## PROCESS VERIFICATION INSPECTION CHECKLIST

<table>
<thead>
<tr>
<th>Date of Inspection</th>
<th>Firm #</th>
<th>Current FDA License #</th>
<th>Total Time of Inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Firm Name</td>
<td>Owner/Parent Firm (If Different)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td>Address</td>
<td></td>
<td></td>
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<tr>
<td>City &amp; State</td>
<td>City &amp; State</td>
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<tr>
<td>Telephone</td>
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<td></td>
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</tr>
<tr>
<td>Responsible Individual &amp; Title:</td>
<td>Type of Commercial Feed Manufacturer:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume of Business:</td>
<td>Commercial Feed mill</td>
<td>Custom Formula Mixer</td>
<td></td>
</tr>
<tr>
<td>Bulk = Sacked = % Medicated =</td>
<td>Commercial Feed mill</td>
<td>Custom Formula Mixer</td>
<td></td>
</tr>
<tr>
<td>(Categories indicate the percentage of feed distributed in CA)</td>
<td>Ingredients = Premixes =</td>
<td>Premix Mineral facility</td>
<td></td>
</tr>
<tr>
<td>Ingredients = Premixes =</td>
<td>Concentrates = Complete Feed =</td>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

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:_________________________________________
__________________________________________________________________________
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.

SAMPLES TAKEN

- ISSUED SUMMARY REPORT