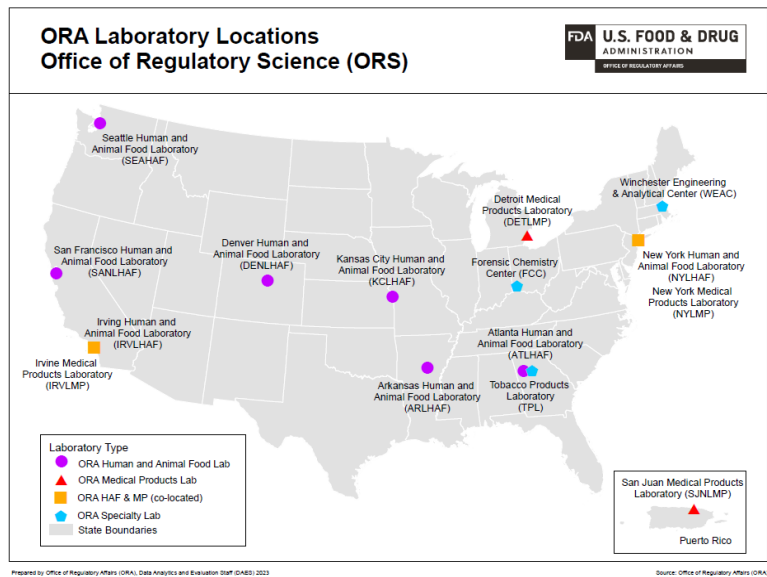


FDA EXTERNAL FACT SHEET

Office of Regulatory Affairs (ORA), Office of Regulatory Science (ORS)

ORS operates ORA’s 15 ISO:IEC 17205 accredited laboratories, located strategically across the United States and its territories. ORS supports the Agency’s mission to protect public health by providing a strong scientific basis for decision making and problem solving through the analysis of samples, by conducting applied research and method development, by supporting compliance and surveillance programs, by ensuring strong laboratory operations, and by ensuring safe working conditions for all ORA employees. The laboratories are aligned into two commodity-driven programs – Medical Products and Specialty Laboratory Operations and Human and Animal Food Laboratory Operations to ensure adequate service to all programs across the country.



Approximately 930 scientists and support staff within ORS. These individuals support the scientific mission of the Agency with expertise in chemical, microbiological, engineering, radiochemical, and forensic methods of analysis. As a direct result of this work, the FDA is able identify products found to be in violation of the Food, Drug and Cosmetic Act and take action to prevent importation or initiate domestic compliance action.

ORS is led by a Director who, along with a senior management team, oversee day-to-day operations and provides strategic scientific leadership, coordination, and expertise to ORA laboratories and leaders. The ORS Director position reports directly to ORA’s Deputy Associate Commissioner for Regulatory Affairs (DACRA).

ORS includes four offices: the Office of Safety; the Office of Research Coordination, and Evaluation (which includes laboratory quality system oversight and support); the Office of Human and Animal Food Laboratory Operations; and the Office of Medical Products, and Specialty Lab Operations (which includes the Forensic Chemistry Center, the Tobacco Products Laboratory, and the Winchester Engineering Analytical Center).

For more information, visit: [About the Office of Regulatory Affairs](#) or contact: 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.