FARM ANIMAL CARE VERSION 4 STANDARD

✓ The facility has permanent (written or electronic) treatment records for the treatment of the facility's common diseases that include:

- Date of treatment
- Animal treated identification
- Name of treatment used
- Disease/condition being treated
- Dosage administered
- Route of administration
- Duration of the treatment
- Specified withdrawal times for milk and meat to ensure food safety

UNDERSTANDING FARM TREATMENT RECORD REQUIREMENTS

Standard Component	Information to Include
Date of treatment	Month, day, year
Animal treated identification	Brite tag, vaccination tag, dangle tag, button tag, tattoo, ranch brand with cow number
Name of treatment used	Drug(s) or medication(s) used
Disease/condition being treated	Respiratory, Gastrointestinal, Reproductive, Metabolic, Mammary Infection, Injury
Dosage administered	Dosage amount (ml/cc, mg/g of pills, etc.) Frequency (once daily (SID), twice daily (BID), three times daily (TID), etc.)
Route of administration	*IM* – Intramuscular (Administered in the muscle) *IMM* – Intramammary (Administered in the udder and does not use needle), Designate quarter(s) treated *IV* – Intravenous (Administered in the vein) *SQ* – Subcutaneous (Administered under the skin)
Duration of treatment	Hours, days, weeks or months of treatment
Specified withdrawal times	Refer to drug bottle or FARM Drug Residue and Prevention Manual

BACKGROUND

Treatment records may consist of paper and file folders, card files, appointment book-type calendars, monthly paper calendars, electronic computer records, etc. as long as they include all of the above components. Documentation should be permanent and readily retrievable.

This standard is supported by the most current version of the *Grade "A" Pasteurized Milk Ordinance*, the FDA's Compliance Policy Guide (CPG) Sec. 615.200 Proper Drug Use and Residue Avoidance by Non-Veterinarians , and FDA's Adequate Drug Treatment Records Help Ensure Food Safety guidance.

"The Federal Food, Drug, and Cosmetic Act (FFDCA) defines a new **animal drug** (in part) as **any drug intended for use for animals** other than man, the composition of which is not generally recognized, among experts qualified by scientific training and experience, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling."

"The FFDCA defines the term **"drugs"** to include, among other things, "articles intended for **use in the diagnosis, cure, mitigation, treatment, or prevention of disease** in man or other animals" and "articles (other than food) **intended to affect the structure or any function of the body of man or other animals.**" [See Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & (C)]

Per FDA's definition of drug, the following would fall under the expectation of being recorded in drug treatment records:

- **Antibiotics (ex. Draxxin ®, Excede®)**
- **Hormones (ex. oxytocin, reproductive hormones)**
- **Antiparasitics (ex. dewormers, delousers),**
- **Non-steroidal anti-inflammatories (NSAIDs) (ex. flunixin, meloxicam)**

USDA-APHIS REGULATION OF VACCINES

USDA-APHIS regulates veterinary biologics (vaccines, bacterins, antisera, diagnostic kits, and other products of biological origin) to ensure that these biologics are pure, safe, potent and effective. This work is done by APHIS Center for Veterinary Biologics (CVB) and is centered around enforcement of the Virus Serum Toxin Act.

9 CFR 112.2 a 8 outlines that vaccines for use in food producing animals, must have a withholding (withdrawal) statement of not less than 21 days. Longer withdrawal periods may be necessary as deemed by the Administrator.

Due to vaccines' potential impact on food safety, maintaining vaccination records is a best practice when documenting treatment records.

VALUE OF MAINTAINING TREATMENT RECORDS

Keeping adequate drug treatment records for food-producing animals and training all family and non-family employees involved in the treatment of food-producing animals is essential in helping to keep unsafe food from reaching consumers.

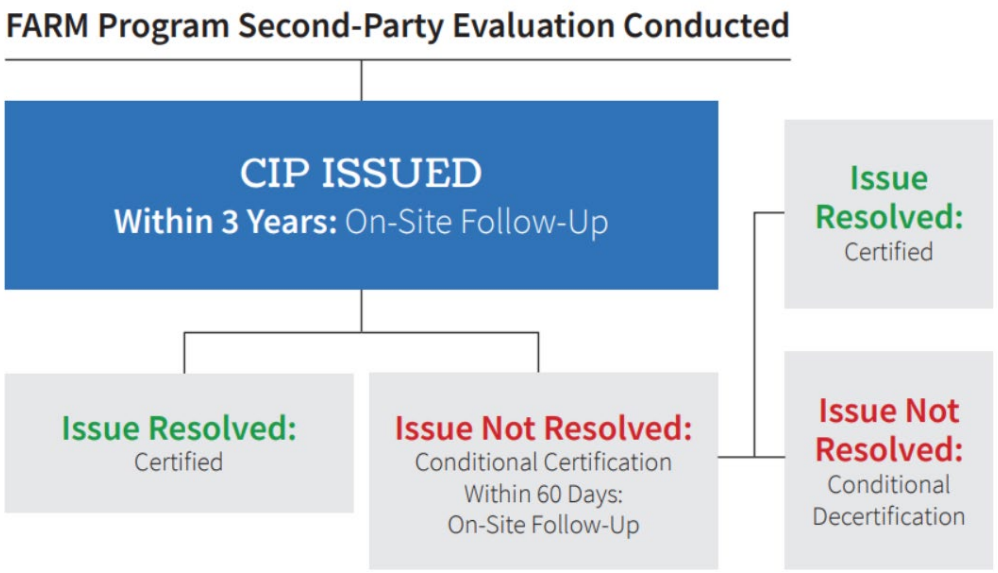
Farmers should keep written or electronic records of all animals treated with drugs **for at least two years** in the event there is a need to trace back or follow up on a milk or meat residue. Keeping drug records can:

- Prevent an accidental milk or meat violative residue
    - The proper use or misuse of some animal drugs may cause prolonged residues in milk (4 to 45 days) and meat (18 to 24 months) Source: https://www.fda.gov/media/140394/download
    - In cases involving illegal drug residues in dairy cows, district courts have agreed with the U.S. government that the failure of a dairy farm to keep adequate records of the administration of drugs constituted inadequate control measures. The courts found that these inadequate control measures created "insanitary conditions" and, therefore, adulterated the food under the FFD&C Act. Source: https://www.fda.gov/animal-veterinary/animal-health-literacy/adequate-drug-treatment-records-help-ensure-food-safety
- Ensure an effective herd health plan
- Improve the ability of the veterinarian to provide appropriate oversight of all drug use
- Reduce liability
- Decrease drug cost and improve antimicrobial stewardship

Veterinarians must maintain written or electronic records for all extra-label drug use as it is required by 21 CFR 530 A for at least two years. It is recommended to document all drugs use for a minimum of two years after an animal leaves the farm or is no longer in production to meet federal and state rules and policies. Record keeping allows for the veterinarian to have a history to which he/she can review to prescribe effective therapy and to serve as protection in case of regulatory follow-up.

CORRECTIVE ACTION

Failure to meet the standard at the time of an evaluation, will generate a Continuous Improvement Plan (CIP), that is required to be met within three years or less.



Continuous Improvement Plans require that action has been taken to meet the standard within a minimum of three years or less as determined by the program participant. Failure to meet this standard within this allotted timeframe will result in the facility being placed on Conditional Certification leading to Conditional Decertification if standards are not met after the designated timeframe. The program participant (the co-op or processor through which the farm is participating) will be delisted from FARM if they continue to procure milk from a Conditionally Decertified facility. FARM Animal Care Program evaluators may create CIPs for additional areas beyond the Version 4 standards if deemed necessary.

Certified: A facility that is up to date with its FARM Animal Care evaluation in accordance with the program evaluation cycle, does not have any overdue corrective action plans and is not subject to the FARM Willful Mistreatment or Neglect Protocol (WMNP).

Conditional Certification: If corrective action plans are not satisfactorily resolved by date set by FARM and the FARM Animal Care Participant, the facility will have a Conditional Certification for up to 60 days; a FARM Animal Care Participant may continue to procure milk from a facility with a Conditional Certification and remain in good standing with FARM. Once the plan is resolved within the 60 day period, the facility will be returned to full Certification status.

Conditional Decertification: If corrective action plans are not satisfactorily resolved by the date set by FARM or the FARM Animal Care participant, and the facility has had conditional certification for 60 days without satisfactorily resolving the plan, the facility will be considered conditionally decertified. A FARM Animal Care participant may not continue to market milk from a facility with a conditional decertification and remain in good standing with FARM. Evidence of plan resolution must be provided to FARM for the facility to be returned to full certification status.

RESOURCES

https://nationaldairyfarm.com/producer-resources/resource-library/

Daily Treatment Record
PDF | Customizable Excel

Individual Animal Treatment Record
PDF | Customizable Excel

FARM Drug Residue & Prevention Manual