponsors and the public that describes the FDA's interpretation of or policy on regulatory issues.

2. Authority and Effective Date.

The functional statements for the Division of Pharmacology Toxicology for Rare Diseases, Pediatrics, Urology & Reproductive Medicine were approved by the Secretary of Health and Human Services on September 25, 2019.

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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 Pharmacology Toxicology for Rare Diseases, Pediatrics, Urology & Reproductive Medicine organization structure depicting all the organizational structures reporting to the Director.

Division of Pharmacology Toxicology for Rare Diseases, Pediatrics, Urology & Reproductive Medicine (DCDGED).