FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

FDA INSPECTIONS SUMMIT

15TH Annual

November 17, 2020

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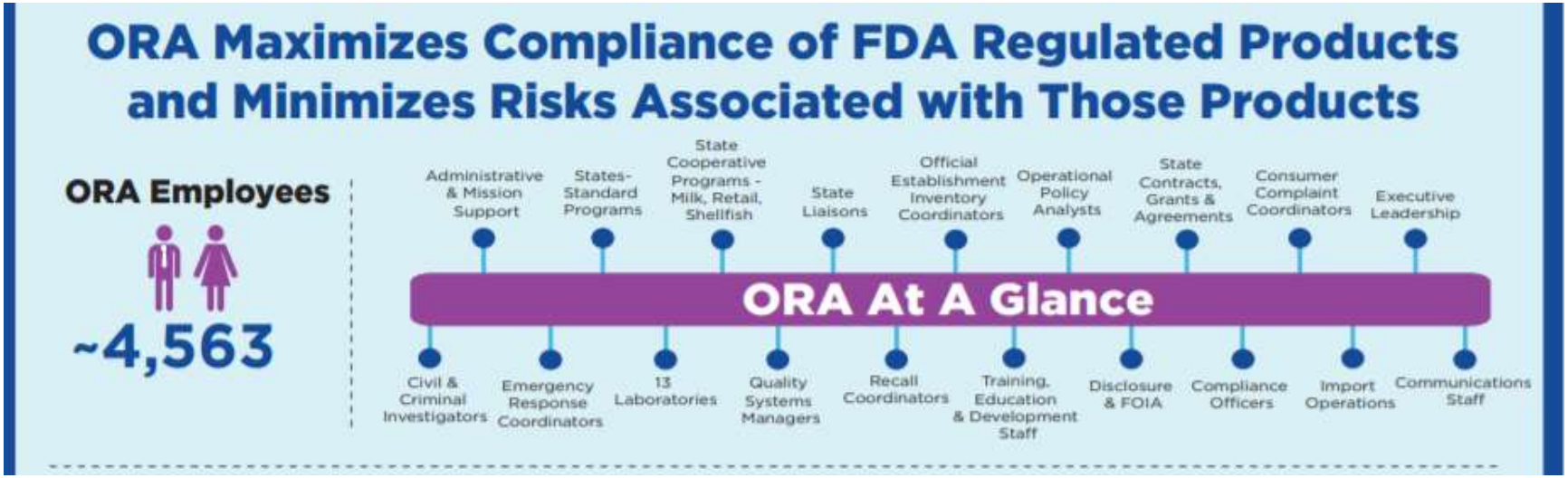
Assistant Commissioner for Medical Products and Tobacco Operations Regulatory Affairs

Keynote Address

ORA'S ROLE AND FUNCTIONS

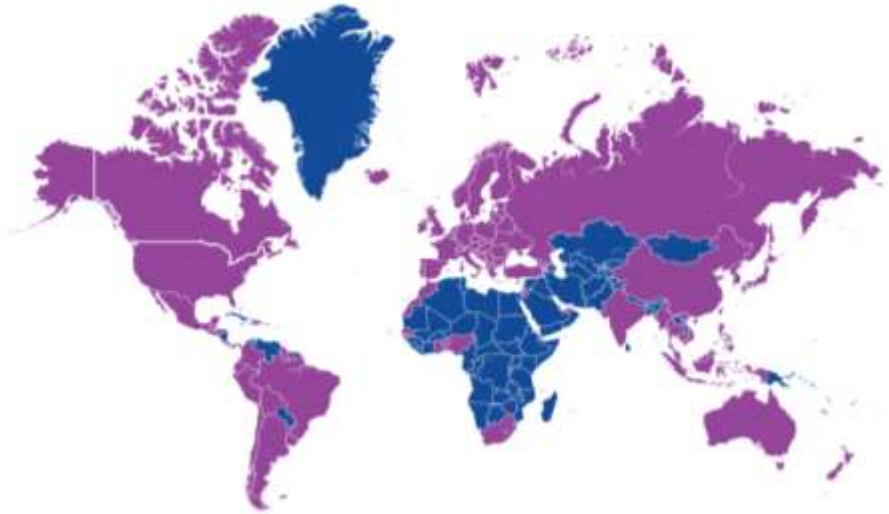


INSPECTIONS: ORA'S GLOBAL REACH

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	

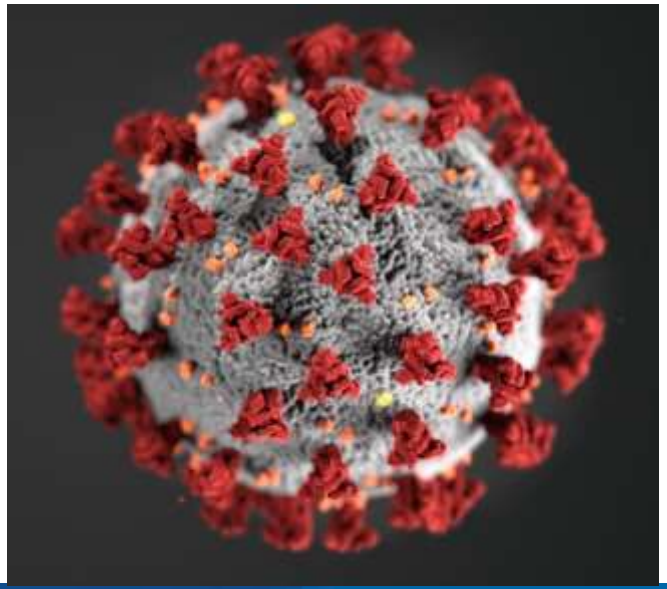
Countries Where ORA Conducts Inspections



UPDATES

- New ORA Leadership
  - Associate Commissioner for Regulatory Affairs
  - Deputy Associate Commissioner for Regulatory Affairs
  - Assistant Commissioner for Medical Products and Tobacco Operations

COVID-19 PANDEMIC



FDA ACTIVITIES DURING COVID-19 AS RELATED TO MEDICAL PRODUCTS

- March 10 and 18 announcements to postpone foreign and domestic inspections
- Continued mission critical inspections on a case-by-case basis
  - Potentially serious public health hazard
  - Essential product shortage
  - Pre-approval inspection needed for novel or pandemic-related product or treatment
- Using statutory authorities to collect records in lieu of inspections and other tools

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

FDA ACTIVITIES DURING COVID-19 AS RELATED TO MEDICAL PRODUCTS

- Office of Medical Products and Tobacco Operations (OMPTO)
  - Conducted mission critical, onsite drug & BIMO inspections
  - Section 704(a)(4) of the Federal, Food, Drug, and Cosmetic Act. This provision, in place since Food and Drug Administration Safety and Innovation Act (FDASIA 2012) allows for **records request** in advance or in lieu of an inspection
    - Section 706, Records for inspection section – request includes description of information requested, reasonable timeframe, within reasonable limits, reasonable manner.

RECORDS REQUEST

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

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

PRIORITIZED DOMESTIC INSPECTIONS

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

EXPLORING REMOTE REGULATORY ASSESSMENTS

- Voluntary 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

MEDICAL PRODUCT PROGRAM UPDATES

- Biologics –
  - Workshop for the Reproductive Tissue
  - On-site investigations intended to support COVID-19 countermeasures

MEDICAL PRODUCT PROGRAM UPDATES

- Medical Devices –
  - Remote QSIT assessments
  - Anticipating 2021 FDA publishing Proposed Rule for transition of quality system regulation to ISO 13485:2016

MEDICAL PRODUCT PROGRAM UPDATES

- Pharma Program –
  - Center of Excellence for Outsourcing Compounding virtual conference
  - Expanding MRA
  - Mission Critical Assignments (inspections & sample collections)

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

ONGOING ACTIVITIES

- Hand Sanitizers
- Collaboration on APIs & Sterile Finished Dosage
- Compliance

GOING FORWARD

- Current challenges present opportunities to reassess how we work
- ORA will continue to work to enhance our response
- Continued collaboration with other regulators
- PICS & Inspection Reliance

Questions?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