FDA

Office of Enforcement and Import Operations

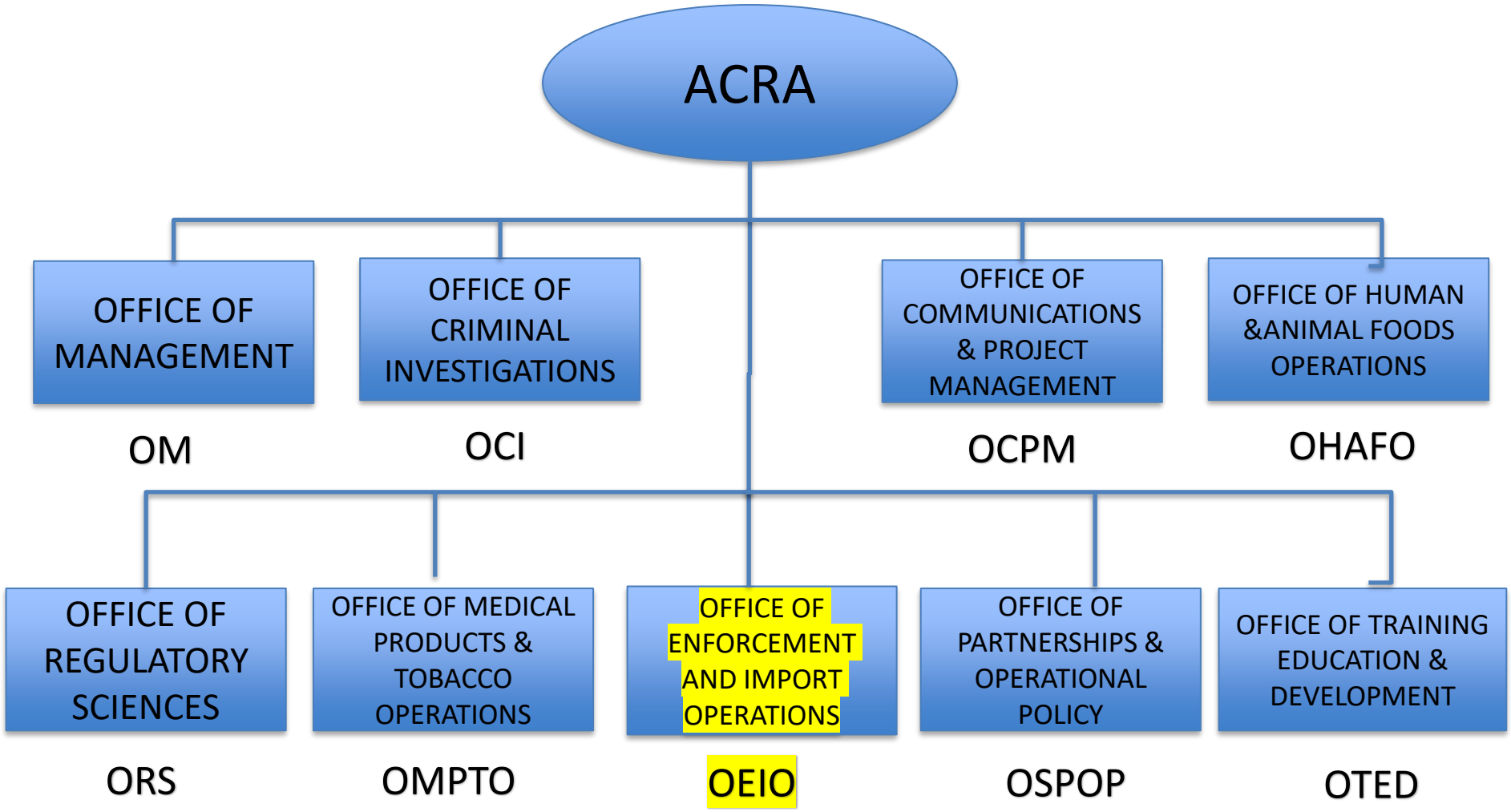
U.S. FOOD & DRUG ADMINISTRATION

WESCCON

October 22, 2020

Dan Solis
Acting Assistant Commissioner

ORA Organizational Chart



FDA ORA PROGRAM ALIGNMENT

Human and Animal Food Program

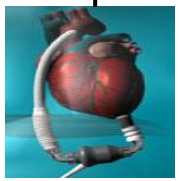
Scott MacIntire
Acting Director, HAF-W

Vinetta Howard King
Director, HAF-E

Pharmaceutical Quality Program

Alonza Cruse,
PQ Director

Medical Device Program



Jan Welch,
Medical Device Director

Biologics Program

Ginnette Michaud,
Biologic Director

Tobacco Program

Paul Perdue
Director, Tobacco Operations

Enforcement and Import Operations Program

Dan Solis, Acting Assistant Commissioner
Office of Enforcement and Import Operations

BIMO Program

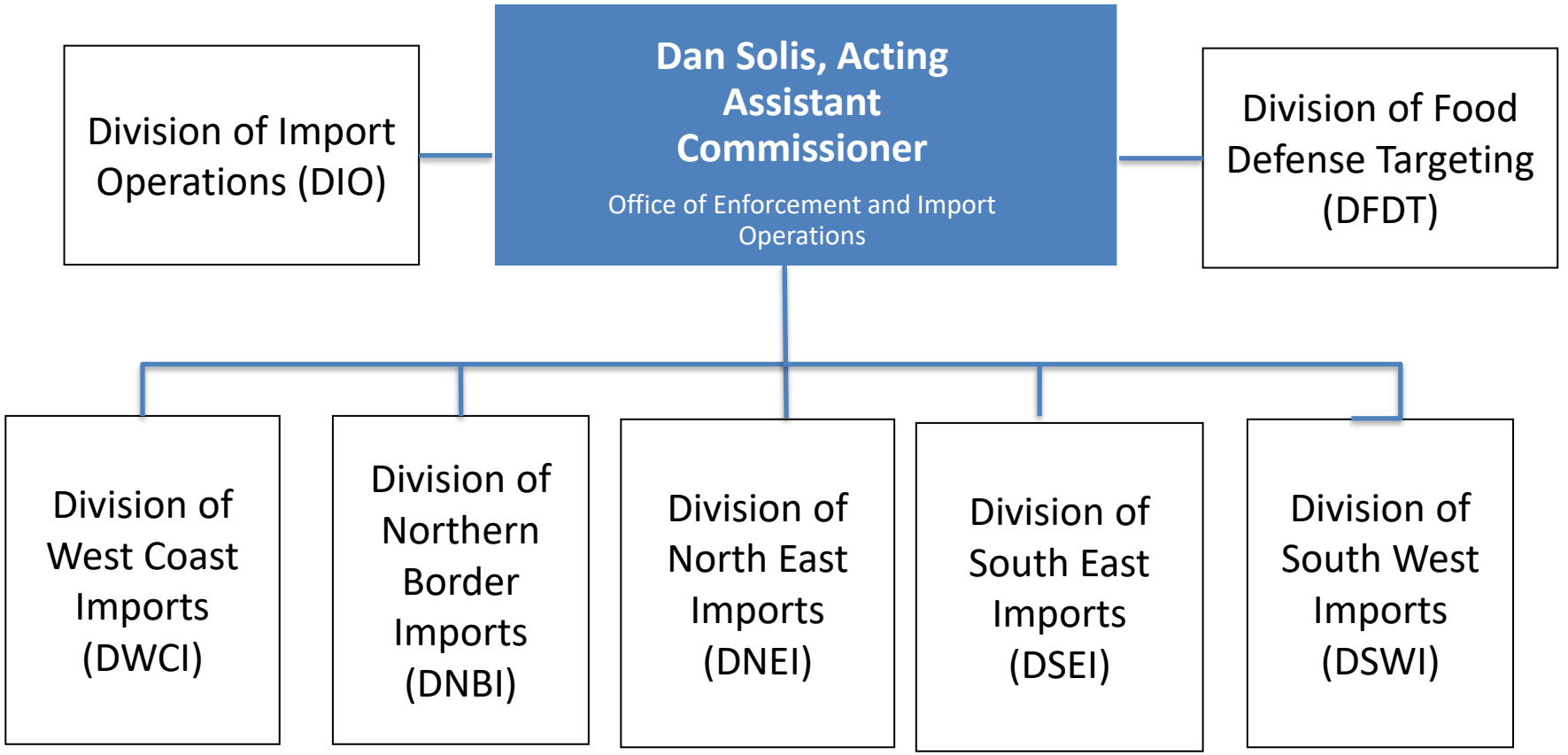
Chrissy Cochran, PhD
Bioresearch Monitoring Director

ORA – Office of Regulatory Affairs 3 Main Offices in FDA investigating covid-19 Fraud Products

- Office of Enforcement and Import Operations (OEIO)
- Office of Criminal Investigations (OCI)
- Division of Enforcement – Health Fraud Branch

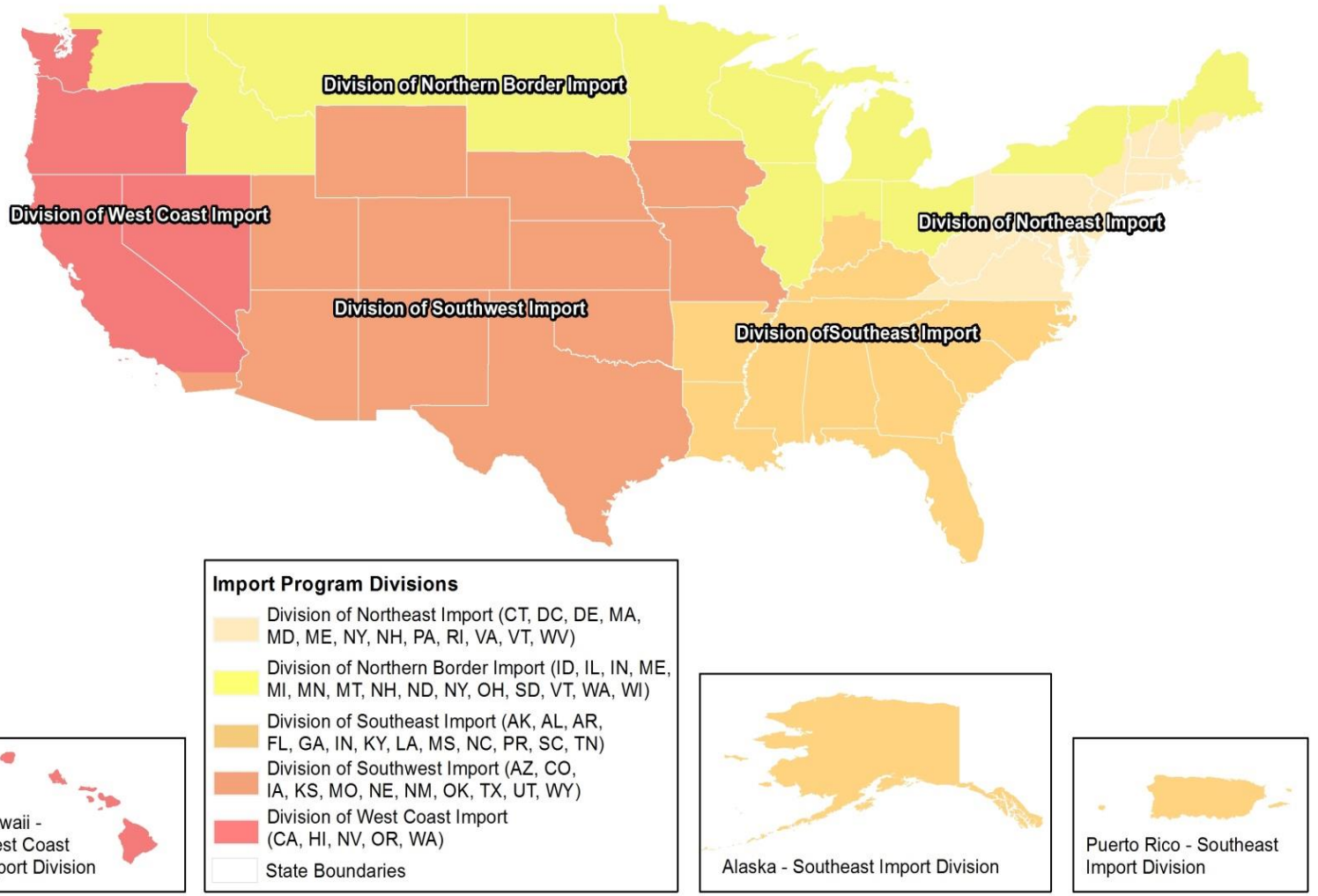
Office of Enforcement and Import Operations

U.S. FOOD & DRUG ADMINISTRATION



Office of Enforcement and Import Operations (OEIO)

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



Source: ORA

Prepared by Office of Regulatory Affairs (ORA) Division of Planning, Evaluation & Management (DPEM), Program Evaluation Branch, 2017

FDA's New Legislations

- **The Family Smoking Prevention and Tobacco Control Act (TCA**). Signed into law on June 22, 2009. Gives FDA authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health. Aims to curb the trend of new users becoming addicted before they are old enough to understand the risks and ultimately dying too young of tobacco-related diseases.

- **Food and Drug Administration Safety & Innovation Act (FDASIA**). Signed into law on Jul. 9, 2012. Expands the Agency's authorities and strengthens the agency's ability to safeguard and advance public health by giving the authority to collect user fees, promoting innovations, increasing stakeholder involvement and enhancing the safety of the drug supply chain
  - Prescription drug provisions (PDUFA V)
  - Medical Device Provisions (MDUFA III)
  - Generic Drug User Fee Amendments of 2012 (GDUFA)
  - Biosimilar User Fee Act (BsUFA)

- **Drug Quality and Security Act (DQSA**). Signed into law on Nov. 27, 2013. Outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S.

- **Food Safety Modernization Act (FSMA**). Signed into law on January 4, 2011. The most sweeping reform of **our food safety laws in more than 70 years**. It aims to ensure the U.S. food supply is safe by shifting the focus **from responding to contamination to preventing** it.
  - Seven Proposed Rules right now (2016 Some Published Guidelines):
    - Produce Safety
    - Preventive Controls for Human Food
    - Preventive Controls for Animal Foods
    - Foreign Supplier Verification Program (FSVP)
    - Accreditation of third-party auditors for foreign facilities
    - Mitigation for Intentional Adulteration of Food
    - Sanitary transportation of human and animal food

7

FDA's New Legislations

- SUPPORT Act - The SUPPORT (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment [SUPPORT] for Patients and Communities) Act was enacted on October 24, 2018. This new law grants FDA additional import authorities that FDA believes will meaningfully advance efforts to stop illegal and unsafe drugs from being imported into the United States. For example, the SUPPORT Act includes:
  - Improvements to the infrastructure and resources of International Mail
  - Authority to treat an FDA-regulated article as a drug if that article contains an active ingredient that is found in an FDA-approved drug or licensed biologic, and the ingredient presents a significant public health concern;
  - Authority for FDA to debar people who have been convicted of a felony involving illegal importation of drugs or controlled substances, or who have engaged in a pattern of illegally importing controlled substances or certain adulterated or misbranded drugs; and
  - Authority for FDA to treat any imported drugs as illegal from a person who has engaged in a pattern of importing adulterated or misbranded drugs if the shipments are from the same manufacturer, distributor, or importer

8

What did FDA do during COVID-19?

- Imported Food Security, Safety and maintaining food supply chain continued to be a priority and was essential activity
- Continued to examine, interdict, test and refuse adulterated imported food
- Continued to examine, interdict, test and refuse unapproved, fraudulent and counterfeit Medical Products at Ports of Entry and Mail facilities.
- FDA, with CBP seized, and interdicted fraudulent test kits and destroyed unapproved drugs and opioids, including hand sanitizers, face mask and other medical products.
- Conducted Remote FSVP and if needed visit on-site inspections. CSO's explored new remote, regulatory tools (iPad, iPhone, portable cameras, secured doc – cloud and block chain technologies)
- Investigated, with OCI, those who circumvented import process.

9

Critical FDA Work During Pandemic

- Only those “Mission Critical” inspections were conducted.
- New tools – preassessment remotely
- Used “cloud” applications for document exchange
- Import Work considered “essential activities”.
- For Import Sample collection, arranged for CDC guidelines be executed before going to firm and performed work in isolated conditions
- Used CES and other Customs Facilities to obtain samples. Samples brought to FDA
- Health Fraud continued to surveillance on internet and send out warning letters, as well as advertise fraudulent products and “do not use” list.
- FDA worked with CBP/HSI to investigate vendors selling counterfeit and fraudulent products.
- FDA worked with CDC and EPA on sanitizing products

Emergency Use Authorization (EUA)

- Statutory Authority allowing the Secretary of DHHS to authorize the introduction into IS, the use of unapproved medical products or authorize unapproved uses of approved medical products
- During emergency, actual or potential

Pre - Emergency Use Authorization (Pre-EUA)

- Submission sent to the Center to allow FDA to begin review of data/information prior to submission of an EUA request
- Can be submitted at any time prior to or during a declared emergency

Criteria for Issuance of Emergency Use Authorization (EUA)

- Serious or life threatening disease or conditions caused by a chemical, biological, radiological, or nuclear agent(s)
- Scientific evidence, product maybe effective in diagnosing, treating, or preventing: serious or life-threatening disease
- Known and potential benefits outweigh the known and potential risks of the product when used to diagnose, treat, or prevent the serious or life-threatening disease or condition
- There is no adequate, approved, and available alternative to the candidate product for diagnosing, treating or preventing the serious or life-threatening disease or condition

Latest Information from FDA

- 10/21/20 = US Agent Voluntary Identification System (VIS) for Food Facility Registration: Guidance for Industry.
  - The purpose of this guidance is to announce that FDA has established a U.S. Agent Voluntary Identification System (VIS) in conjunction with our food facility registration database, the Food Facility Registration Module (FFRM).
  - The purpose of the VIS is to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. This guidance provides information for U.S. agents and foreign facilities importing food into the U.S. who choose to utilize the VIS.
  - Posted to the FDA website on 10/16/20. It is immediately in effect and subject to comment in accordance with FDA GGPs

Latest Information from FDA

- 10/21/20 = US Agent Voluntary Identification System (VIS) for Food Facility Registration: Guidance for Industry.
  - The purpose of this guidance is to announce that FDA has established a U.S. Agent Voluntary Identification System (VIS) in conjunction with our food facility registration database, the Food Facility Registration Module (FFRM).
  - The purpose of the VIS is to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. This guidance provides information for U.S. agents and foreign facilities importing food into the U.S. who choose to utilize the VIS.
  - Posted to the FDA website on 10/16/20. It is immediately in effect and subject to comment in accordance with FDA GGPs

Latest Information from FDA

- 10/15/20 = **FDA Reissues Emergency Use Authorization for Certain Non-NIOSH-Approved Filtering Face-Piece Respirators Manufactured in China**
  - FDA reissued the Emergency Use Authorization (EUA) for certain filtering face-piece respirators (FFRs) that are manufactured in China and are not approved by NIOSH.
  - Under June 6, 2020 version of this EUA, a respirator was authorized if it met any of three predetermined eligibility criteria. Effective immediately, the reissued EUA no longer includes the three eligibility criteria, meaning the FDA will no longer review requests nor add to the list of authorized respirators–known as Appendix A—of this EUA based on those criteria.
  - The FDA recognizes there is still a shortage of FFRs, and to provide additional capacity as needed, the agency is continuing the EUA of respirator models that are already included in Appendix A.
  - **Since pandemic, agency supports the PPE needs of our health care personnel by issuing EUAs. As part of our continuing work to meet the demands of this public health emergency, we undertook and completed a shortage assessment and concluded that reissuing this EUA was appropriate to reflect the current U.S. demand for these products" from CDRH**

Latest Info

- The FDA issued a Consumer Update entitled, Advisory Committees Give FDA Critical Advice and the Public a Voice. It describes how the FDA relies on its many advisory committees to help it make sound decisions based on the best science available.
- Testing updates:
  - As of today, 282 tests are authorized by FDA under EUAs; these include 220 molecular tests, 56 antibody tests, and 6 antigen tests.

Thank You For Your Attention!

Email address:
Dan.Solis@fda.hhs.gov

Or

WCID@fda.hhs.gov

Thank you!

19


FDA
U.S. FOOD & DRUG
ADMINISTRATION

U.S. FOOD & DRUG ADMINISTRATION

FDA REMOTE FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP)

DWCI

WESCCON 2020

October 22, 2020

Background Information

- FDA Food Safety Modernization Act of 2011 – creation of a food system to prevent contamination instead of reacting to problems after they occur
- FSVP Rule applies to imported food products mandating that foods imported from other countries be held to the same high standards required of domestic food
- Importers accountable for verifying that foreign suppliers producing food in a manner that meets US safety standards
- FSVP Inspections cover human and animal food importers subject to **21 CFR part 1, subpart L**

Remote FSVP Inspections

In March 2020, FDA given authority to *temporarily* conduct remote FSVP Inspections due to the COVID-19 Pandemic

- FDA assignment amended to include instructions for performing remote FSVP inspections
- Allows initial, reinspection, and compliance inspections to be conducted remotely
- Allows for on-site FSVP inspections where deemed appropriate
  - For any reinspection, it is not mandatory for the FDA Investigator to make pre-inspection contact with the FSVP importer

Pro's and Con's of Conducting Remote FSVP Inspections

- FDA Investigators initially had many questions and concerns that were addressed by DWCI and the Agency
- Conducting FSVP inspections on the West Coast is going well
- We have approval to continue conducting remote FSVP inspections for FY 21

Pro's

- Providing same level of public health protection
- FDA Investigators feel the FSVP-Importer is being held to the same standard as when conducting on-site inspections
- Allows different offices within DWCI to conduct inspections outside of local geographic area
- We are granting firms more time to comply with our records request due to the pandemic
- FDA Investigators have more time to review records

Con's

- Inspections take longer to conduct (contact with firm, receiving records, etc.)
- Some FSVP-Importers non-responsive
- Firms have reduced their business hours and staff
- FSVP records are not readily available
- Translation of records can take longer when the translator is outside the USA (also affected by pandemic)
- Challenge to conduct an FDA Team inspection and train FDA Investigators
- FDA Investigators miss the face-to-face interaction

Types of Communication, Document Exchange Methods for Remote FSVP Inspections

- Multiple phone call and email exchanges
- WebEx, Skype, Zoom
- Electronic Records Preferred
- Large data files take time to send, receive, open
- Multiple emails with Attachments
- Phone call, email, or read receipt needed to confirm documents received (FDA-482d, FDA-483a, Records Identification Letter)

QUESTIONS?


FDA
U.S. FOOD & DRUG
ADMINISTRATION