Foreign Supplier Verification Programs (FSVP)

Presenter:
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Overview

• FDA Data Dashboard and TRACK
• Temporary use of UNK
• FSVP Remote inspections and RRAs
• FSVP Guidance for Industry
Enforcement Actions:
Warning Letters

- Warning Letters issued = serious observations made; importer fails to comply
- Continued non-compliance after Warning Letter may result in placement on Import Alert
- FY19 - 1st Warning Letter issued
- FY20 – 45 Warning Letters issued
- FY21 – 58 Warning Letters issued
- FY22- approx 62 Warning Letters issued
Enforcement Action:
Import Alert 99-41

• FSVP Import Alert 99-41 published on July 31, 2019

• Removal from IA 99-41 is non-traditional (i.e., private laboratory testing)

• Importer must demonstrate compliance through submission of documentation of corrective actions taken
FDA Data Dashboard

- External resource portal
- Intended for industry and stakeholder use
- Review compliance history of foreign supplier
- Determine approval and potential hazards
Firm/Supplier Evaluation Resources

The Firm/Supplier Evaluation Resources is:

• Located within the FDA Data Dashboard

• Used by importers and manufacturers/processors to perform evaluation for foreign supplier approval and compliance with FDA food safety regulations

• Compliance includes whether supplier is the subject of a warning letter, import alert, or other FDA compliance action (food safety)
Imported Food Safety Measures

Number of Inspections by Classification

Percent of Inspections by Classification

Temporary Use of UNK

• Compliance with Providing an Acceptable UFI for the FSVP Regulation: GFI
  – Policy allowing temporary use of UNK. Updated Apr. 27, 2022
  – Developed to provide importers time to obtain DUNS
  – Avoid delays during entry process
• Importers must comply with section 1.509 (legal name, email address, and DUNS)
Outreach for impacted members of industry:

- April 2021: Monthly automated emails sent to FSVP importers and filers associated with UNK. Information includes:
  - Section 1.509 FSVP requirements
  - How to obtain a DUNS number
  - Potential repercussions for non-compliance
- Messages sent via CBP’s CSMS- included 30 day notice before end-dating UNK
- Direct outreach to filers to encourage communication with FSVP importers to obtain or provide a DUNS
Remote FSVP Inspections

• April 3, 2020 – In response to COVID-19, FDA announced implementation of remote FSVP importer inspections

• Remote Regulatory Assessment vs. Remote FSVP Inspection

• Some situations have warranted an onsite inspection (i.e., foodborne illness outbreak)
Remote FSVP Inspections and RRAs

- Overall positive feedback received from both, FDA investigators and industry; examples include:
  - Convenient (i.e., elimination of travel)
  - Efficient (i.e., ability to conduct multiple inspections simultaneously)
  - Decrease in stress and intimidation factors

- What to expect moving forward
FSVP Importer Portal for FSVP Records Submission

• Program efficiency
• Centralized location to communicate
• Allow users to submit large size documents
• Control types of records FDA received
• Communicate investigation status
• Control and prevent uploads after inspection close-out
FSVP Guidance for Industry and other items

• Expected issuance date of February 2022

• Reminders for industry?

• How can we partner together?
Questions?