OVERVIEW OF ORA’S
OFFICE OF HUMAN AND
ANIMAL FOOD OPERATIONS

International Citrus and Beverage Conference
September 20, 2018

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OFFICE OF REGULATORY AFFAIRS
DIVISION OF COMMUNICATIONS
How much do you know about FDA?

Which item is *not* under the jurisdiction of the Food and Drug Administration?
a. Spam
b. puppy food
c. chocolate covered cherries
d. frozen spinach
e. imported caviar
a. pesticide residues in lettuce
b. canned tomatoes
c. oven cleaner
d. spaghetti
e. pet turtles
a. baby pacifiers
b. baby bottle nipples
c. ceramic ware for food use
d. coffee mugs
e. eye chart
a. kidney dialysis machine
b. tongue depressor
c. toothpaste
d. fluoridated toothpaste
e. hair dryer
The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.
Overview

• FDA is responsible for the oversight of more than $2.5 trillion in consumption of food, medical products, and tobacco.

• FDA-regulated products account for about 20 cents of every dollar spent by U.S. consumers.
Overview (Cont.)

• FDA regulates about 75 percent of the U.S. food supply. This includes everything we eat except for meat, poultry, and some egg products.
USDA vs. FDA
USDA vs. FDA (Cont.)

**Poultry**

**USDA:** Domestic, such as domesticated chickens, turkeys, ducks, geese, and guineas. USDA also inspects raltses and squab, including emus.

**FDA:** Non-specified, such as wild turkeys, ducks, and geese.

**Red Meat**

**USDA:** Cattle, sheep, swine, goats, horses, mules, and other equine, as well as their carcasses and parts.

**FDA:** Non-specified red meats, such as bison, rabbits, game animals, zoo animals, and members of the deer family including elk and moose.

**Eggs**

**USDA:** Egg products, such as dried, frozen, or liquid eggs. USDA regulates egg product processing plants, such as plants that break and pasteurize eggs.

**FDA:** Shell eggs of domestic chickens, turkeys, ducks, geese, or guinea. FDA regulates egg processing plants, such as plants that wash, sort, and pack eggs.

**Products with Meat**

**USDA:** Products with more than 3% raw meat, 2% or more cooked meat or other portions of the carcass, or 30% or more fat, tallow, or meat extract, alone or in combination. USDA regulates products with 2% or more cooked poultry, or more than 10% poultry skins, giblets, fat, and poultry meat in any combination.

**FDA:** Products with less than 3% raw meat, less than 2% cooked meat or other portions of the carcass, or less than 30% fat, tallow, or meat extract, alone or in combination. FDA regulates products with less than 2% cooked poultry, or less than 10% poultry skins, giblets, fat, and poultry meat (limited to less than 2%) in any combination.
FDA Jurisdiction

- Foods
- Drugs
- Biologics
- Cosmetics
- Medical devices
- Veterinary products
- Radiation-emitting products
- Tobacco Products
## FDA Registered Facilities

<table>
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<tr>
<th>Program</th>
<th>Domestic</th>
<th>Foreign</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Drugs</td>
<td>1,403</td>
<td>385</td>
<td>1,788</td>
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<tr>
<td>Animal Food</td>
<td>17,941</td>
<td>6,636</td>
<td>24,577</td>
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<tr>
<td>Biologics</td>
<td>6,336</td>
<td>660</td>
<td>6,996</td>
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<tr>
<td>Human Drugs</td>
<td>3,204</td>
<td>7,147</td>
<td>10,351</td>
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<tr>
<td>Human Food</td>
<td>84,838</td>
<td>108,539</td>
<td>193,377</td>
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<tr>
<td>Medical Devices</td>
<td>13,790</td>
<td>13,110</td>
<td>26,900</td>
</tr>
<tr>
<td>Tobacco</td>
<td>3,039</td>
<td>0</td>
<td>3,039</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>130,551</strong></td>
<td><strong>136,477</strong></td>
<td><strong>267,028</strong></td>
</tr>
</tbody>
</table>
Program-Aligned Organizational Model

OFFICE OF THE ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS

OFFICE OF MANAGEMENT

OFFICE OF COMMUNICATIONS AND PROJECT MANAGEMENT

OFFICE OF CRIMINAL INVESTIGATIONS

OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS

OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS

OFFICE OF REGULATORY SCIENCE

OFFICE OF PARTNERSHIPS AND OPERATIONAL POLICY

OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS

OFFICE OF TRAINING, EDUCATION AND DEVELOPMENT
WHY OHAFO?

“A specialized office to help protect and promote the safety of human and animal food products.”

--ORA Office of Human and Animal Food Operations
About OHAFO

• Program within the Office of Regulatory Affairs (ORA)
• Advise and counsel agency leaders on food product field operations, work planning and emergency response activities.
• Collaborate with the Office of Food and Veterinary Medicine’s (OFVM) Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) on all FDA-regulated human and animal food products.
• State Evaluations of Milk/Shellfish Programs
• Technical Assistance and Program Standards Support
• Serves as the Agency’s focal point for auditing state and international programs.
• Works with CFSAN and the States to help protect and promote the safety and quality of the nation’s domestically produced and imported shellfish, milk, and retail foods.
Office of Human and Animal Food Operations

Michael Rogers, MS
Assistant Commissioner for Human and Animal Foods

Ellen Buchanan
Director, Audit Staff

Laurie Farmer
Director, Office of State Cooperative Programs

Vinetta Howard-King
Director, Office of Human and Animal Foods East [acting]

Joann Givens
Director, Office of Human and Animal Foods West
Office of State Cooperative Programs

Division of Retail Food Protection

Division of Milk Safety

Division of Shellfish Sanitation
HAF 4E

Director
Ramon Hernandez

Deputy Director
Elizabeth “Bess” Ormond

Director of Investigations
Vacant

Director of Compliance
Edwin Ramos
OHAFO Field Operations

**Status Quo**

- District Offices: physical locations of ORA’s district offices are maintained
- District Director: remains most senior FDA official in field and remains responsible for all staff in their geographic location regardless of aligned program
- State Liaison and Emergency Response Coordinator: remains contact for localities and states

**New Components and Roles**

- Program Divisions: replaces former ORA regions
- Program Division Directors: co-title for District Directors capturing their geographic oversight of OHAFO operations outside of their district office
- Office of State Cooperative Programs
ORA AND FDA CENTERS: ALIGNING FOR THE FUTURE
Human and Animal Food

• Annual Strategic Priorities for Human and Animal Food
  – Implementation of FSMA rules
  – Training
  – Modernized GMP, cGMP for Animal Food
  – PC, Sprouts, Produce, FSVP
  – Sanitary Transport
  – Inspections
  – Compliance
  – Samples (Environmental and Finished) and Analyses
  – Follow-up to Class 1 Recalls
  – Follow-up to Foodborne Outbreaks
  – Collaboration with federal, state local public health officials

• Annual Work Plans
  – ORA/CFSAN
  – ORA/CVM
OHAFO Contacts and Resources

- General OHAFO Inquiries: engageora@fda.hhs.gov
- All local inquiries: District Director
- State and local inquiries: State Liaison
- State Cooperative Programs: Field Specialist
- Learn more: www.FDA.gov/ORA
  - OHAFO Fact Sheet
  - ORA Headquarters and District Contact Information
  - Investigations Operations Manual
Public Affairs Contacts

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  – Imports

• Stewart Watson – stewart.watson@fda.hhs.gov
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ORA Ombudsman

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www.fda.gov/ORAOmbudsman

• Objective third party to assist in resolution
• Help navigating the Agency and ORA
• Concerns or compliment about Agency conduct
Questions
They Make Us Say This

Per 21 C.F.R. 10.85(k), information in this presentation is an informal communication that represents my best judgment at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.