



“GO 101”

An Overview of the Office of Global Regulatory Operations and Policy

January 2017

U.S. Food and Drug Administration

What We'll Cover....

- I. About FDA
- II. About GO – the Office of Global Regulatory Operations and Policy
- III. GO's World
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- IV. Summary

I. About FDA

- FDA is responsible for over \$2 trillion in medical products, food, cosmetics, dietary supplements and tobacco.
- FDA-regulated products account for about 20 cents of every dollar of annual spending by U.S. consumers.
- The agency has approximately 16,200 full-time employees located around the world.
- FY 2016 budget is \$4.74 billion.

II. About GO – Our Goals

- Ensure our domestic and imported food is safe by identifying drivers of change in food safety oversight.
- Ensure that tobacco products are regulated effectively.
- Ensure that Americans have safe, effective, and high-quality medical products.
- Build and use mutual reliance with trusted regulatory partners and industry to advance public health.
- Coordinate across the Agency to identify and target those areas of greatest risk in the global supply chain.

The Composition of GO

1. Office of Regulatory Affairs (ORA):

- Approximately 4,890 employees, including more than 1,800 investigators, in offices throughout the U.S.
- Field staff performs inspections and investigations at manufacturing sites, farms, warehouses, and ports. Provides leadership on import and enforcement policies.
- Collaborates with state, local, tribal, and territorial regulatory partners, and administers contracts, grants and cooperative agreements to advance integration.
- Maximizes compliance and minimizes risk associated with FDA-regulated products in all areas – food, animal feed, medical products and tobacco.
- Contains the Office of Criminal Investigations (OCI); more than 270 employees of which more than 220 are Special Agents. OCI conducts investigations which include the distribution of counterfeit and unapproved drugs, product tampering, and health fraud.

What does GO *do*?

- Our professionals conducted more than 16,100 domestic inspections in FY 2016. That amounts to roughly 1,340 inspections a month -- or 44 inspections every day of the week.
- Our 650 laboratory analysts reviewed approximately 35,200 lab samples in FY 2016, more than 78 each day of the year.
- In FY 2016, OCI cases resulted in 257 arrests, 274 convictions, and more than \$374 million in fines, restitutions, and asset seizures and forfeitures.
- Overseas, our personnel conducted 3,512 inspections in FY 2016, in locations ranging from China to Chile to India.
- Along with the Office of Foods and Veterinary Medicine, GO has undertaken an operational plan to implement FSMA, the Food Safety and Modernization Act.
- GO has helped achieve the signing of more than 148 international arrangements with more than 43 nations and multilateral partners regarding FDA's product quality and safety efforts.
- GO contracts with its state partners in the performance of more than 21,100 food, feed, drug and device inspections annually in programs that reach all fifty states.
- GO professionals oversee more than 34 million shipments of FDA-regulated products at 46 ports of entry and international mail facilities.

The Composition of GO

2. Office of International Programs (OIP)

- OIP contains approximately 154 employees, including FDA and locally engaged staff, in Belgium, China, Chile, Costa Rica, India, Mexico, and the United Kingdom.
- OIP serves as the FDA's focal point for international efforts. This includes managing engagement with global regulatory partners, ministries of health and agriculture, U.S. Government Agencies, industry, and other relevant stakeholders.

III. GO's World

1. Collaborating with FDA Centers to achieve the Agency's public health objectives.
2. Responding to globalization by working with international stakeholders to leverage information and target risk.
3. New legislation
 - Food Safety and Modernization Act (FSMA)
 - FDA Safety and Innovation Act (FDASIA)
 - Drug Quality and Safety Act (DQSA)

IV. Globalization...By The Numbers

- **Foreign production of FDA-regulated goods and materials has exploded over the last decade.**
- **FDA-regulated products originate from more than:**
 - 150 countries
 - 130,000 importers
 - 300,000 foreign facilities
- **Number of FDA-regulated shipments at 300 U.S. ports has more than doubled during the last ten years.**
 - In 2006, approximately 15 million shipments of imported food and medical products crossed our borders. In 2013, that number was 29 million. In 2015, 34 million.

...and more...

- **Drugs and Devices**

- Today, nearly 35 percent of medical devices used by Americans are made overseas.
- And approximately 80 percent of the manufacturers of active pharmaceutical ingredients (APIs) used in the United States are located abroad.

- **Food**

- Approx. 15% of food consumed by U.S. households is imported.
- Approx. 50% of fresh fruits and 25% of fresh vegetables consumed by U.S. households are imported.
- Approx. 85% of seafood eaten domestically comes from outside the U.S.

Beyond the Numbers: The Challenge of the Global Supply Chain

- Tracking and tracing a product is complex due to the increased number of involved individuals, producers, and companies, many of which are geographically dispersed.
- Growing availability of distribution channels for products – think “Internet.”
- Always the bad actors: Counterfeiting of products for economic or other reasons.

New Legislative Authorities

- **Food Safety and Modernization Act (FSMA)**
 - Shifts focus from responding to food contamination to preventing it.

- **Food and Drug Administration Safety and Innovation Act (FDASIA)**
 - Provides FDA more authority to ensure quality and availability of safe and effective medical products.

- **Drug Quality and Security Act (DQSA)**
 - Outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs distributed in the U.S.

IV. Summary

- GO has nearly 5,100 individuals working throughout the U.S. and the world, ensuring that our food is safe and that our medical products are safe, effective and of high quality.
- GO is meeting the challenges of globalization and is continually working to improve global regulatory systems and target risk in the vast and complex global supply chain.
- GO is committed to implementing new legislative authorities that respond to current and future regulatory needs.
- All of these efforts are directed at advancing the public health of the American people.



Global Regulatory Operations and Policy

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