

FDA EXTERNAL FACT SHEET

About the Office of Enforcement and Import Operations

A specialized office that serves to protect public health through risk-based enforcement strategies designed to ensure the safety and suitability of regulated products destined for the US marketplace.

The Office of Enforcement and Import Operations (OEIO) provides direction, assistance, management and oversight of field import operations, including investigational and compliance activities; and serves as the agency focal point for headquarters/field relationships on all import programs, operations, and problems. OEIO establishes field uniformity for import activities through adherence to procedural policy and managing automated systems operations, and establishes import quality control program. OEIO coordinates agency import activities with U.S. Customs and Border Protection, including the development and institution of joint regulations, procedures, policies, and operations; and coordinates activities with other federal agencies and foreign governments with border responsibilities through interagency agreements, memoranda of understanding, and informal working relationships. With the addition of the Division of Food Defense Targeting (DFDT), OEIO will liaise with law enforcement agencies to obtain and respond to intelligence concerning potentially hazardous human and animal food products destined to be offered for import into the United States. It will continue to provide subject matter expertise and direction for the development of import policies and new import procedures and regulations, as well as support and direction for designated compliance and recall operations that cut across programs. Under Program Alignment, existing port of entry import staff will remain in their current locations and be organized into five areas of responsibility to include the Northeast, Southeast, Southwest, Western and Northern Border Divisions.

The enforcement component within OEIO provides a quality assurance function in compliance casework across programs, permitting the agency to manage, measure, and improve the quality of its work products in coordination with Quality Management staff. OEIO provides management and oversight of the Agency's debarment program relevant to FDA compliance. It serves as the clearance point and coordinator for all administrative warrants and actions, and liaises with ORA and Centers to ensure coordination of evidence. OEIO also oversees all ORA recall operations and the health fraud enforcement activities.

[Douglas Stearn](#) directs the Office of Enforcement and Import Operations and has responsibility for managing operations related to imports, data systems, recalls, and enforcement issues. Contact OEIO at engageORA@fda.hhs.gov.

For more information visit:

- [ORA Office of Enforcement and Import Operations](#)
- [Office of Regulatory Affairs](#)

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.