

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

Inspection Updates

HAF W6 cGMP / PCAF



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
 - FACT sheet : <https://www.fda.gov/animal-veterinary/development-approval-process/fact-sheet-veterinary-feed-directive-final-rule-and-next-steps>



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-pro

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 -

<https://www.federalregister.gov/documents/2016/04/06/2016-07330/sanitary-transportation-of-human-and-animal-food>

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



FSVP Final Rule - <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals>

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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**Human Animal Food Division 6 West
Protecting Human and Animal Health**

Thank you!



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