FDA CENTERS FOR PRODUCT REVIEW*

Who is responsible for ensuring that drugs and other medical products used by rare disease patients are safe and effective?

IS IT A...

DRUG?

CDER

Center for Drug Evaluation and Research oversees:

- Drugs (including generic drugs)
- Some biological therapeutics
- Products you might not think of as 'drugs', like sunscreen and fluoride toothpaste

fda.gov/drugs

BIOLOGICAL PRODUCT?

(Vaccine or gene therapy)

CBER

Center for Biologics Evaluation and Research oversees:

- Vaccines
- Blood and blood products
- Cell, gene, and tissue therapies

fda.gov/vaccines-blood-biologics

DEVICE?

CDRH

Center for Devices and Radiological Health oversees:

- Medical devices
- Radiation-emitting electronic products (including non-medical products like microwave ovens)

fda.gov/radiation-emitting-products

MEDICAL FOOD?

CFSAN

Center for Food Safety and Applied Nutrition oversees:

- Foods, including medical foods (foods to address disease-specific nutritional and metabolic needs under the supervision of a physician)
- Dietary supplements
- Cosmetics

fda.gov/food

To learn more, visit: rarediseases.org/rdca-dap

*The Centers highlighted here review products used in rare diseases. It is not an exhaustive list of all FDA Centers that engage in product review.
The Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP) is an integrated database and analytics hub that is designed to be used in building novel tools to accelerate drug development across rare diseases. It has been developed by the Critical Path Institute (C-Path) and the National Organization for Rare Disorders (NORD) through a collaborative grant from the U.S. Food and Drug Administration (FDA). Data for the platform is shared from various sources including clinical data from industry, research data from academics, patient registry data from NORD and other patient registry sources willing to share. Types of accepted data will continue to expand as the platform develops. For more information, visit c-path.org/rdca-dap. NRD-2289

RDCA-DAP®
Rare Disease Cures Accelerator
Data and Analytics Platform

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