

FDA

U.S. FOOD & DRUG
ADMINISTRATION

OFFICE OF REGULATORY AFFAIRS

Food and Drug Law Institute Annual Conference

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Associate Commissioner for Regulatory Affairs

Keynote Address

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ORA'S ROLE AND FUNCTIONS

ORA Maximizes Compliance of FDA Regulated Products and Minimizes Risks Associated with Those Products

ORA Employees




~4,563

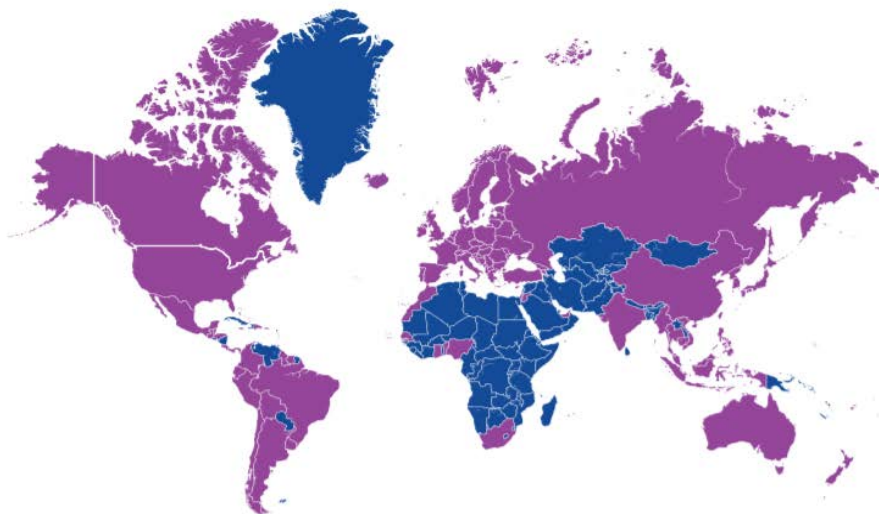


INSPECTIONS: ORA'S GLOBAL REACH

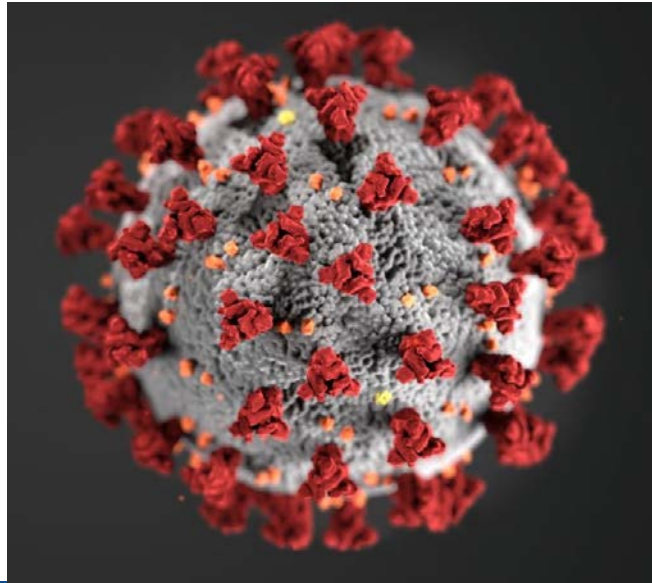
ORA's Global Inspections:

United States	Czech Republic	Japan	Singapore
Albania	Denmark	Jordan	Slovakia
Argentina	Dominican Republic (the)	Korea (the Republic of)	Slovenia
Armenia	Ecuador	Latvia	South Africa
Australia	Estonia	Lithuania	Spain
Austria	Faroe Islands	Macedonia	Suriname
Bahamas	Fiji	Malaysia	Sweden
Barbados	Finland	Malta	Switzerland
Belarus	France	Marshall Islands	Taiwan
Belgium	Georgia	Mauritius	Thailand
Belize	Germany	Mexico	Tonga
Benin	Ghana	Moldova	Trinidad & Tobago
Bolivia	Greece	Morocco	Turkey
Bosnia-Herzegovina	Grenada	Netherlands	Ukraine
Brazil	Guatemala	New Zealand	United Arab Emirates
Bulgaria	Guyana	Nigeria	United Kingdom
Burma (Myanmar)	Honduras	Norway	Uruguay
Cambodia	Hong Kong SAR	Panama	Vietnam
Canada	Hungary	Peru	Western Samoa
Cape Verde	Iceland	Philippines	
Chile	India	Poland	
China	Indonesia	Portugal	
Colombia	Ireland	Romania	
Costa Rica	Israel	Russia	
Croatia	Italy	Senegal	
Cyprus	Jamaica	Serbia	

 Countries Where ORA Conducts Inspections



COVID-19 PANDEMIC



INSPECTIONS

- On-site domestic and foreign surveillance inspections were postponed in March 2020
- Mission-critical inspections continued; 200 performed since March 2020



COVID-19 ADVISORY RATING SYSTEM

- Created to determine when and where it is safest to conduct domestic inspections
- Uses real-time data to assess the number of COVID-19 cases in a local area
- Helps to protect our staff and the employees of the facilities we regulate

PRIORITIZED DOMESTIC INSPECTIONS

- Pre-announced
- Ensure safety of employees
- Personal protective equipment

OPTIMIZING OPERATIONS

- Exploring technology tools
- Video

RECORDS REQUEST

- Section 704(a)4 of the Federal Food and Drug Cosmetic Act
- Mutual Recognition Agreement
- Approaches help inform decisions related to drug approvals and shortages



EXPLORING REMOTE REGULATORY ASSESSMENTS

- Mechanism to help make important regulatory decisions
- Involves a remote view of records that a firm is required to maintain for the FDA's review



FOREIGN SUPPLIER VERIFICATION FORM

- Critical to ensure the safety of food from foreign suppliers
- Remote FSVP Assessment Protocols began in March 2020; nearly 700 inspections conducted and nearly a dozen warning letters issued due to findings
- Only in certain circumstances will on-site inspections be performed

OPTIMIZING OUR INSPECTION PROCESS

- COVID-19 highlighted interconnected global manufacturing and supply system
- Opportunities to optimize inspectional work through process improvements and increased collaboration with stakeholders
- Interim report available at the end of 2020 and a final report in summer of 2021

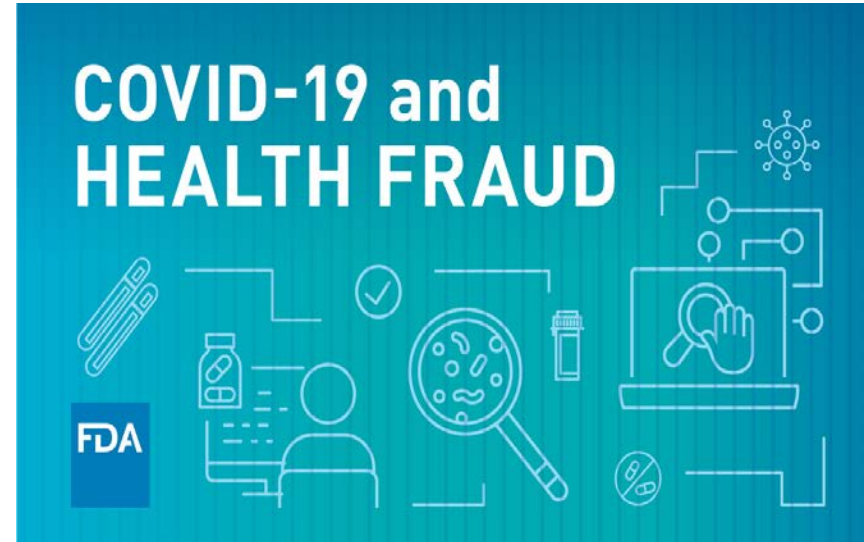
NEW ERA FOR SMARTER FOOD SAFETY BLUEPRINT



- Strengthens how the FDA approaches the safety and security of our nation's food supply
- Seeks to collaborate and work with our stakeholders in new and creative ways

OPERATION QUACK HACK

- Leverages agency expertise and analytics to protect consumers from fraudulent products
- Online marketplaces have removed more than 500 products at FDA's request
- Information on reporting fraud or violations is found on <https://www.fda.gov/safety/report-problem-fda/reporting-unlawful-sales-medical-products-internet>



GOING FORWARD

- Current challenges present opportunities to reassess how we work
- ORA will continue to work to enhance our response
- We will continue to encourage high standards in food and medical safety, including supply chains



Questions?



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