Inspection Status / Frequent Observations in cGMP / PCAF

Short Training for Small Businesses
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Inspection Updates

HAF W6 cGMP / PCAF

Current work for FY 20 includes inspection covering cGMP / PCAF VFD (Veterinary Feed Directive), Medicated Feeds, BSE.

Work interruptions due to COVID-19

When inspecting – investigators are covering multiple programs

- Covering FSVP
- Sanitary Transport
What are we seeing during inspection?

• PCAF / cGMPs

• VFD - https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-vfd
  – Info for veterinarians, feed distributors, and animal producers
Are you a Qualified Facility?

- Sales and market value of food
- $2.5 million three year average
  - FSMA Inflation Adjusted Cut Offs
- **GFI: Determination of Status as a Qualified Facility**
- Attestation
  - Form FDA 3942b
Are you following the CGMPs?

• Housekeeping requirements
• GFI#235: Current Good Manufacturing Practice Requirements for Food for Animals
• Separate from 21 CFR 225

Subpart B—Current Good Manufacturing Practice

§507.14 Personnel.
§507.17 Plant and grounds.
§507.19 Sanitation.
§507.20 Water supply and plumbing.
§507.22 Equipment and utensils.
§507.25 Plant operations.
§507.27 Holding and distribution.
§507.28 Holding and distribution of human food by-products.
Inspection Updates

HAF W6 cGMP / PCAF

• Common inspection citations:
  – Failure to identify/implement a preventive control
  – Hazard analysis
  – No written food safety plan
  – Food safety plan not done/overseen by PCQI
  – Failure to establish/implement corrective action procedures
  – Failure to validate preventive control
  – Failure to conduct a reanalysis
Sanitary Food Transportation Act

Guidance for Industry

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-sanitary-transportation-food
Sanitary Food Transportation Act

Passed in 2005
Final Rule issued – effective 06 June 2016
FR Notice -
Sanitary Food Transportation Act

In HAFW6, We are seeing firms use,

• Semi-trucks
  Refrigerated trailers
  Ambient trailers

• Records for
  Training
  Receiving
  Inspection/maintenance
  Temperature control
Foreign Supplier Verification Programs

Are you Importing a Food with a Hazard Requiring a Preventive Control?

• Foreign Supplier Verification Program rule

• Manufacturer/Processor
  – Deemed in compliance if you have established and implemented a supply-chain program under PCs

Draft GFI: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
Foreign Supplier Verification Programs

In HAFW6, we are seeing firms use,

• Written Food Safety Plan with hazard analysis.
• Established/written supply-chain program under 21 CFR 507, Subpart E.
• Conducted and documented on-site audit of foreign supplier.
• Sampling incoming ingredients for microbiology and maintained written laboratory reports.
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