



FDA's Office of Regulatory Affairs Aligns for the Future

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Acting Director, ORA Office of Enforcement and Import
Operations

December 2017

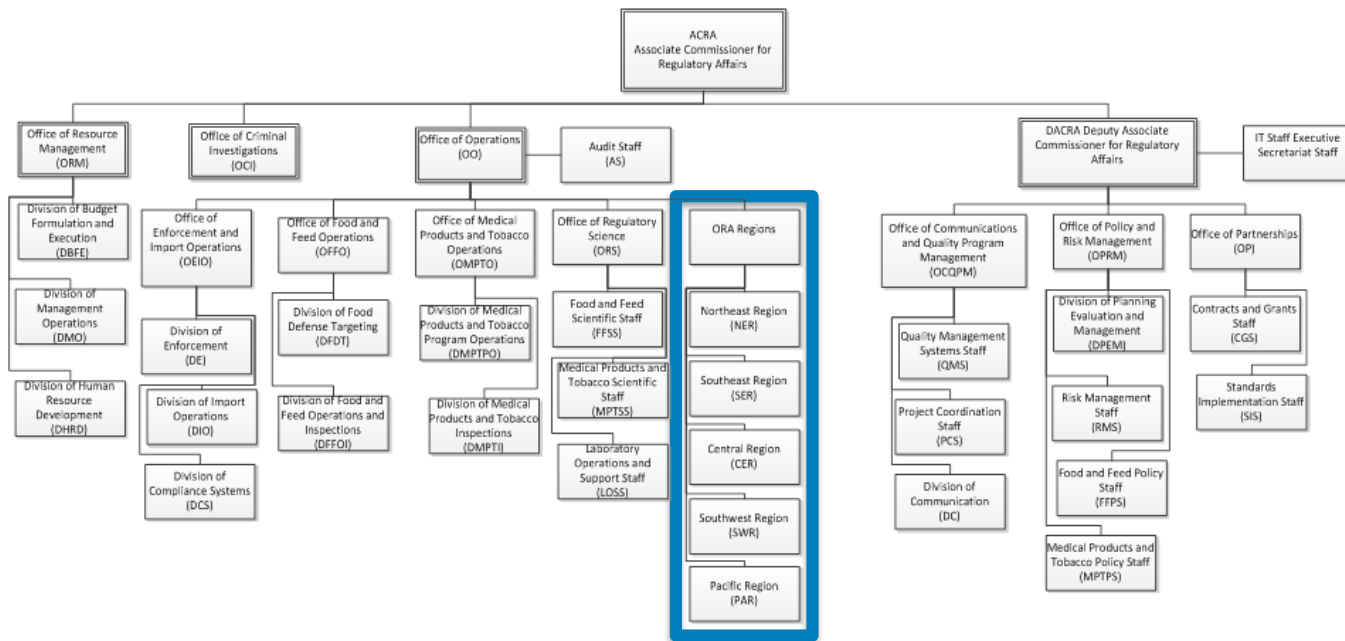


*“...Modernize and strengthen the
FDA workforce to improve public
health response.”*

**2013 FDA Program Alignment
Charge**

OLD

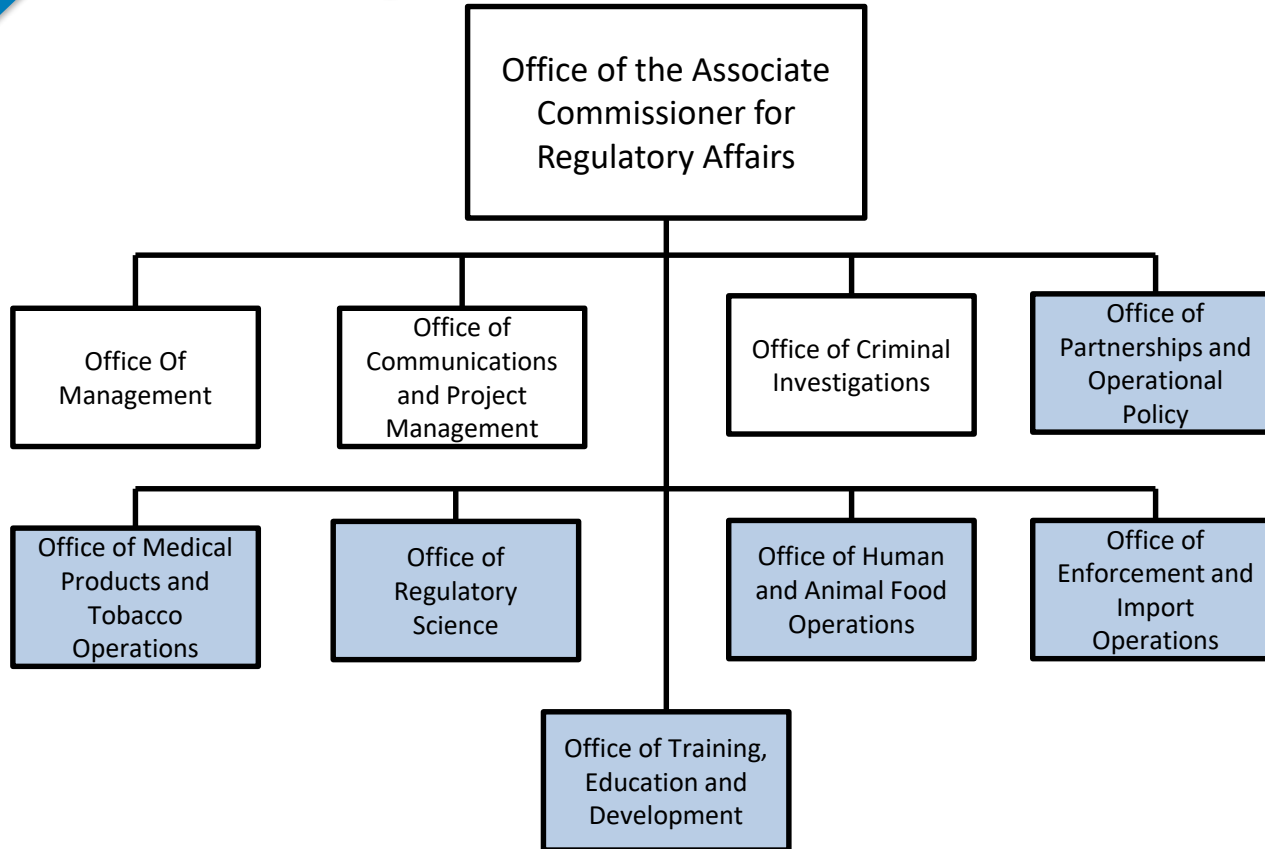
Geographically Aligned Organizational Model



New

Program Aligned Organizational Model

FDA



Program Alignment: Key Changes

| From | To |
|--|---|
| Geographic management of operations | <p>Program management of operations, management teams based on staff:</p> <ul style="list-style-type: none"> • Bioresearch Monitoring 2 management teams • Biologics 2 management teams • Human and Animal Food 12 management teams • Medical Device and Radiological Health 3 management teams • Pharmaceutical Quality 4 management teams • Tobacco • Plus Imports as a program 5 management teams |
| Regional Food & Drug Directors | Program Directors |
| Degrees of program specialization for investigations, compliance and operational managers | Exclusive specialization in one program for investigations, compliance and operational managers |
| 20 District Directors who manage the geographic district and all programs operations within the district | 20 District Directors who manage the geographic district and only one program for operations. Plus eight new program division directors who manage program operations only – total 28 management teams |
| One import district and a range of import operations embedded within the 16 other districts | Five import divisions (four of them new) covering all borders, managing import operations nationally as a program |

Program Alignment: Key Changes

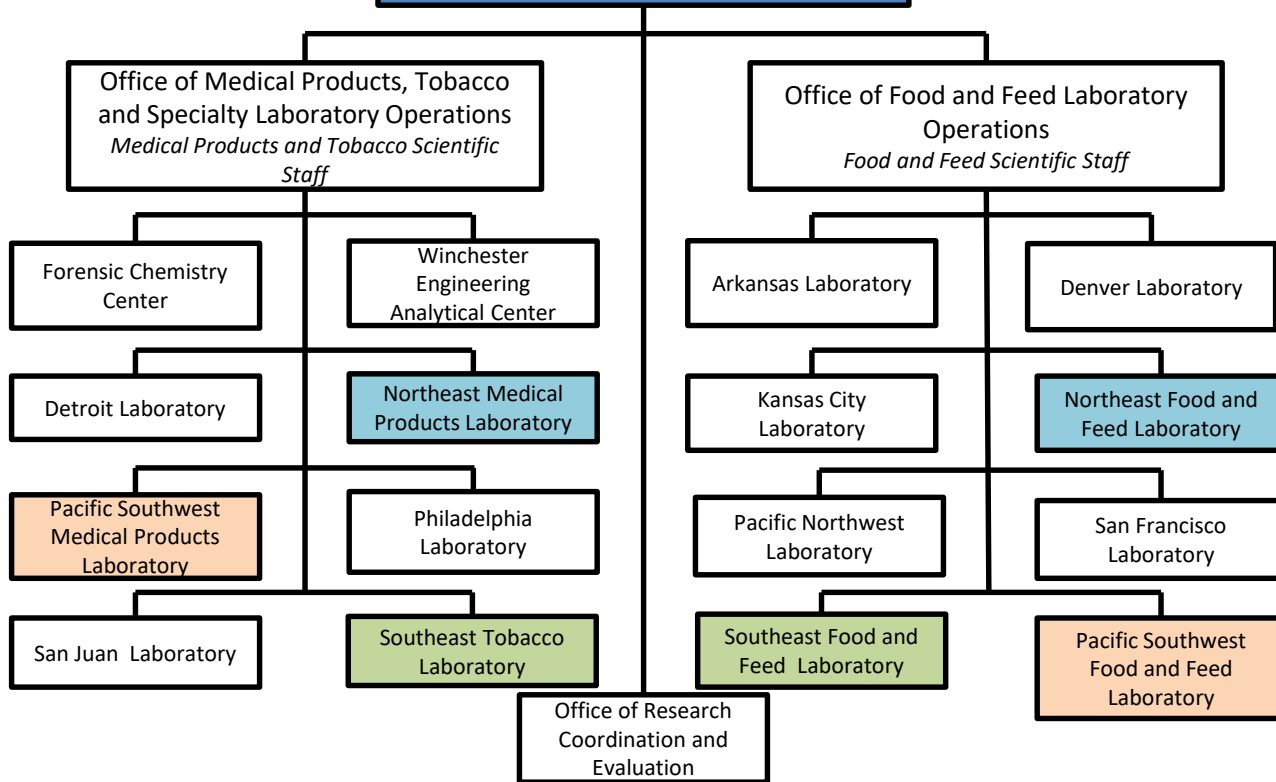
| From | To |
|---|---|
| 13 labs reporting into the regions | National Lab Management – 13 labs reporting into ORA's Office of Regulatory Science with three additional directors managing separate lab program operations and specialization |
| Division of Human Resource Development within the Office of Resource Management | Office of Training, Education and Development |
| State Cooperative Programs decentralized across five regions – shellfish, milk, retail | Office of State Cooperative Programs under the Human and Animal Food Operations, as a single national program(s) |
| Functions based in geography: consumer complaint coordinators, state liaisons, emergency response coordinators | Retain certain functions based in geography: consumer complaint coordinators, state liaisons, emergency response coordinators |
| Functions decentralized local reporting: Freedom of Information (FOI) staff, industrial hygienists (IH), and administrative staff | Staff remain embedded locally, but report into a single office: FOI staff report into Division of Information Disclosure; IHs report into the Office of Regulatory Science; administrative staff report into the Office of Management |

Office of Regulatory Science

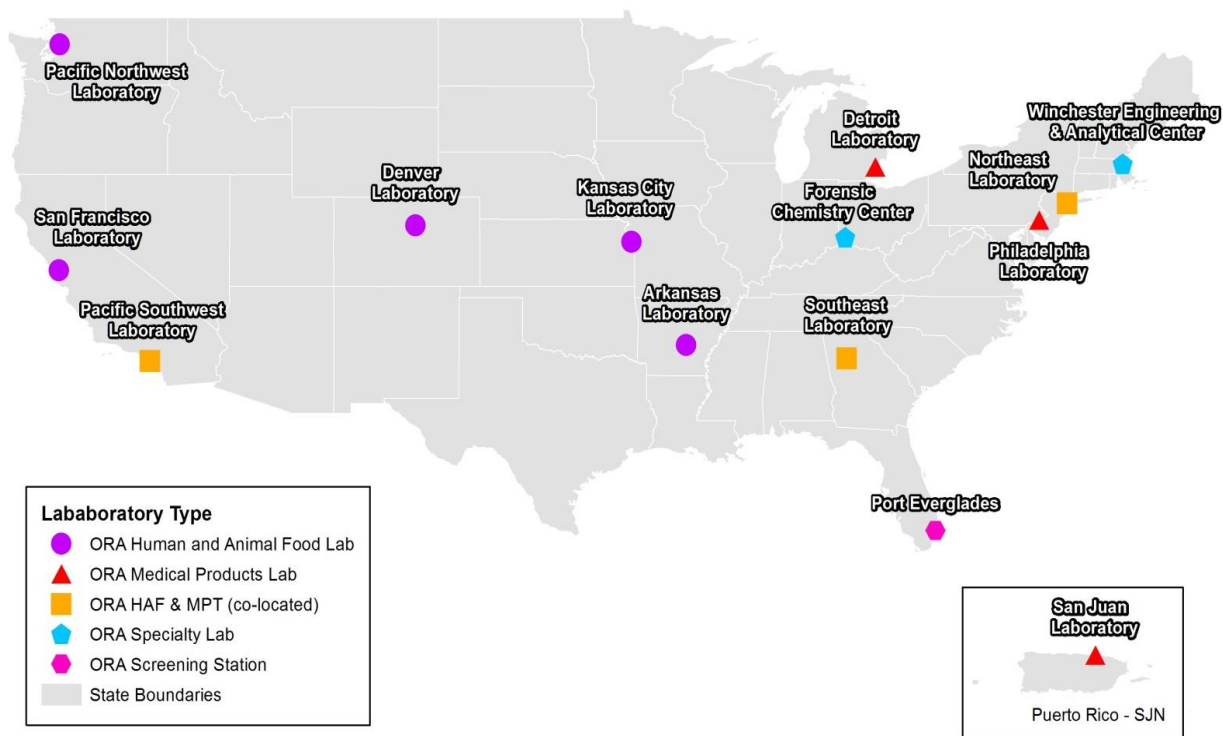


Dr. Paul Norris
Director
Office of Regulatory
Science

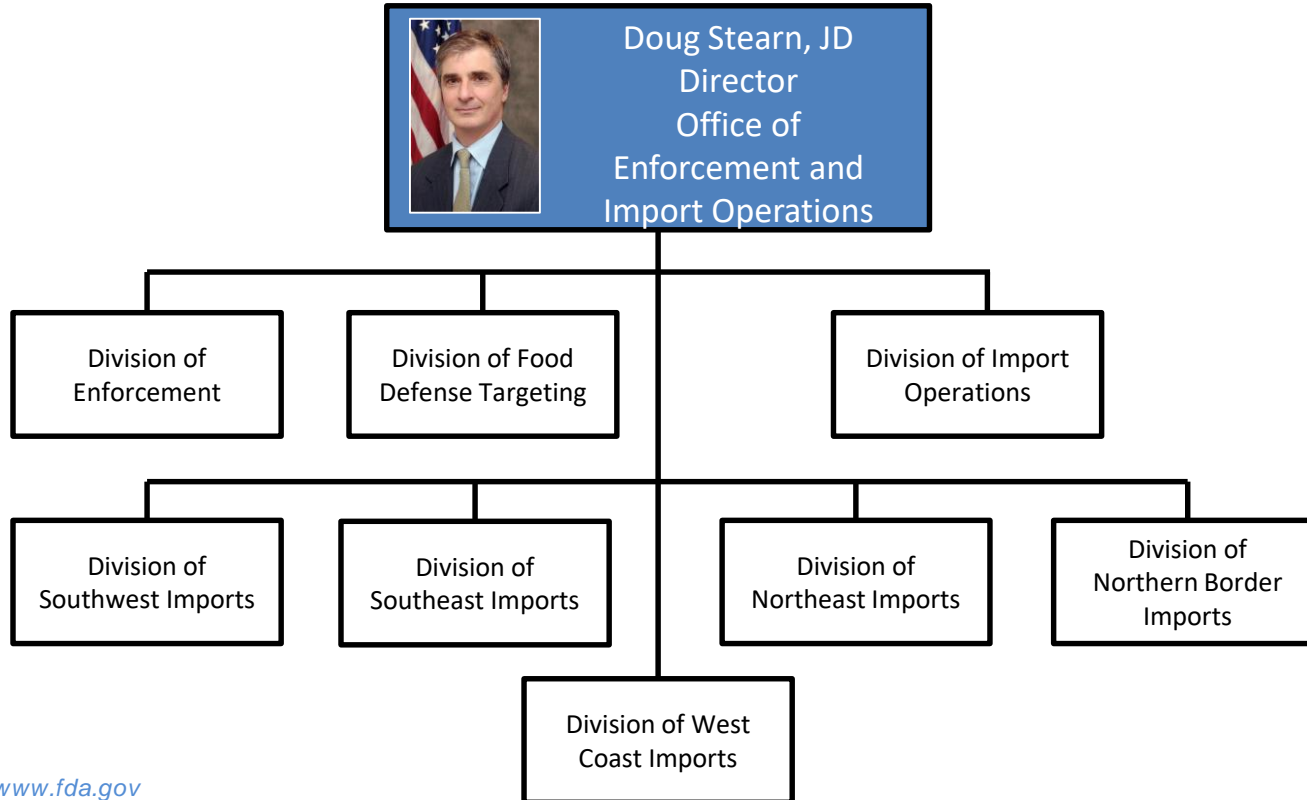
*Office of Business and Safety
Operations – Immediate
Office (Lab Planning, Safety,
and Training Staff)*



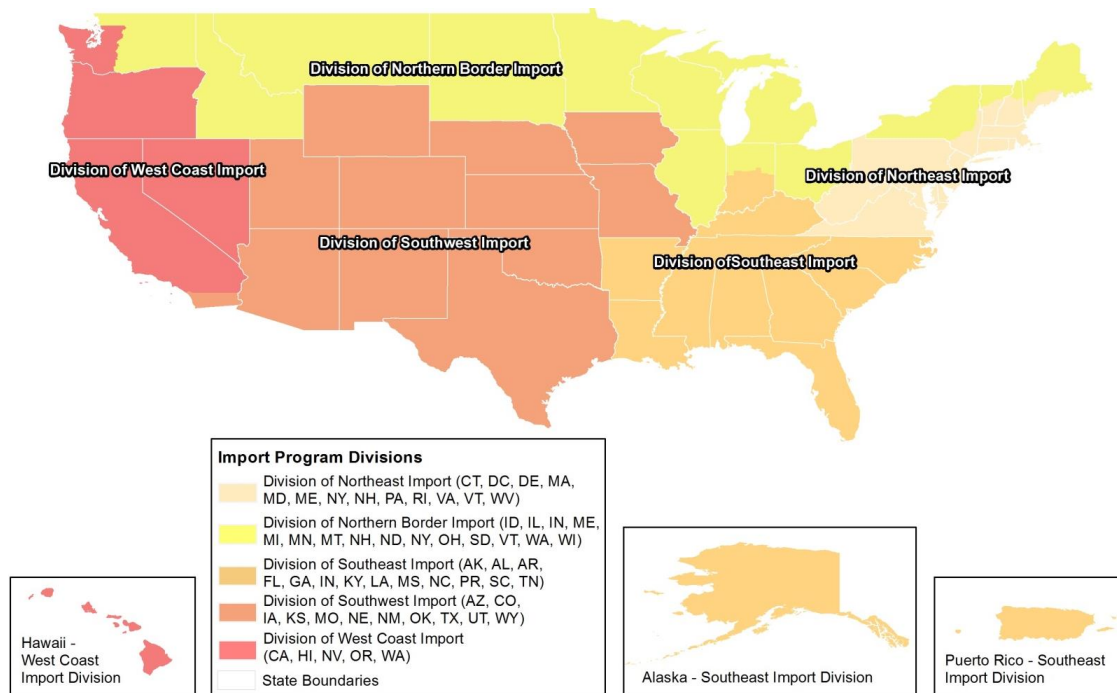
Office of Regulatory Science



Office of Enforcement and Import Operations



Office of Enforcement and Import Operations

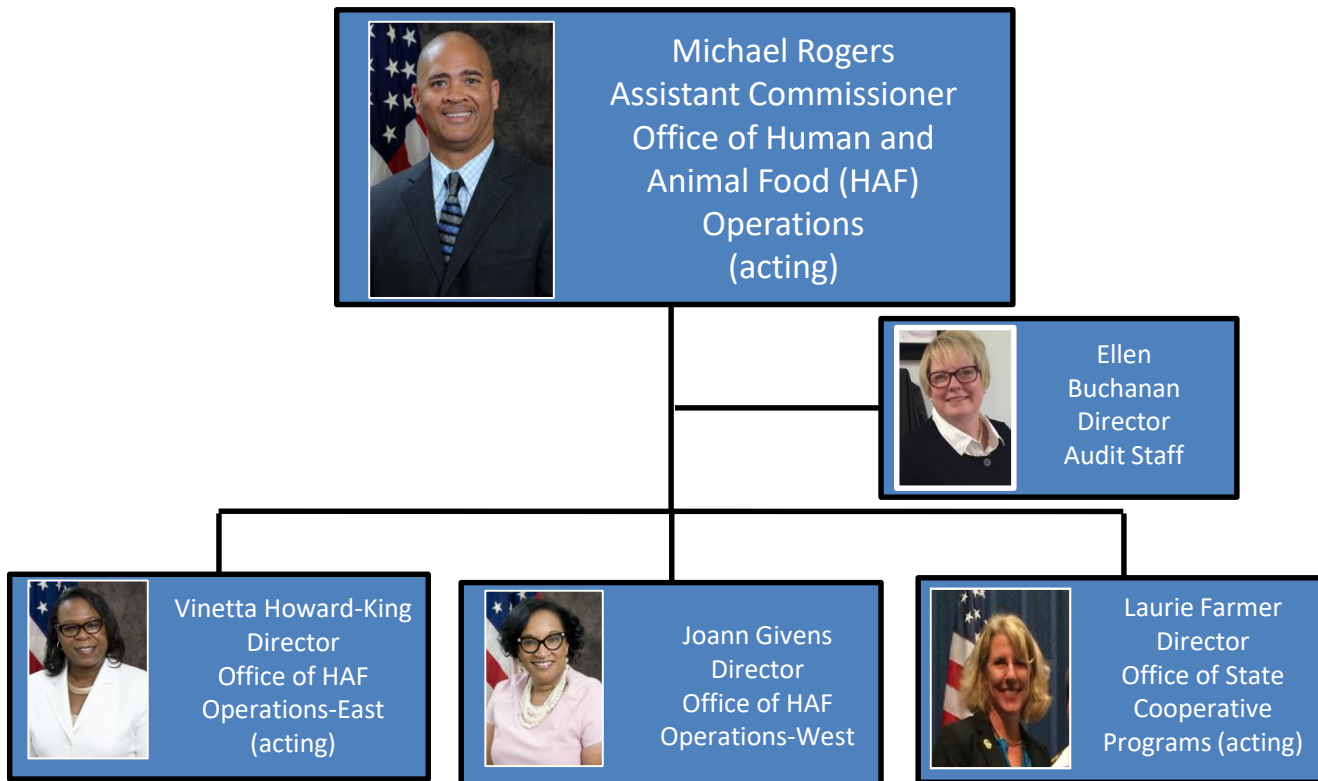


Office of Enforcement and Import Operations

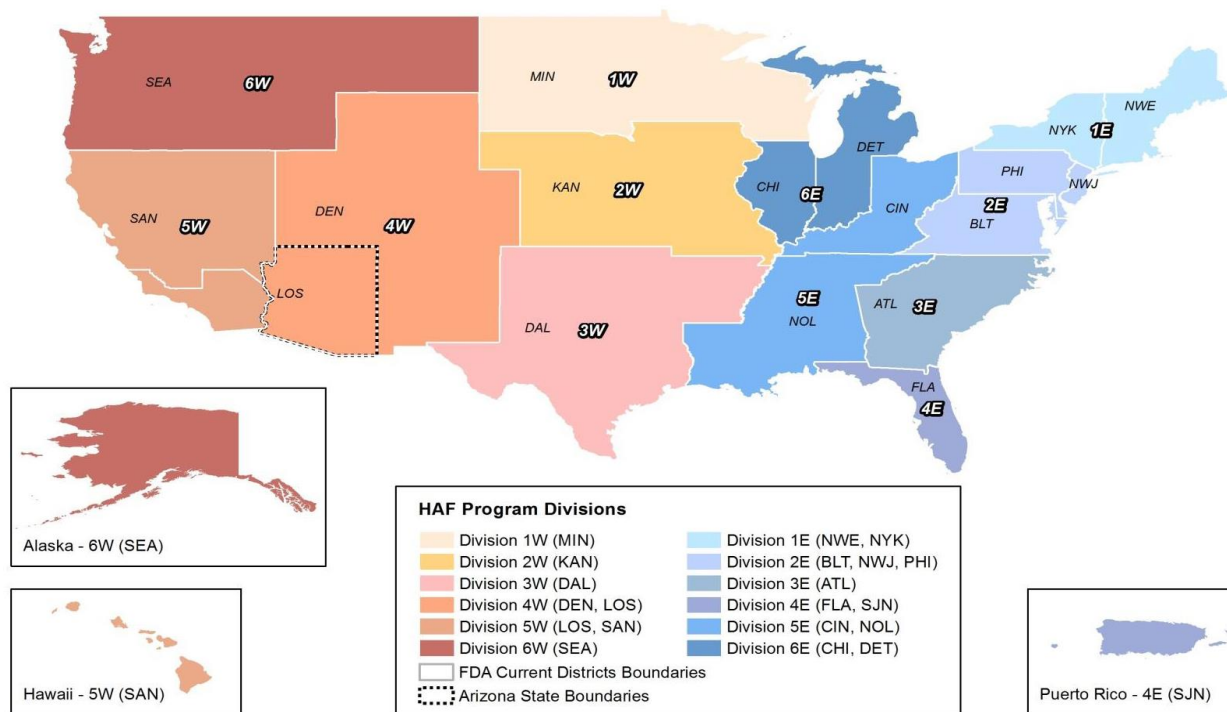


| Office/Division | Title | Name |
|-------------------------------------|-----------------|---------------------------|
| OEIO | Director | Doug Stearn |
| | Deputy Director | Armando Zamora |
| Division of Enforcement | Director | Scott MacIntire |
| Division of Food Defense Targeting | Director | Angel Suarez |
| Division of Import Operations | Director | John Verbeten |
| Division of Southwest Imports | Director | Todd Cato |
| Division of Southeast Imports | Director | Ruth Dixon |
| Division of Northeast Imports | Director | Matthew Palo (acting) |
| Division of Northern Border Imports | Director | Keith Jasukaitis (acting) |
| Division of West Coast Imports | Director | Dan Solis (acting) |

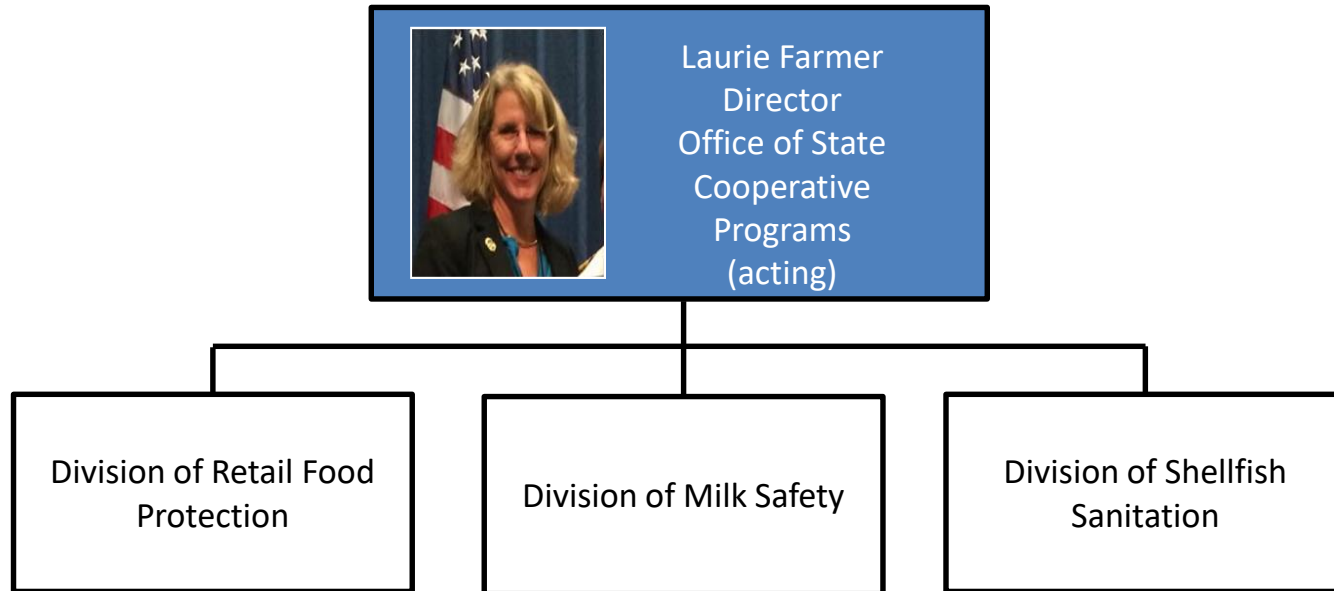
Office of Human and Animal Food Operations



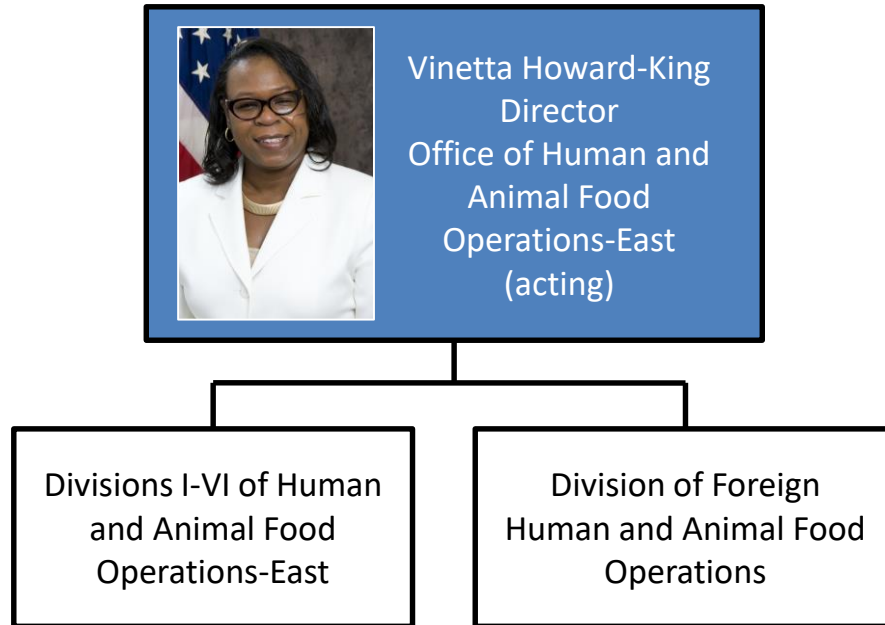
Office of Human and Animal Food Operations



Office of State Cooperative Programs



Office Of Human and Animal Food Operations-East

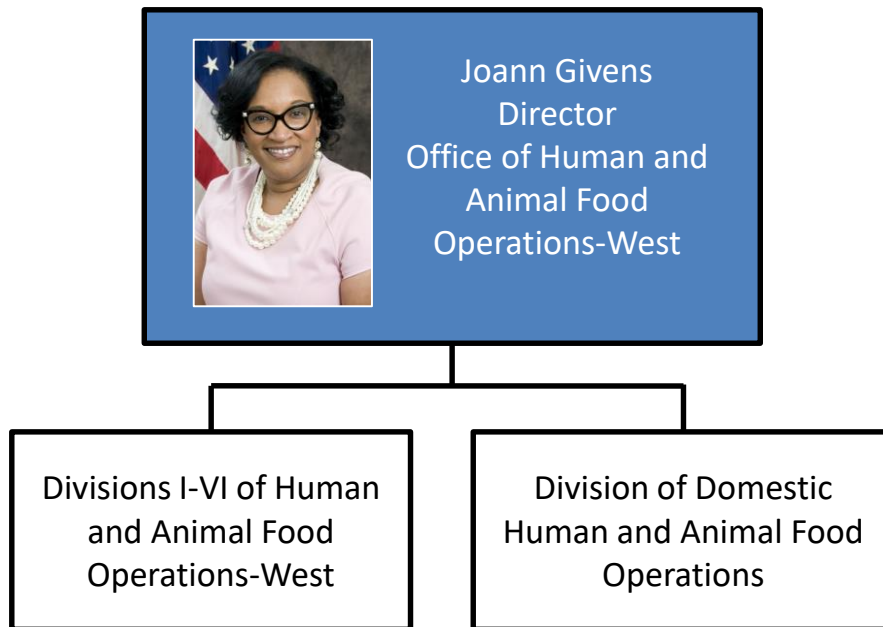


Office of Human and Animal Food Operations - EAST



| Office/Division | Title | Name |
|-----------------------------|---------------------------------------|---------------------------------|
| OHAFO East Immediate Office | Director | Vinetta Howard-King (acting) |
| OHAFO East Immediate Office | Deputy Director | W. Charles Becoat |
| OHAFO East Division 1 | Program Director/District Director | Ron Pace |
| OHAFO East Division 2 | Program Director/District Director | Evelyn Bonnin |
| OHAFO East Division 3 | Program Director/District Director | Ingrid Zambrana |
| OHAFO East Division 4 | Program Director/District Director | Maridalia Torres |
| OHAFO East Division 5 | Program Director/District Director | Steven Barber |
| OHAFO East Division 6 | Program Director/District Director | William Weissinger |

Office Of Human and Animal Food Operations-West



Office of Human and Animal Food Operations - WEST



| Office/Division | Title | Name |
|-----------------------------|------------------------------------|-------------------------|
| OHAFO West Immediate Office | Director | Joann Givens |
| OHAFO West Immediate Office | Deputy Director | Glenn Bass |
| OHAFO West Division 1 | Program Director/District Director | Michael Dutcher, DVM |
| OHAFO West Division 2 | Program Director/District Director | Cheryl Bigham |
| OHAFO West Division 3 | Program Director/District Director | Edmundo Garcia, Jr. |
| OHAFO West Division 4 | Program Director/District Director | LaTonya Mitchell-Holmes |
| OHAFO West Division 5 | Program Director/District Director | Darla Bracy |
| OHAFO West Division 6 | Program Director/District Director | Miriam Burbach |

What's Next?

- Complete the first phase - realignment
- Continue to invest in ORA's culture and values
- Advance the next phase – operational change

