FDA's Office of Regulatory Affairs: Transforming ORA's Operations and Organization

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DENVER DISTRICT
FDA

Office of the Commissioner

Office of Foods and Veterinary Medicine

Center for **F**ood **S**afety & **A**pplied **N**utrition

Center for **V**eterinary **M**edicine

Office of Medical Products & Tobacco

Center for **D**evices & **R**adiological **H**ealth

Center for **B**iologics **E**valuation & **R**esearch

Center for **D**rug **E**valuation & **R**esearch

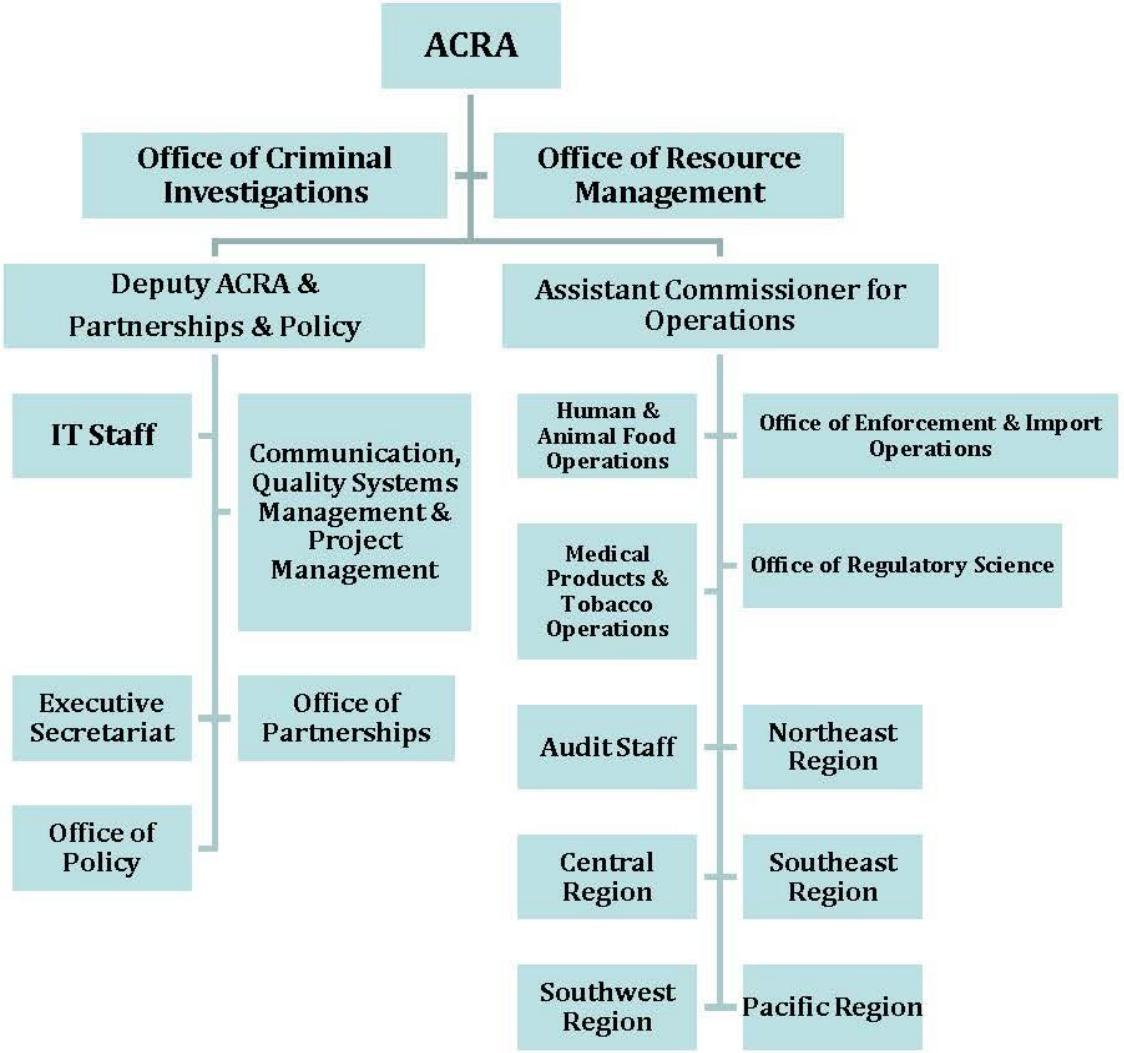
Center for **T**obacco **P**roducts

Office of Global Reg. Ops & Policy

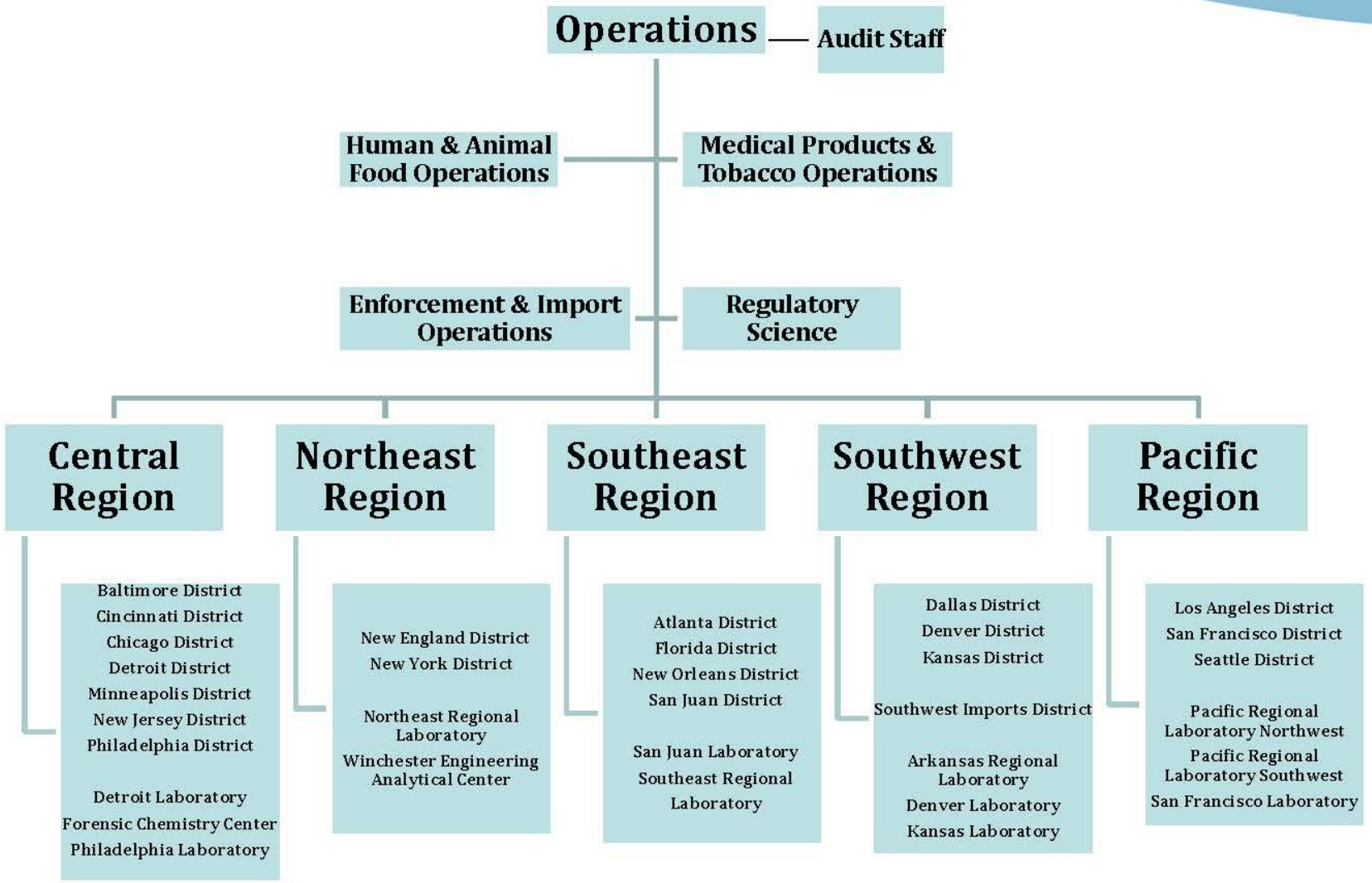
Office of **R**egulatory **A**ffairs

Office of **I**nternational **P**rograms

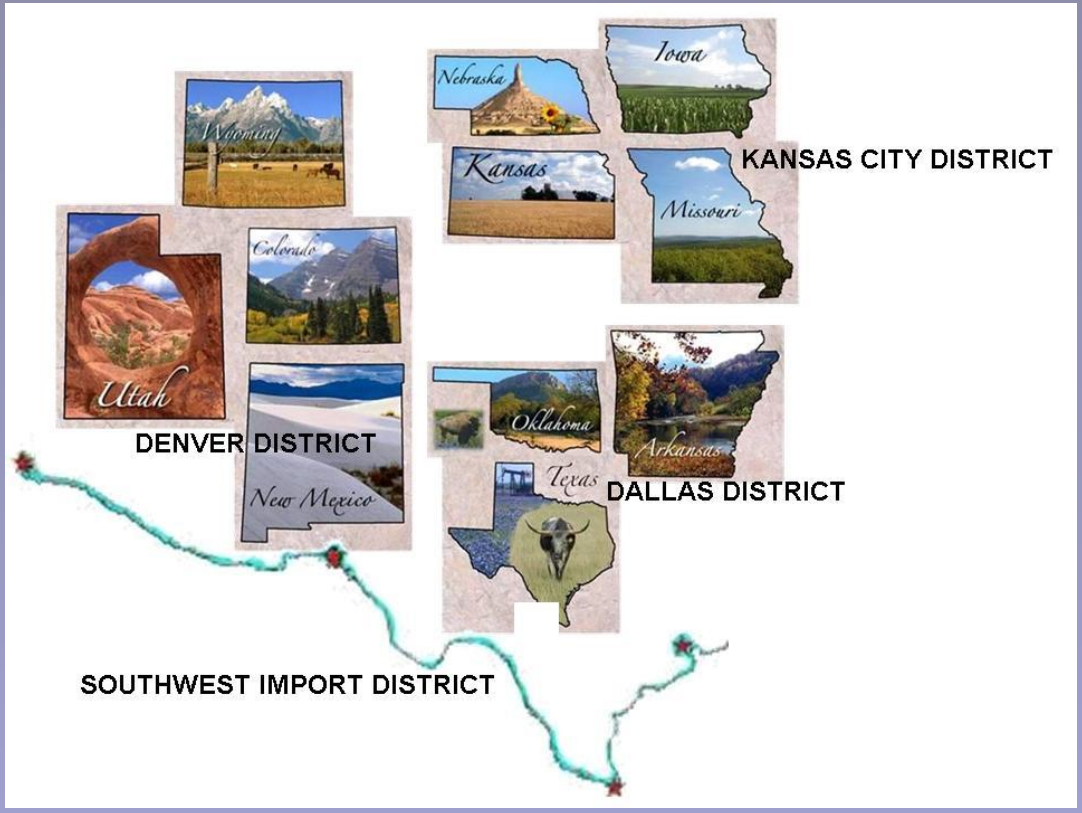
ORA Organizational Chart - Current



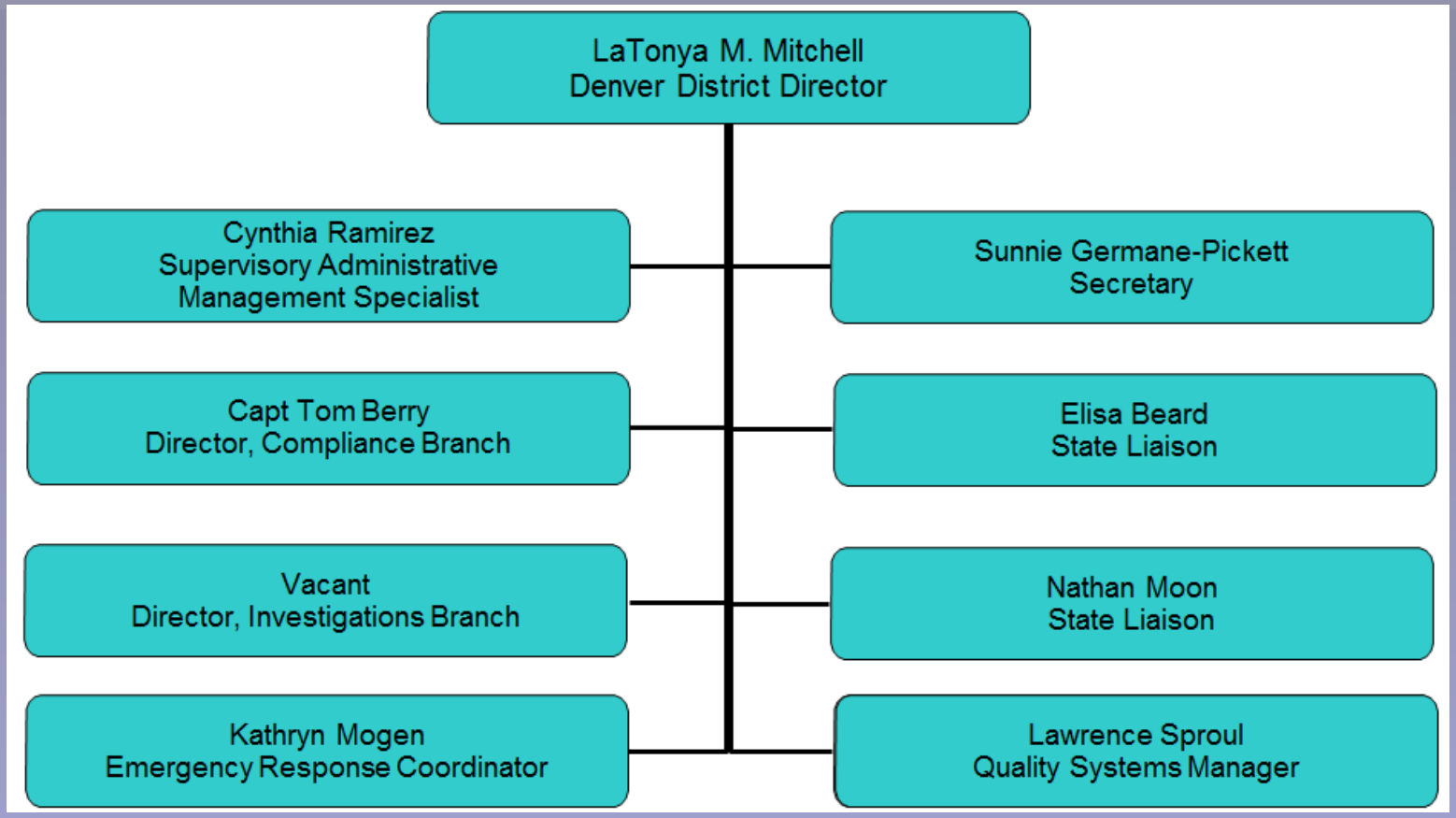
ORA Operations - Current Structure



Southwest Region



Denver District Office



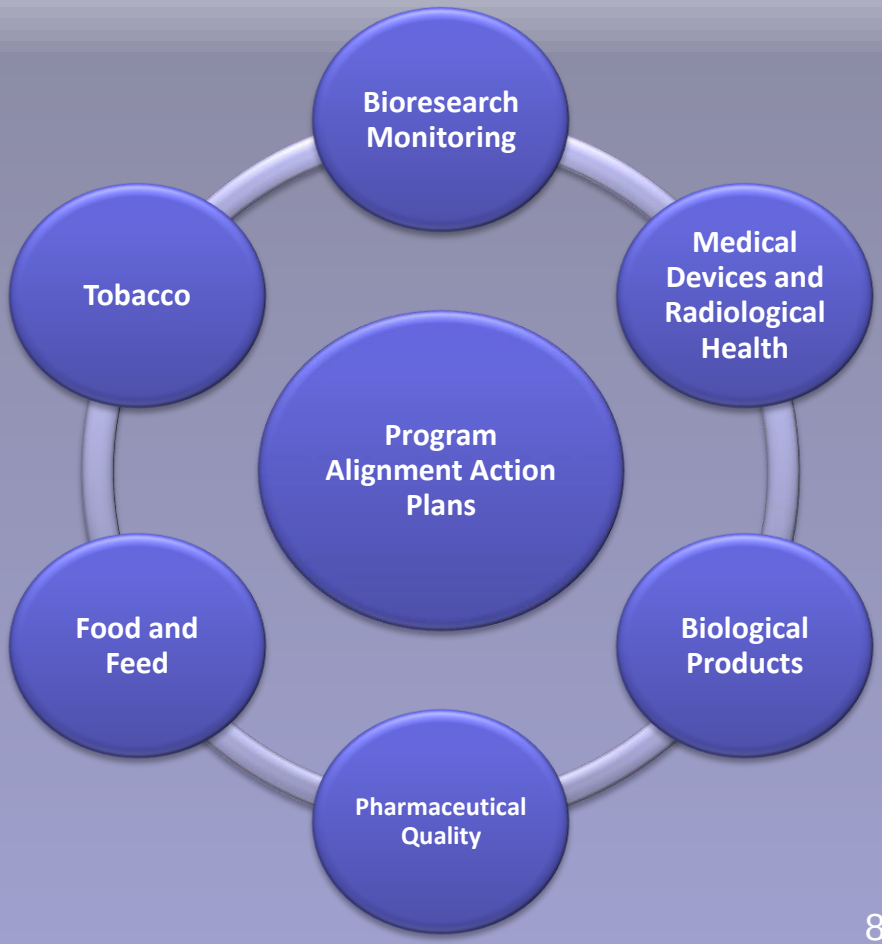
DEN-DO Staff

	On Board Mid-Year	Ceiling
2013	75	82
2014	68	82
Current	79	87

Program Alignment Action Plans

- FDA's directorates, centers and the Office of Regulatory Affairs collaborated on a set of six fiscal year 2015 Program Alignment Action Plans to define ways to transition the agency to distinct commodity-based and vertically-integrated regulatory programs.

- Key areas in this multi-year effort include specialization, training, work planning, compliance policy and enforcement strategy, imports, laboratory optimization and information technology.



Action Plan Highlights:
Expand Compliance Tools

- ORA field investigators will work with subject matter experts from the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine to make decisions in real time.

- We will work with firms to achieve prompt correction of food safety deficiencies to help implement the preventive approaches outlined by the FDA Food Safety Modernization Act.

- If industry does not quickly and adequately correct critical areas of noncompliance that could ultimately result in food borne outbreaks, we will use our enforcement tools, including new tools such as those provided under FSMA, as appropriate.

Action Plan Highlights:

Jointly Develop New Inspection Approaches

- The Center for Drug Evaluation and Research and ORA are piloting a new paradigm for inspections and reports to advance pharmaceutical quality, standardize our approach to inspection data gathering to inform “quality intelligence” of sites and products.
- The Center for Devices and Radiological Health and ORA plan, for example, will begin to focus some inspections on characteristics and features of medical devices most critical to patient safety and device effectiveness. ORA investigators will perform these inspections utilizing jointly developed training.

Action Plan Highlights:
Establish Senior Executive Program Directors in ORA

- For example, in the past the Center for Drug Evaluation and Research would work with several ORA units responsible for the pharmaceutical program.

- Now, the centers will have a single operational Senior Executive in ORA responsible for each commodity program, allowing ORA to streamline decision making and operations.

ORA's Approach to Increased Specialization

- ORA's current district structure will remain the same, but align to commodity areas with operational management and staff specializing in a program.
- The current Regional Food and Drug Director positions will become Program Executives responsible for each commodity area.

Specializing ORA's Operational Staff

Movement from our geographically-based management to a program-based management model will increase opportunities for staff.

Investigators, compliance officers and operational managers will specialize in a single program area.

Next Steps

In FY15 ORA managed each Program Alignment Action Plan as a project with cross-agency team members to ensure we fulfilled our commitments.

In FY16 we will begin to transition to the specialized management model and assign operational staff a commodity program area, and execute action plans with each center.

Implementing the new specialized management model and our action plans will take time, commitment, and continued investment and the organization will continuously monitor and evaluate its efforts.