FDA EXTERNAL FACT SHEET

FDA Office of Regulatory Affairs, Office of Regulatory Science Program Alignment: Aligning for the Future

In May 2017, the U.S. Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) will begin operating under a new commodity-based organizational model. This organizational model will allow ORA to more effectively execute its mission to protect consumers and enhance public health by maximizing compliance of FDA-regulated products and minimizing risk associated with those products. The new organizational model also strengthens how ORA's lead operational program offices work with FDA centers to more effectively plan and execute annual work plans, coordinate compliance and enforcement actions, improve cross-agency communication and collaboration, and establish clear roles and responsibilities for field activities.

The changes within ORA are in response to the FDA's Program Alignment and ORA's Lab Optimization initiatives. ORA launched a "lab optimization" initiative in 2009, as a means to address workload and workflow issues across the 13 laboratories. In 2012, a phased plan was developed to centralize reporting from district to region — then, ultimately, into ORA's Office of Regulatory Science (ORS) — and to recruit a senior scientist to lead ORS and the laboratories.

Program Alignment was introduced in September 2013 by the FDA Commissioner, who charged ORA and the centers to modernize and strengthen the FDA's workforce to improve our public health response by keeping pace with the acceleration of scientific innovation, global expansion of markets, and modern legal authorities. When FDA issued the charge for program alignment in 2013, it presented an opportunity to leverage the lab optimization work already underway by raising its visibility and bringing it under the umbrella of the program alignment initiative. Learn more about Program Alignment at www.fda.gov.

For more information, visit:

- About the Office of Regulatory Affairs
- Program Alignment and ORA
- Field Science and Laboratories

Please direct questions or comments to: engageORA@fda.hhs.gov

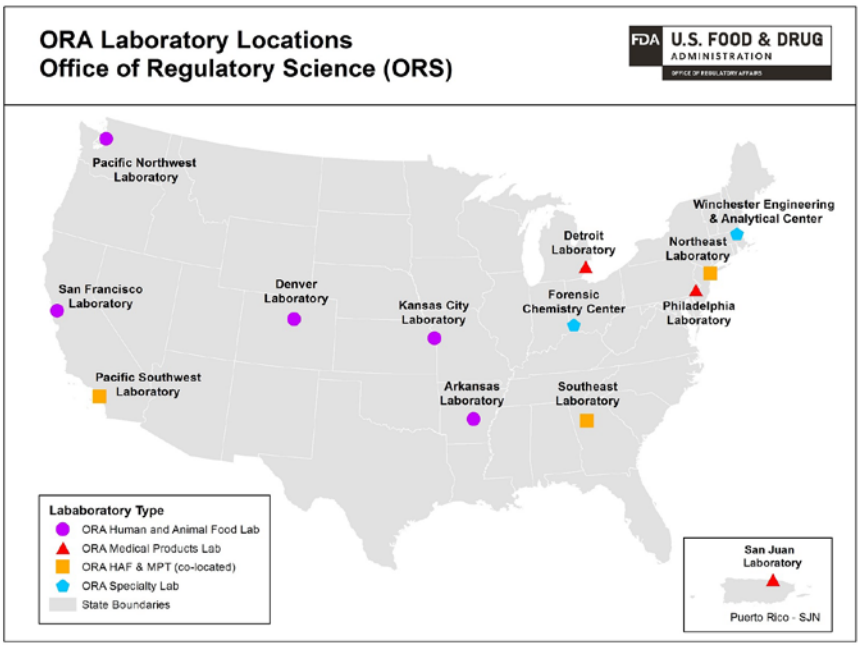
The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

About the Office of Regulatory Science

A nationwide network of laboratories that protect public health by producing data that enables FDA to make science-based regulatory decisions.

The Office of Regulatory Affairs (ORA) operates 13 regulatory laboratories, located strategically across the United States, to support FDA's mission to protect the public health and to create new knowledge in the field of regulatory science. The labs specialize as Human and Animal Food (HAF) Labs or Medical Product, Tobacco, and Specialty (MPTS) Labs, as shown in the figure below.



Approximately 1000 scientists and support staff are assigned to ORS. These individuals work in headquarters and labs across the United States to develop and execute compliance and surveillance programs, analyze samples, strengthen laboratory operations, ensure lab safety, and produce quality data that is the foundation for regulatory decisions. As a direct result of this work, FDA is able to prevent distribution of products found to be in violation of the Food, Drug and Cosmetic Act. The success of FDA activities to protect the public health often depends on the ability of the agency's laboratories to quickly and accurately analyze samples.

Director Paul Norris, DVM, MPA, oversees the day-to-day operations of the Office of Regulatory Science. He is based in Arkansas and reports directly to ORA’s associate commissioner for regulatory affairs.

ORS includes four offices: the Office of Business and Safety Operations (which includes the Lab Work Planning and Metrics Staff and the Safety and Risk Management Staff), the Office of Research Coordination and Evaluation (which includes laboratory quality management oversight), the Office of Human and Animal Food Laboratory Operations (which includes the specialized HAF labs), and the Office of Medical Products, Tobacco, and Specialty Lab Operations (which includes the MPTS labs).

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