CALIFORNIA DEPARTMENT OF FOOD & AGRICULTURE

State of California
Department of Food and Agriculture
Safe Animal Feed Education Program
513-067 (Rev. 4/2014)

PROCESS VERIFICATION INSPECTION CHECKLIST

Date of Inspection	Firm #	Current FDA License #	Total Time of Inspection

Firm Name	Owner/Parent Firm (If Different)
Address	Address
City & State	City & State
Telephone	Telephone
Responsible Individual & Title:	Type of Commercial Feed Manufacturer: Commercial Feed mill _____ Custom Formula Mixer _____ Premix Mineral facility _____ Other _____
Volume of Business: Bulk = Sacked = % Medicated = (Categories indicate the percentage of feed distributed in CA) Ingredients = Premixes = Concentrates = Complete Feed =	
List Species and Class of Animal for which Commercial Feed Manufactured or Distributed.	

KEY:

☐ = Not Inspected or Does not apply ☑ = Inspected and in compliance ☒ = Inspected and NOT in compliance

PROTEIN PRODUCTS PROHIBITED IN RUMINANT FEED

(See attached: report of inspection for 21 CFR 589.2000& 2001)

1. Does this firm receive any mammalian protein prohibited in ruminant feed other than sacked pet food. Yes ☐No ☐

2. Does this firm handle commercial feed that is intended for the feeding of ruminant animals. Yes ☐ No ☐

IF FIRM HAS A PRODUCTION FLOW CHART AVAILABLE, PLEASE COPY AND REFERENCE FOR INSPECTION

PURCHASING AND RECEIVING FEED INGREDIENTS

☐ 1. All feed and/or feed ingredient manufacturers have agreements with the firm that they are in compliance with the provisions of the ruminant feeding ban. (FDA's BSE-prevention regulation 21CFR 589.2000 & 2001)

☐ 2. All feed and/or feed ingredients are manufactured by firms that are on an existing approved supplier list, that has been established by either/or manufacturing plant inspections, supplier certification, purchase contract specifications, and monitoring product quality and safety.

☐ 3. All feed and/or feed ingredients are delivered by firms (i.e. trucking companies) that have agreed not to cross-contaminate or adulterate the product and that all the required labeling accompanies each delivery.

☐ 4. Trucks, railcars, and ships are sampled and examined for gross adulteration before/during unloading.

☐ 5. All feed and/or feed ingredients are approved for use in commercial feed and are from licensed manufacturers.

☐ 6. All feed and/or feed ingredients are inspected visually during the receiving process to confirm identity, checked for required labeling and received in good condition.

DRUG ROOM AND/OR CONCENTRATE HAND-ADD AREA

☐ 1. Drug room and/or concentrate hand-add area can be secured and access is limited to trained personnel.

☐ 2. Drugs are labeled and approved for use in commercial feed including appropriate species, drug levels, and approved use.

☐ 3. Drugs & high-risk minerals are stored in original containers and lot integrity is preserved, and have not expired.

4. The firms drug inventory system:

☐ A. Makes a daily comparison between actual amount of drug used and theoretical drug usage.

☐ B. Have drug inventory records that agree with actual drug inventory on hand.

☐ C. Includes a working definition of what it considers as constituting a significant discrepancy in the drug inventory.

☐ D. Includes procedures for holding feeds on the premises until a significant discrepancy is reconciled.

☐ 5. Scale used to weigh drugs, high-risk and other hand-adds is accurate and calibration is checked regularly. (Certified to be accurate annually)

☐ 6. Scale sensitivity is appropriate for the demands of the feed formulas being utilized.

☐ 7. Identity and security of weighed material is maintained from the scale to the mixer.

☐ 8. Firm maintains receipt records for each lot of drugs received.

List drugs & high-risk minerals present:_____

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MAINTENANCE

☐ 1. Magnets and screens are routinely checked for proper operation and cleaning to minimize the risk of adulteration. (this activity is documented)
☐ 2. Hand-add areas are constructed and maintained to prevent adulteration of feed by drugs and high-risk minerals.
☐ 3. All scales and metering devices are accurate and calibration is checked. (Certified to be accurate annually.)
☐ 4. All computerized and/or automated equipment has been verified to be able to perform as intended.

EQUIPMENT

☐ 1. Since installation, the firm has determined the mixers ability to produce a uniformly mixed feed. (mixer study/mixer profile annually)
☐ 2. All equipment is of suitable size, design, construction, and precision for the intended purpose.
☐ 3. Scales, metering devices, mixers and other equipment are designed to facilitate inspection and cleaning, and are properly maintained and operated to minimize the risk of adulteration.

CLEANOUT PROCEDURES

☐ 1. Clean out procedures in use are adequate to prevent adulteration of feed. Describe procedures in use. (sequencing, flushing, and physical).
☐ 2. There is documentation that equipment cleanout procedures are actually being performed.
☐ 3. Sampling and laboratory testing have verified effectiveness of clean out procedures.

BULK AND SACKED FEED INGREDIENT STORAGE

☐ 1. Products containing prohibited materials, such as meat & bone meal, are processed, conveyed and stored separately from ruminant feeds and written cleanup procedures are in place for bulk, sacks and pet food.
☐ 2. Damaged, moldy or otherwise adulterated products are not present.
☐ 3. Ingredients are stored apart from hazardous materials and unapproved feed additives. (i.e. pesticides, lubricants, petroleum products, caustic chemicals and cleaning agents)
☐ 4. All feed and/or feed ingredients to be used in the further manufacture of feed and/or feed ingredients are stored in a manner that identifies the feed and/or feed ingredient and minimizes the risk of adulteration.
☐ 5. The firm does not use feed and/or feed ingredients considered adulterated in the manufacturing of feed and/or feed ingredients unless made safe for their intended use.
☐ 6. The firm has established and implemented inventory practices for feed and/or feed ingredients, including inventory rotation, that minimize the risk of adulteration.

FORMULAS

☐ 1. Formulas are reviewed for safety, regulatory compliance, and suitability for the intended species and specific class of animal.

☐ 2. Formulas are reviewed for compatibility with equipment limitations.

☐ 3. Formulas are consistent with the guarantees and ingredients on the labeling. (Check a few formulas and labels)

PRODUCTION RECORDS

1. Mixing records are maintained to chronicle sequence and quantity of batches produced daily.
   - ☐A. Provide a complete and traceable history of the production of a batch or production run.
   - ☐B. Written endorsement by a responsible person.
   - ☐C. Name and quantity of drug or high-risk components used.

☐ 2. Acceptable deviations of actual from theoretical batch weights have been determined.

☐ 3. A comparison of theoretical versus actual batch weights is recorded.

☐ 4. A comparison of actual production versus final load weight or bag count is documented.

☐ 5. Significant discrepancies are investigated and the records show the corrective actions taken.

☐ 6. The production formula agrees with the formula in the master record file.

☐ 7. The firm maintains records sufficient to document the production history of the feed and/or feed ingredients manufactured for at least two years from the date of disposition.

LABELS

☐ 1. A label that facilitates safe and effective use is affixed to, or accompanies, all feed and/or feed ingredients being distributed

☐ 2. Labels contain a list of ingredients and all guarantees required by law.

☐ 3. Medicated feeds are clearly identified.

☐ 4. Drug levels are guaranteed at federally approved levels and are approved for the intended species/class of animal.

☐ 5. Applicable warning statements as required by law are present and prominent (i.e. BSE, drugs, NPN, and selenium).

☐ 6. Feeding and/or mixing directions are adequate for the safe, approved and intended use of the commercial feed.

☐ 7. Labels are stored, handled and used in the establishment in a manner that minimizes errors.

SHIPMENT AND DISTRIBUTION/PACKAGING

☐ 1. Return and/or reworked feed is identified, labeled and stored to prevent commingling with other feed.
☐ 2. Identity and integrity of finished bulk and packaged feeds are maintained from the mixer to the truck.
☐ 3. Trucks, railcars and ships are inspected for cleanliness and integrity prior to bulk loading.
☐ 4. Trucks are loaded and unloaded to prevent the commingling of feeds and eliminate residues from drugs, high-risk minerals or prohibited materials.
☐ 5. Distribution records that include a code, lot numbers, or weight certificates are maintained for all finished feed and/or feed ingredients.
☐ 6. The firm maintains records for each feed and/or feed ingredient identifying the immediate recipient, quantity, type/name, lot code if available, and date shipped for at least two years from the date of shipment.

RECALL & COMPLAINT PROCEDURES

☐ 1. All feed can be traced back and traced forward by a code or lot number that identifies each load, package or production run for at least two years
☐ 2. The firm has a written Standard Operating Procedure for a recall of feed and/or feed ingredients in accordance with the procedures outlined by the Food and Drug Administration.
☐ 3. A customer complaint form has been developed and a file is available on site for inspection.
☐ 4. A complaint follow-up is documented and includes findings and resolution.

BIO-SECURITY/GROUNDS

☐ 1. Entrances into feed manufacturing areas are secured and/or monitored at all times.
☐ 2. Critical areas of manufacturing such as receiving, hand adds, control rooms, and load out or packaging areas are secured or monitored at all times.
☐ 3. The firm has control measures in place to minimize pest infestation of feed and/or feed ingredients.

PERSONNEL & SUPERVISION

☐ 1. Quality assurance and feed safety training incorporating Standard Operating Procedures (SOP's) are documented and acknowledged by all personnel.
☐ 2. Supervisors are knowledgeable of all aspects of the firms SOP's and/or quality assurance program.

QUALITY CONTROL & LABORATORY ANALYSIS

☐ 1. All finished feed products are sampled and visually inspected by trained personnel.

☐ 2. Medicated feeds are analyzed at least once per year for each drug in use, three times per year for Category II type A.

☐ 3. All out of tolerance assay results are investigated to verify that formulation and manufacturing processes are in control to minimize the risk of adulteration.

☐ 4. The firm maintains test results for adulterants and records of any investigations and corrective actions taken when adulterants are detected, for at least two years after the investigation.

☐ 5. The firm developed written SOP's for all critical areas of feed manufacturing including process controls.

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SAMPLES TAKEN

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☐ ISSUED SUMMARY REPORT