



Fact Sheet

Office of Regulatory Affairs Headquarters Reorganization

Why Reorganize?

- FDA faces a time of remarkable transformation due to the rapid modernization and globalization of our regulated products, and the new legislative authorities provided by Congress.
- ORA's headquarters reorganization is a positive step forward to better position us to meet those new demands and better protect public health..
- The headquarters reorganization is designed with a place for everyone and includes new career growth opportunities.
- We have strong, experienced leaders who are committed to the success of ORA and will carry this reorganization forward.

What the Reorganization WILL Do?

- The reorganization makes it possible for ORA to better operate in the new environment by aligning our organizational structure with the work we need to do every day.
- The reorganization is designed to better position ORA to:
 - Address the new legislative authorities
 - Develop new strategies needed for strategic and risk-based oversight and enforcement of regulated products in an increasingly complex global regulatory environment
 - Jointly develop strategic direction between ORA and the centers across similar commodities and risks
 - Strengthen and integrate policy decisions, risk management and work planning for more strategic, risk-based decision making
 - To gather better data for analysis
 - Apply and advance regulatory science in ORA
 - Improve it capabilities
 - Improve communications on public health to consumers and external stakeholders
 - Enhance coordination, integration and communication across ORA about internal operations, high-level and cross-agency projects, and quality initiatives
 - Increase our partnerships with federal, state and local officials, foreign entities, and others

The Details

- We designed the reorganization to integrate and coordinate operations, policy, communications, partnerships, budget and resources across ORA headquarters.

- **Operations** - The Offices of Regional Operations and the Office of Enforcement will be transitioned, as will the Divisions of Domestic Field Investigations and Division of Foreign Field Investigations. Most of their functions will be combined and handled by three offices: Office of Food and Feed Operations (OFFO), Office of Medical Products and Tobacco Operations (OMPTO), and Office of Enforcement and Import Operations (OEIO).
 - The new offices remove the current domestic and international distinctions, unify domestic, and border enforcement and compliance systems, reflecting our move to a global approach to our operations.
 - In addition, the offices provide senior level management for Food and Feed, Medical Products and Tobacco.
 - OFFO is composed of the Division of Food Defense Targeting and the Division of Food and Feed Program Operations and Inspections.
 - OMPTO will be comprised of the Division of Medical Products and Tobacco Program Operations and the Division of Medical Products and Tobacco Inspections.

- There will be a new Office of Enforcement and Import Operations (OEIO) that will combine most of the functions of the Office of Enforcement and the operational aspects of the Division of Import Operations and Policy. The new office will unify domestic and border enforcement and compliance systems, reflecting the increasingly complex regulatory environment.
 - This office combines much of OE's Division of Compliance Management Operations (DCMO) and Division of Compliance Information and Quality Assurance (DCIQA) and ORO's Division of Import Operations and Policy (DIOP).
 - The Division of Import Operations in OEIO will have staff dedicated to implementing new programs like the Foreign Supplier Verification Program.
 - The Division of Compliance Systems in OEIO will consolidate current domestic enforcement, recalls, and import IT system business ownership and maintenance into one Division (and two branches) and provides for more unified interactions with the ACRA IT staff.

- Supporting all of these operational offices will be a new Office of Regulatory Science. It will carry forward most of the functions of the old Division of Field Science and have staff that specializes in tobacco, medical products or food and feed. This office will also include a Laboratory Operations and Support Staff that will provide centralized support to the labs.

- Overseeing these four operational offices will be a new Office of Operations. This will be headed by the Assistant Commissioner for Operations and provide support to inspections, compliance, laboratory, and field operations.
 - This office will house a new Audit Staff that will provide oversight and conduct assessments on those parties (here and abroad) with whom we work and/or have contracts.
 - Finally, our five regional offices and our laboratories will report to this new Assistant Commissioner.
 - The Office of Operations will report to the ACRA.

- **Policy** - On the policy side of the organization, a number of planning and analysis functions had been dispersed throughout our organization. The reorganization will change that by creating a new Office of Policy and Risk Management that will combine policy, risk management, and planning.
 - It will consolidate current policy staff from various ORA HQ components such as the Office of Enforcement's Division of Compliance Policy and policy staff from the Office of Regional Operations' Division of Import Operations and Policy into specialized areas, have staff expert in each of the operational divisions, and will be headed by the Assistant Commissioner for Compliance Policy.
 - It furthers ORA's goal to be strategic and fully integrate risk management and data analysis into all policy decisions by bringing ORA's risk management resources, data evaluation, and management resources into one office.
 - It will integrate work planning with policy and risk management.
 - This Office will report to the Deputy ACRA.

- **Communications and Quality Program Management** – The newly established Office of Communications and Quality Program Management consists of internal communications, project coordination, and quality management staff.
 - The Internal Communications Staff will establish an internal communications program that will develop and implement ORA-wide internal communications strategies to engage and inform staff.
 - The Project Coordination Staff will manage critical projects across ORA.
 - The Quality Management Staff will continue to ensure our products, processes, procedures, and systems continually improve, strengthening our overall operation and effectiveness.
 - The Office will report to the Deputy ACRA.

- **Partnerships** - To be successful in our increasingly complex regulatory environment requires leveraging resources and developing and managing partnerships. This reorganization incorporates the division of Federal-State Relationships into the Office of Partnerships.
 - In addition to implementing the relevant state provisions within FSMA, the Office of Partnerships will also work with federal partners, continue work with the state on inspections for the Partnership for Food Protection; and be responsible for implementing programs such as the Manufactured Food Regulatory Program standards.
 - This Office reports to the Deputy ACRA.

- **Budget and Resources** - The Office of Resource Management will remain but has been modified to take a more strategic approach to resource management.
 - It will include a new Division of Budget Formulation and Execution, which will formulate and execute the annual budget. Combining the functions of budget formulation and execution along with the management of grants and contracts under one division will provide ORA with better oversight of its funds. It will also allow for better communication between financial management staff and budget formulation staff who currently resides in separate divisions.
 - In addition, ORM will continue to include the Division of Management Operations and the Division of Human Resources and Development.
 - This Office reports to the ACRA.

- **ACRA's Immediate Office** – The immediate office of the ACRA will also include a few changes.
 - ORA's Senior Scientist will report directly to the ACRA, reflecting the importance of sound regulatory science in our decision-making.
 - The Senior Advisor for IT will lead the IT Staff, acknowledging the key role of IT in ORA operations.
 - The External Relations Staff will improve communication and public health messaging to consumers, the media and to stakeholders, proactively telling the ORA story.
 - The Executive Operations Staff will be retitled to Executive Secretariat Staff and work closely with external relations on the communications aspects of our oversight.

What the Reorganization WILL NOT do?

- Makes no structural changes to the regional or district offices, laboratories, or the Office of Criminal Investigations
- Bargaining Unit Employees
 - There are no changes to the conditions of employment for the affected bargaining unit employees.
 - If any changes to the conditions of employment arise because of the reorganization, it will be negotiated prior to the implementation, in accordance with the Collective Bargaining Agreement. ORA will work directly with labor union officials to ensure that all requirements pursuant to our Collective Bargaining Agreement are met.

Next Steps

- As much as possible, permanent and acting leadership will be in place by 10/1 to drive the implementation strategy and maintain continuity going forward.
- Some of the leadership positions that are new or were previously vacant have been filled on an interim basis by appointments to ensure the continuity of our work. We are currently working to get these positions advertised and competed in the near future. Information will be posted to the ORA Intranet site over the course of the transition.
- Questions and feedback should be sent to the "AskACRA" email account (askacra@fda.hhs.gov). Staff will be able to reach out to the senior leadership team with any questions or issues.