

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 Regulatory Operations

Division of Regulatory Operations for Rare Diseases, Pediatrics, Urology & Reproductive Medicine

Effective Date: September 25, 2019

- 1. Division of Regulatory Operations for Rare Diseases, Pediatrics, Urology & Reproductive Medicine (DCDGLG).**
 - A. Serves as the regulatory leader on product-specific review teams, providing day-to-day regulatory guidance to review staff on product-specific issues.
 - B. Provides office and division leadership with regulatory expertise on products related to rare diseases, pediatrics, & men's and women's health and cross-cutting programs, ensuring consistency with legal and regulatory requirements, as well as office-wide policies.
 - C. Manages and coordinates regulatory operations for a portfolio of regulated products, from the investigational stage through marketing application review and post-marketing oversight.
 - D. Functions as the communication liaison between other Office of New Drugs offices, centers, Food and Drug Administration and the regulated industry for product-specific interactions.
 - E. Collaborates in the design and implementation of processes and policies as needed to ensure compliance with relevant laws, regulations, and user fee program commitments.

2. Authority and Effective Date.

The functional statements for the Division of Regulatory Operations 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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Division of
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Pediatrics, Urology & Reproductive Medicine

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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 Regulatory Operations, Division of Regulatory Operations for Rare Diseases, Pediatrics, Urology & Reproductive Medicine organization structure depicting all the organizational structures reporting to the Director.

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