

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

Effective Date: September 25, 2019

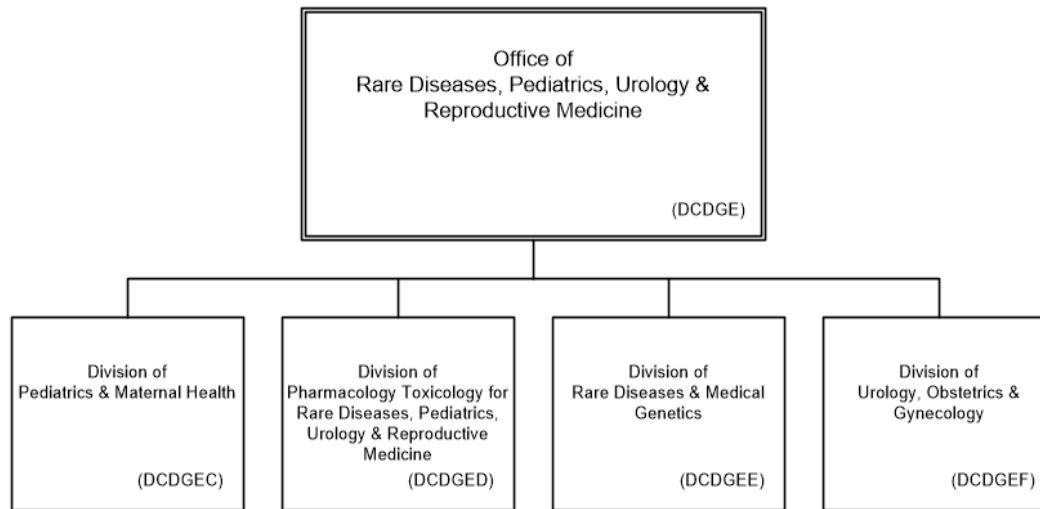
- 1. Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine (DCDGE).**
 - A. Reviews notices of claimed investigational exemptions for Investigational New Drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials.
 - B. Evaluates for safety and effectiveness and approves New Drug Applications (NDAs) and Biologic Licensing Applications (BLAs) for products regulated by this Office, and evaluates supplements that propose changes in the conditions upon which NDA/BLA approvals are based.
 - C. Develops policy and procedures governing the review and evaluation of drug investigations and NDAs/BLAs.
 - D. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs for products regulated by this Office.
 - E. 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.
 - F. Works collaboratively with the Office of Surveillance and Epidemiology to conduct continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by IND sponsors, by NDAs applicants, and from other sources.
 - G. Monitors, evaluates, and develops policy for drug labeling. Initiates necessary actions to maintain industry compliance with drug labeling regulations.

- H. Participates in Food and Drug Administration (FDA) sponsored consumer and professional educational programs on drug standards.
- I. Develops, in coordination with other FDA components, guidance for staff, sponsors and the public that describes the FDA's interpretation of policy on regulatory and scientific issues that involve the office.

2. Authority and Effective Date.

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

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Staff Manual Guide 1263.60
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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 organization structure depicting all the organizational structures reporting to the Director.

Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine (DCDGE).

These organizations report to the Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine:

Division of Pediatrics & Maternal Health (DCDGEC)

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

Division of Rare Diseases & Medical Genetics (DCDGEE)

Division of Urology, Obstetrics, & Gynecology (DCDGEF)