

AMDUCA Revisited

October 20, 2005 (updated: January 2014) — Harry Snelson

In 1996, the US Food and Drug Administration (FDA) issued a final rule implementing the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). This rule delineated the guidelines governing the extra-label use of animal and human drugs and applies to both prescription and over-the-counter (OTC) drugs. Prior to the enactment of AMDUCA, the use of any drug except in a manner specifically outlined on the label rendered the drug "unsafe" in the eyes of the law.

This Act only allows for drug use under AMDUCA to treat disease, not for production uses. AMDUCA does not allow for extra-label use if there exists an approved food-animal drug which contains the needed ingredient, in the proper dosage form and is labeled for, and effective against, the condition being treated. Extra-label use of a drug is approved if the existing labeled drug is clinically ineffective provided that the veterinarian has a basis for determining that the approved drug is ineffective in the animals being treated. Drug cost is not an acceptable reason for extra-label use.

According to the FDA, the extra-label use of drugs for reproductive purposes would, in most cases, not be considered treatment and is thus not allowed under AMDUCA. Preventive extra-label use is allowed if the veterinarian can substantiate that the health of the animals is threatened. However, AMDUCA does not allow for the extra-label use of any drugs administered through the feed. Extra-label administration of feed-grade antibiotics is illegal under all circumstances.

Drugs may be used in an extra-label manner as prescribed under AMDUCA only if all the following conditions are met:

1. There is a valid Veterinarian/client/patient relationship
 - a. The vet has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the vet's instructions.
 - b. The vet has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the vet has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premise(s) where the animal(s) are kept.

c. The vet is readily available for follow-up evaluation, or has arranged for emergency coverage, in the event of adverse reactions or failure of the treatment regimen.

2. Use is permitted only by or under the supervision of a veterinarian. It is illegal for a layperson to use drugs in an extra-label manner without the approval of a veterinarian.

3. Only FDA-approved animal and human drugs may be used in an extra-label manner.

4. AMDUCA applies only to dosage form drugs and drugs administered in the water. The Act does not allow for extra-label use through the feed.

5. The veterinarian is responsible for establishing prolonged withdrawal times to ensure no violative residues or any residues which may cause public harm. Some additional information may be found at <http://www.farad.org/>.

6. FDA may specifically disallow the use of certain drugs or classes of drugs. This means it is illegal to use these drugs in an extra-label manner under any circumstances in food animals. The following drugs are prohibited for extra-label use in food animals (as of April, 2012):

- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol (DES)
- Dimetridazole
- Ipronidazole
- Other Nitroimidazoles
- Furazolidone, Nitrofurazone, Other Nitrofurans
- Sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine)
- Fluoroquinolones
- Glycopeptides (example: vancomycin)
- Phenybutazone in female dairy cattle 20 months of age or older
- Adamantane and neuraminidase inhibitor classes of drugs that are approved for treating or preventing influenza A are prohibited therapy in chickens, turkeys, and ducks (Effective: June 20, 2006)
- Cephalosporin (excluding cephapirin) in cattle, swine, chickens, or turkeys

- Using cephalosporin drugs at unapproved dose levels, frequencies, durations or routes of administration is prohibited;
- Using cephalosporin drugs in cattle, swine, chickens or turkeys that are not approved for use in that species (e.g., cephalosporin drugs intended for humans or companion animals);
- Using cephalosporin drugs for disease prevention.

7. AMDUCA only allows for the therapeutic extra-label use of drugs. Use for production reasons is not allowed. Drug cost is not a factor in determining extra-label drug use.

8. Records must be maintained indicating the drug used (name and active ingredient), route of administration, dosage, number of animals treated, species treated, condition being treated, duration of treatment and withdrawal time. These records must be kept for 2 years and are subject to FDA inspection.

9. Drugs dispensed for extra-label use must be labeled individually and the label must contain the name and address of the prescribing veterinarian (or the name of the veterinarian and the name and address of the dispensing pharmacy), the established name of the drug, directions for use (including species, identification of the animal or herd, flock, pen, lot, or other group; dosage frequency, route of administration and duration of therapy), any cautionary statements and withdrawal time. The FDA states that case-labeling is appropriate when large numbers of animals need to be treated in an extra-label manner for a short period.

AVMA has designed a brochure and a flow chart to aid veterinarians with decision-making regarding the appropriate use of drugs in an extra-label manner. These reference materials can be accessed at <https://www.avma.org/KB/Resources/Reference/Pages/AMDUCA.aspx>. In addition, veterinarians who have questions about AMDUCA or the extra-label use of drugs may contact FDA/CVM Division of Compliance, 7519 Standish Place, HFV-230, Rockville, MD 20855, (240) 276-9200.

Sources:

FDA AMDUCA Federal Register Notice

http://www.aasv.org/documents/AMDUCA_FR_Notice.pdf

Waddell, John T. *A Practical Look at AMDUCA and the Risks for Swine Veterinarians*; Proceedings AASV Annual Meeting 2001; pp. 321 - 329; 2001.