Washington State Department of Agriculture

Animal Feed Program
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Current Good Manufacturing Practices (cGMP) Inspection Checklist for Medicated Feed Establishments (21 CFR 225)

Establishment

Establishment Name	Phone Number	License/Registration Number	
Name of Person In Charge (PIC)	Title of Person in Charge	Email	
Address	City	State WA	Zip Code

Processing Type

- ☐ Extrusion
- ☐ Heating
- ☐ Milling
- ☐ Mixing
- ☐ Pelleting
- ☐ Refrigeration
- ☐ Rendering
- ☐ Salvaging
- ☐ Steam Flaking
- ☐ Thermal Processing
- ☐ Other: _____ _____ _____

Animal Class

- ☐ Swine
- ☐ Broiler
- ☐ Starter
- ☐ Layer-Breeder
- ☐ Turkeys
- ☐ Beef
- ☐ Dairy
- ☐ Equine
- ☐ All Stock
- ☐ Goat
- ☐ Sheep
- ☐ Ducks/Geese
- ☐ Fish
- ☐ Rabbits
- ☐ Wild Bird
- ☐ Custom Formula

Ingredient

- ☐ Alfalfa
- ☐ Amino Acids
- ☐ Animal Products
- ☐ Meat&Bone Meal (equine/porcine)
- ☐ Meat & Bone Meal (bovine)
- ☐ Barley
- ☐ Brewers
- ☐ Preservatives
- ☐ Citrus
- ☐ Cottonseed
- ☐ Distillers
- ☐ Drugs & Medicated Feeds
- ☐ Enzymes
- ☐ Fats & Oils
- ☐ Fermentation
- ☐ Human Food By-Products
- ☐ Grain Sorghums
- ☐ Lespedeza
- ☐ Maize
- ☐ Marine
- ☐ Milk
- ☐ Mineral
- ☐ Miscellaneous
- ☐ Molasses
- ☐ Non-Protein Nitrogen
- ☐ Oats
- ☐ Other Oilseed
- ☐ Technical Additives
- ☐ Processed Animal Waste
- ☐ Rice
- ☐ Rye
- ☐ Screenings
- ☐ Soybean
- ☐ Special Purpose
- ☐ Vitamins
- ☐ Wheat
- ☐ Yeast

Establishment Type

- ☐ Manufacture
- ☐ Distribute
- ☐ Process
- ☐ Transload
- ☐ Pack/Repack
- ☐ Guarantor
- ☐ Hold
- ☐ Other: _____

Product Type

- ☐ Raw
- ☐ Dry
- ☐ LACF
- ☐ Treat
- ☐ Other: _____

Storage Type

- ☐ Ambient
- ☐ Refrigerated
- ☐ Frozen

Shipping Containers or Vehicles

- ☐ Own
- ☐ N/A
- ☐ 3rd Party: _____

Inspection

Name of Lead Inspector	Title of Lead Inspector	Date of Inspection
Name of Accompanying Inspector	Title of Accompanying Inspector	Hours of Inspection

Notice of Inspection is hereby given pursuant to RCW 15.53.9024(1)

RCW 15.53.9024 — Inspections of facilities, vehicles, equipment, etc.—Verification of records and procedures—Notice—Official samples—Warrants authorized.

(1) For the purpose of enforcement of this chapter, and in order to determine whether its provisions have been complied with, including whether an operation is subject to such provisions, inspectors duly designated by the director, upon presenting appropriate credentials, and a written notice to the owner, operator, or agent in charge, are authorized (a) to enter, during normal business hours, any facility within the state in which commercial feeds are manufactured, transloaded, processed, packed, distributed, or held for distribution, or to enter a vehicle being used to transport or hold such feeds; and (b) to inspect at reasonable times and within reasonable limits and in a reasonable manner, the facilities, or vehicles and all pertinent equipment, finished and unfinished materials, containers, labeling, and records. The inspection may include the verification of only such records, and production and control procedures as may be necessary to determine compliance with this chapter and its rules.

WAC 16-250-148 Current good manufacturing practice and hazard analysis and risk-based preventive controls.

The department adopts the following federal regulations as current good manufacturing practice:

(1) The regulations prescribing good manufacturing practices for Type B and Type C medicated feeds as published in 21 C.F.R. Part 225.1 – 225.202.

(2) The regulations prescribing good manufacturing practices for Type A medicated articles as published in 21 C.F.R. Part 226.1 – 226.115.

WAC 16-250-164 Veterinary feed directive.

(1) The department adopts the definitions of 21 C.F.R. Part 558.3(b).

(2) The department adopts the requirements of 21 C.F.R. Part 558.6 – Veterinary feed directive drugs.

IN = In compliance | OUT = Out of compliance | CDI = Corrected During Inspection | TA = Technical Assistance | N/O = Not Observed | N/A = Not Applicable

If OUT, CDI, or TA is checked for any questions, explain in Comments section.

I. Personnel

This section covers management and employee responsibility to ensure safe medicated feed.

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. Do the employees involved in the manufacture of medicated feed understand the manufacturing or control operation(s) they perform, including the location and proper use of equipment? *
☐	☐	☐	☐	☐	☐	2. Is there a program to evaluate and supervise the employees on an on-going basis? *

II. Buildings and Grounds

This section covers exterior grounds and the overall size, construction, maintenance, and housekeeping of the buildings.

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. Is there adequate space for receiving, processing, manufacturing, and storage of medicated feed?
☐	☐	☐	☐	☐	☐	2. Is there access for routine maintenance and cleaning of equipment?
☐	☐	☐	☐	☐	☐	3. Is the facility constructed and maintained in a manner to minimize vermin and pest infestation?
☐	☐	☐	☐	☐	☐	4. Is proper housekeeping evident in the mill; clear of sweepings, broken bags, or accumulated dust that may contaminate the feed? *

III. Equipment

This section covers requirements of equipment used.

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. Is the equipment capable of producing medicated feed of intended potency, safety, and purity?
☐	☐	☐	☐	☐	☐	2. Is the equipment designed, constructed, installed and maintained to facilitate inspection and use of cleanout procedures? And to prevent lubricants and coolants from becoming unsafe additives? *
☐	☐	☐	☐	☐	☐	3. Is the equipment maintained in a reasonably clean and orderly manner?
☐	☐	☐	☐	☐	☐	4. Are the scales and liquid metering devices of suitable size, design, construction, precision and accuracy for their intended purposes? Is the accuracy verified at least once a year? *

IV. Work and Storage Areas

This section covers the storage of chemicals.

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. Is the work area and equipment for the production or storage of medicated feed or components not used for manufacturing or storing of fertilizers, herbicides, insecticides, fungicides, rodenticides and other pesticides unless such articles are approved for use in the manufacture of animal feeds?
☐	☐	☐	☐	☐	☐	2. Are the work areas and equipment used for the production or storage of medicated feeds or components physically separated from work areas and equipment used for the manufacture of animal feeds? *

V. Components

This section covers the procedures, storage, and inventory control of animal drugs.

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. Are procedures established, adequate, and maintained for the identification, storage, and inventory control?
☐	☐	☐	☐	☐	☐	2. Are packaged Type A articles and Type B feeds stored in designated areas in their original closed containers?
☐	☐	☐	☐	☐	☐	3. Are bulk Type A articles and Type B feeds identified and stored in a manner to maintain their identity, strength, quality and purity?
☐	☐	☐	☐	☐	☐	4. Are all Type A articles and Type B feeds used in accordance with their labeled mixing directions?

VI. Laboratory Assays

This section covers laboratory controls to verify and document proper potency.

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. When laboratory results indicate a medicated feed is not within permissible limits, does the firm immediately investigate and correct?
☐	☐	☐	☐	☐	☐	2. Are the investigation and corrective action records kept on the premises for at least one year?

VII. Equipment Clean Out Procedures

This section covers procedures to ensure proper potency and prevent contamination.

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. Are adequate clean out procedures established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and non-medicated feeds?
☐	☐	☐	☐	☐	☐	2. Does the company use flushing? * Is the flushing material identified, stored, and used in a safe manner? *
☐	☐	☐	☐	☐	☐	3. Does the company use sequencing? * Was it designed to prevent contamination prior to first use? *

*Only required for FDA licensed medicated feed mills

VIII. Labeling

This section covers medicated feed labels and labeling.

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. Are labels received, handled and stored in a manner which prevents label mix-ups and assures that the correct labels and labeling are used for the medicated feed?
☐	☐	☐	☐	☐	☐	2. Are all deliveries of medicated feed, whether bagged or bulk, adequately labeled to assure that the feed can be safely and effectively used?
☐	☐	☐	☐	☐	☐	3. Are labels proofread against the Master Record File, initialed, and dated; old, obsolete labels disposed of? *

IX. Records

This section covers records and their retention.

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. Are records showing the formulation and date of mixing or date of shipment maintained for at least one year after the last date of shipment?
☐	☐	☐	☐	☐	☐	2. Are records adequate to facilitate the recall of specific batches of medicated feed that have been produced and distributed by the firm?
☐	☐	☐	☐	☐	☐	3. Is a Master Record File prepared, checked, dated, initialed, and complete with all necessary information? *

X. Miscellaneous

This section covers approvals and veterinary feed directive requirements.

For any "YES" answers below, provide a brief explanation of any perceived evidence from either record review or inspectional observations of the following situations or conditions (attach additional pages if needed).

IN	OUT	CDI	TA	N/O	N/A	
☐	☐	☐	☐	☐	☐	1. Are there sales of medicated feeds not sold on the order of a licensed veterinarian?
☐	☐	☐	☐	☐	☐	2. Does the facility manufacture medicated feeds without required approvals?
☐	☐	☐	☐	☐	☐	3. Does the facility manufacture any unapproved medicated feed combinations?
☐	☐	☐	☐	☐	☐	4. Are medicated feeds manufactured from unapproved drugs/Type A Articles?
☐	☐	☐	☐	☐	☐	5. Does the facility manufacture medicated feed for a non-approved species (i.e., extra-label use of a feed)?
☐	☐	☐	☐	☐	☐	6. Does the facility ever use formulations of feeds with a higher or lower drug level than for what is approved?

XI. Drug Components On Hand

This section documents the drug components observed in the establishment.

Trade Name	Distributor	Drug & Potency	Lot Number	Exp. Date

Comments

Other Activities performed by the facility:

Post Inspection
The observations and findings were reviewed with the person in charge. The following points were those agreed on by that person and the WSDA inspector.

Name of Inspector(s)	Signature of Lead Inspector	Date