

# CALIFORNIA GOOD MANUFACTURING PRACTICES 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:   |                          |
| Volume of Business:Bulk =%Sacked =%Medicated =%  |        | Commercial Feed mill  |                          |
| (Categories indicate the percentage of feed distributed in CA)<br>Ingredients = Premixes =<br>Concentrates = Complete Feed = |        | Integrated Feed Mill Vit/Mineral Premix Facility  |                          |
|  |        |   |                          |
|  |        | List Species and Class of Animal for which Commercial Feed Manufactured or Distributed. |                          |

Boxes marked below on the left indicate no score for that box and the respective conditions or practices observed at this facility are not in accordance with that statement on this Checklist. Review the Medicated Feed

Inspection Summary to indicate specific follow-up actions or recommendations for items that are checked.

#### FEED INGREDIENTS

 $\boxtimes$ 

## A) PROTEIN PRODUCTS PROHIBITED IN RUMINANT FEED

- 1. Does this firm receive any mammalian protein prohibited in ruminant feed other than sacked pet food. Yes 🗌 No 🗌
- 2. Does this firm handle feed ingredients or feeds that are intended for the feeding of ruminant animals. Yes 🗌 No 🗌

#### **B) DRUG ROOM AND/OR CONCENTRATE HAND-ADD AREA**

- 3 1. Drugs & high-risk minerals (i.e. concentrated selenium, copper, iodine etc.) are stored in a discrete location.
- 5 2. Drug room and/or concentrate hand-add area can be secured and access is limited to trained personnel.
- 1 3. Drug room and/or concentrate hand-add area is clean, orderly and well lit.
- 5 4. Drugs are labeled and approved for use in commercial feed including appropriate species, drug levels, and proper indications for use.
- 5. Drugs & high-risk minerals are stored in original containers with lot integrity is preserved, and have not expired.

- 5 6. Inventory and usage records are maintained for each drug and/or high-risk minerals.
  - 7. The firms drug inventory system:
    - 1 A. Makes a daily comparison between actual amount of drug used and theoretical drug usage.
    - $1 \square$  B. Have drug inventory records that agree with actual drug inventory on hand.
    - 1 C. Includes a working definition of what it considers as constituting a significant discrepancy in the drug inventory.
    - 1 D. Includes procedures for holding feeds on the premises until a significant discrepancy is reconciled.
- 5 8. Scale used to weigh drugs, high-risk and other hand-adds is accurate and calibration is checked regularly. (Certified to be accurate annually)
- 3 9. Scale sensitivity is appropriate for the demands of the feed formulas being utilized.
- 3 10. Identity and security of weighed material is maintained from the scale to the mixer.
- 3 11. Firm maintains receipt records for each lot of drugs received.
  - 12. List drugs & high-risk minerals present:

#### C) FEED INGREDIENTS

- 5 1. All ingredients are approved for use in commercial feed and are properly labeled.
- 5 2. Expired, damaged, moldy or otherwise adulterated material is not observed.
- 5 3. Prohibited materials, such as meat & bone meal and mammalian blood, are not conveyed in common equipment and are stored separately from ruminant feed ingredients.
- 5 4. Distribution records that include a code or lot numbers are maintained for all finished feed and feed ingredients.

#### D) EQUIPMENT

- 1. Mixers are used according to manufacturer's specifications
  - 1 A. Minimum and maximum capacity limits are known and observed.
  - 1 B. Mixing times have been established and adhered to (Note timing device).
  - 1 C. Limitations on minimum inclusion rates are known and observed.
- 3 2. Sampling and analysis validate mixing specifications.
- 3 3. Sequencing protocols are utilized for the addition of drugs and concentrated ingredients insure uniform distribution.
- 5 4. Since installation, the firm has determined the mixers ability to produce a uniformly mixed feed. (mixer study/mixer profile)
- 1 5. Equipment is constructed to allow inspection and use of clean-out procedures.
- 1 6. All equipment is reasonably clean and properly maintained.
- 3 7. All equipment is of suitable size, design, construction, and precision for the intended purpose.

#### E) CLEANOUT PROCEDURES

- 5 1. Clean out procedures in use are adequate to prevent adulteration of feed. Describe procedures in use. (sequencing, flushing, and physical).
- 1 2. Clean out procedures following mixes containing drugs or high-risk minerals are posted and utilized.
- 5 3. There is documentation that equipment cleanout procedures are actually being performed.
- 5 4. Flush material is identified, stored and utilized in a manner that prevents contamination of other feed.
- 3 5. Sampling and laboratory testing have verified effectiveness of clean out procedures.
- 3 6. Mixers and conveyors do not contain excessive buildup of old material.

## F) FORMULAS

- 5 1. Formulas are reviewed for safety, regulatory compliance, and suitability for the intended species and specific class of Animal.
- 1 2. Formulas are reviewed for compatibility with equipment limitations.
- 1 3. A clear chain of custody and control of formulas exists between formulators and mixers.
- 3 4. Formulas are clearly identified and maintained to ensure correspondence with current labeling.
- 5. Formulas are accurate to produce commercial feed as indicated by its labeling.
   (Note check several formulas and labels for accuracy)
  - 6. List person(s) responsible for formulation.

### G) LABELS

- 1 1. Feed labels are reviewed prior to use and initialed by responsible individual.
- 1 2. Responsibility for the use of new labels and destruction of outdated labels is clearly allocated.
- 5 3. A label is affixed to, or accompanies, all commercial feeds being distributed.
- 5 4. Labels contain a list of ingredients and all guarantees required by law.
- 5 5. Medicated feeds are clearly identified.
- 5 6. Drug levels are guaranteed at Federally approved levels and are approved for the intended species/class of animal.
- 5 7. Applicable warning statements as required by law are present and prominent (i.e. BSE, drugs, NPN, and selenium).
- 5 8. Feeding and/or mixing directions are adequate for the safe, approved and intended use of the commercial feed.
  - 9. List person(s) responsible for designing feed labels.

#### H) PRODUCTION RECORDS

- 1. Mixing records are maintained to chronicle sequence and quantity of batches produced daily.
  - 1 A. Provide a complete and traceable history of the production of a batch or production run.
  - $1\square B$ . Written endorsement by a responsible person.
  - 1 C. Name and quantity of drug or high-risk components used.
- 5 2. Acceptable deviations of actual from theoretical batch weights have been determined.
- 5 3. A comparison of theoretical versus actual batch weights is recorded.
- 5 4. A comparison of actual production versus final load weight or bag count is documented.
- 3 5. Production records include a code or lot number that identifies every load of feed manufactured for at least one year.
- 3 6. Production records are reviewed daily and management is immediately notified of any discrepancies.
- 5 7. Significant discrepancies are investigated and the production records show the corrective actions taken.
- 5 8. The production formula agrees with the formula in the master record file.

## I) LABORATORY ANALYSES OF FINISHED FEED

- 5 1. Medicated feeds are analyzed at least once per year for each drug in use, three times per year for Category II type A.
- 5 2. All out of tolerance assay results are investigated to verify that formulation and manufacturing processes are in control.
- $1 \square 3$ . Corrective actions are documented.