Chapter 2: Dispensing Veterinary Prescription Drugs

2 CE Hours

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Learning objectives

- Identify the agencies involved and areas of responsibility for federal regulation of animal health products, including animal drugs, feed and devices.
- Describe the approval process for use of animal drug products.
- Define what the Food and Drug Administration considers “safe” and “effective” in animal drugs.
- List FDA regulations for dispensing veterinary prescription drugs, including labeling requirements.
- Define veterinary feed directive (VFD) drugs.
- List requirements for use of VFD drugs.
- Identify responsibility for illegal drug residues in foods from animals.
- Define extra-label use of FDA-approved drugs in animals.
- List the circumstances that must exist and steps that veterinarians must take before extra-label drugs may be used.
- List limitations and prohibitions to use of extra-label drugs in food-producing animals.
- List types of FDA regulatory actions for violations of rules on animal drugs.

Introduction

Licensed veterinarians must complete 30 continuing education hours in specified coursework every biennium, including the requirement for 2 hours of continuing professional education in the area of dispensing prescription drugs, fulfilled by this course.

Center for Veterinary Medicine

The Center for Veterinary Medicine (CVM) within the Food and Drug Administration (FDA) helps to ensure the safety of the food supply and assists in providing for the health care needs of animals through the approval and post-approval monitoring of safe and effective animal drugs, medical devices for animals, and oversight of animal feeds. Veterinarians share the mission of ensuring food safety and providing for the health care needs of animals through appropriate and responsible use of FDA-regulated products.

The course provides information on the laws and regulations enforced by the FDA as they relate to veterinary medicine. Under the federal Food, Drug and Cosmetic Act, FDA has the broad mandate to assure safety and effectiveness of drugs (including animal drugs), devices (including veterinary devices) and the safety of the food supply.

Two amendments to the act expanded the veterinarian’s authority in the area of drug use:

- The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), under which veterinarians can use approved animal drugs in an extra-label manner, and they may prescribe approved human drugs for use in animals, under certain specified conditions.
- The Animal Drug Availability Act of 1996 (ADAA), which was enacted to help streamline the animal drug approval process. In addition to adding flexibility to the way FDA regulates animal drugs, ADAA authorized a new category, veterinary feed directive (VFD) drugs, which may be used in animal feeds. The VFD category allows the approval and use of sophisticated new animal drugs in animal feed on a veterinarian’s order, while incorporating safeguards to ensure the safe use of such drugs.

Animal drugs must be safe and effective for their intended use. Section 512 of the act, the basic statutory provision governing new animal drugs, provides that a new animal drug is unsafe unless it is the subject of an approved new animal drug application, and the use of a drug and its labeling conform to the approved application or unless that drug is used for a legal extra-label use by or on the order of a veterinarian [see section 512(a)(4)(A) and 21 CFR Part 530]. An unsafe new animal drug is adulterated and subject to the enforcement provisions of the act. All FDA regulations are codified in Title 21 of the Code of Federal Regulations [1]. Parts 500-599 of the CFR specifically address animal drugs and feeds and how to ensure that animal drugs are safe and effective for their intended uses and do not result in unsafe residues in foods from treated animals.

Who has responsibility?

The Food and Drug Administration is responsible for regulating animal drugs, feeds and foods, devices, and most animal health products; however some classes of animal products come under the jurisdiction of other federal or state government agencies. This is a quick guide to clarify which agency has responsibility for these products.

Pesticides

Germicidal preparations for use on inanimate objects, as well as rodenticides and most insecticides are subject to the federal Insecticide, Fungicide and Rodenticide Act, administered by the Environmental Protection Agency (EPA). However, some products used to control external pests are intended to act systemically and therefore are regulated as drugs by the FDA and not as pesticides by the EPA. For example:

- Topically applied flea control products are usually regulated by EPA.
Orally administered flea control products generally fall under FDA's jurisdiction. FDA is also responsible for enforcing regulations that set the limits of pesticides that are allowed in animal-derived products. Information about EPA pesticide programs may be found on the agency's website at: http://www.epa.gov/pesticides/.

**Veterinary biologics (including vaccines)**

The term “veterinary biologics” includes all viruses, sera, toxins or analogous products of natural or synthetic origin that are intended for use in the treatment of animals and that act primarily through the direct stimulation, supplementation, enhancement or modulation of the immune system or immune response. Such products include but are not limited to vaccines, bacterins, allergens, antibodies, diagnostics, antitoxins, toxoids, immunostimulants, and antigenic or immunizing components of microorganisms intended for use in the prevention, diagnosis, management or cure of disease in animals. The veterinary biologics staff, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, is responsible for regulating veterinary biologics for purity, safety, potency and effectiveness.

**COMMON QUESTIONS REGARDING BIOLOGICS**

**Q: How are veterinary biologics regulated?**

A: The U.S. Department of Agriculture (USDA) is authorized, under the 1913 Virus-Serum-Toxin Act, as amended by the 1985 Food Security Act, to ensure that all veterinary biologics produced in, or imported into, the United States are not worthless, contaminated, dangerous, or harmful.

Federal law prohibits the shipment of veterinary biologics unless these are manufactured in compliance with regulations contained in Title 9 of the Code of Federal Regulations, Parts 101 to 118. Veterinary biologics for commercial use must be produced at a USDA-approved establishment, and be demonstrated to be pure, safe, potent and efficacious.

**Q: Who regulates veterinary biologics?**

A: The Veterinary Biologics Program of the USDA's Animal and Plant Health Inspection Service (APHIS) oversees the veterinary biologics industry in the United States.

This program consists of the Center for Veterinary Biologics and allied services:

- Center for Veterinary Biologics, policy, evaluation and licensing unit, establishes licensing standards; reviews all prelicense documentation; reviews test methods and labels; and issues, suspends, or revokes licenses and permits. It also performs prelicense and surveillance testing; tests products associated with field problems; and develops references, reagents and test methods.
- Center for Veterinary Biologics, inspection and compliance unit, inspects production facilities, methods and records; and investigates suspected legal violations and consumer complaints.
- APHIS’s Investigative and Enforcement Services investigates violations of federal law.

**Q: What licenses or permits are required to manufacture and sell veterinary biologics?**

A: Domestic manufacturers of veterinary biologics made for domestic use or for export are required to possess a valid U.S. veterinary biologics establishment license and an individual U.S. veterinary biologics product license for each product produced for sale.

Foreign manufacturers of veterinary biologics may export veterinary biologics to the United States, provided that the manufacturer’s legal representative (permittee) residing in the United States possesses a valid U.S. veterinary biological product permit to import these products for general distribution and sale. The U.S. Department of Agriculture may also issue veterinary biologics permits for research and evaluation or for transit shipment.

**Q: Are some veterinary biologics exempt from federal regulation?**

A: A veterinary biologic may be exempt from federal regulation in any of the following cases:

- The product was manufactured by veterinarians and intended solely for use with their clients’ animals under a veterinarian-client-patient relationship.
- The product was manufactured by individuals or companies for use only in their own animals.
- The product was manufactured in states with USDA-approved veterinary biologics regulatory programs, for sale only in those states.

**Q: What is required to conduct research with non-exempted experimental veterinary biologics?**

A: An individual or firm must receive USDA authorization prior to conducting research in animals with non-exempted experimental veterinary biologics.

The veterinary biologics pharmacovigilance program is for the ongoing surveillance of adverse events associated with animal vaccines and other immunobiologics, in cooperation with the veterinary profession and the veterinary immunobiologic industry.
OTHER COMMON QUESTIONS ABOUT PHARMACOVIGILANCE

Q: What is an immunobiologic?

A: An immunobiologic product (also known as a biological product) is one that modulates the immune system for the prevention, treatment or diagnosis of disease. Veterinary biological products used to prevent disease include vaccines or toxoids that stimulate an animal to produce antibodies against specific organisms or substances. This is termed active immunization. Passive immunization may be obtained from antibody-containing products such as serum derivatives; they may be used to treat disease. Immunobiological reactions are increasingly used as the basis of test kits for the diagnosis of disease.

Q: How is an immunobiologic produced?

A: The immunologically active ingredients in an immunobiologic may be either antigens or antibodies. Antigens are derived from killed or attenuated live disease organisms, such as viruses and bacteria. Antibodies may be derived from the blood or milk of donor animals that are often immunized against specific antigens. Other components of immunobiologics include the fluid suspension medium, preservatives or antibiotics, stabilizers, and adjuvants, which are substances that enhance the immune reaction. Licensed manufacturers of animal immunobiologics are regularly inspected to verify that production is done in accordance with approved procedures. Products intended for use in animals must be tested for purity, safety and potency before they may be marketed. As a further check on the manufacturer’s quality control, the USDA regularly tests randomly selected lots of all products in its own laboratory.

Q: What is the purpose of postmarketing surveillance?

A: Postmarketing surveillance of veterinary immunobiologics has two main functions. One is to serve as an alert system for detecting the possibility that a product may not be performing as intended. An alert is triggered when information has been received that implicates a product as the cause of events that appear to be unusual in nature or frequency. The immediate response to an alert is an evaluation of the possibility the product is defective. The alert may be confirmed, rejected or more information may be sought. Confirmation of an alert could trigger an intervention. Fortunately, this is a rare occurrence.

Q: What is an adverse event?

A: An adverse event is any undesirable occurrence after the use of an immunobiological product, including illness or reaction, regardless of whether the event was caused by the product.

Q: What adverse events may possibly occur after the use of immunobiologics?

A: Some animals, like people, may be uncomfortable or lethargic the day they are vaccinated. More serious adverse events are a less common possibility. Immune (hypersensitivity) reactions are infrequent but possible after exposure to any immunobiologic, as well as many other substances. Acute anaphylaxis with immediate collapse is a dramatic reaction that may happen shortly after vaccination. It is important to observe an animal for at least an hour after vaccination, so that it may be treated if necessary. Other reactions that have been observed within a day of vaccination include loss of appetite, fever, facial swelling, hives, nasal or ocular discharge, respiratory distress, vomiting or diarrhea. Events occurring a day to two weeks after vaccination include similar events, as well as stiffness, local inflammation and systemic illness, which may or may not be based on an immune reaction. Owners who have any concerns about the health of an animal after the use of an immunobiologic should consult their veterinarian promptly.

Not all properly vaccinated animals will be immune to disease under all circumstances. Many factors affect the response of a particular animal to vaccination and the chance that it will subsequently succumb to disease. Such factors include the animal’s immune competency, its health at the time of vaccination, stress, environment and the virulence of the pathogen. Even under optimal conditions, antigens vary widely in the strength and duration of the disease protection they confer.

Q: How frequently do adverse events occur?

A: Good estimates of the rates of various types of adverse events after the use of veterinary immunobiologics are not readily available. The information we have is based on voluntary spontaneous reports to manufacturers and the USDA. While it may be possible to calculate a reporting rate, the relationship between a reporting rate and an incidence rate is not clear. This relationship may vary by type and severity of event, species, manufacturer, and even from one month to the next. Under appropriate conditions, a reporting rate may sometimes be used to estimate minimum incidence, which may be used for certain comparisons.

Q: What happens when an adverse event is reported?

A: The mission of the USDA is to ensure that animal immunobiologics are in compliance with the Virus-Serum-Toxin Act. Reports are assessed for the possibility of a product deficiency. When necessary, testing is performed or additional information is sought. The USDA is, however, unable to make diagnoses or recommendations specific to individual cases. Some of the manufacturers do provide such services. Receipt of a report by the USDA does not necessarily imply that the product caused an adverse event, or even that a particular event actually occurred.
Q: How can I report an adverse event?

A: Veterinary immunobiologics are regulated by the U.S. Department of Agriculture, Center for Veterinary Biologies (USDA, CVB) under the Virus-Serum-Toxin Act. The CVB maintains pharmacovigilance. An adverse event report enters this program through several channels. Adverse events may be reported to the:

- **Manufacturer.** Many biologics manufacturers maintain veterinary services departments to handle such reports and may also offer diagnostic advice, treatment recommendations and guidance on product use.

- **Center for Veterinary Biologies (CVB).** Once an adverse event has been reported to the manufacturer, the CVB may be contacted by submission of the electronic Adverse Event Report Form by going online to: http://www.aphis.usda.gov/animal_health/vet_bioligies/vb_adverse_event.shtml. A PDF version of this form may be downloaded at the website and submitted by FAX to (515) 232-7120 or by mail to the CVB. Adverse events may also be reported by calling the CVB at 800-752-6255, if necessary.

- Veterinary drugs, medicated feeds, and animal devices are regulated by the Food and Drug Administration, Center for Veterinary Medicine (FDA, CVM) under the Food, Drug and Cosmetic Act. The CVM recommends that you first contact the manufacturer to report an adverse event. To contact the CVM directly, call 888-FDA-VETS.

Q: What should be done if a human is exposed to an animal immunobiologic?

A: In the event of a serious human exposure to a veterinary immunobiologic, such as inadvertently injecting oneself with a vaccine intended for animals, contact your physician or emergency room at once. Be prepared to inform your physician about the product to which you were exposed. Your physician may wish to contact the manufacturer for additional information about the product. The CVB may be able to facilitate the communication of important information, if necessary.

Pet foods

FDA regulations that apply to pet foods are published in Title 21, Parts 501, 573, 582, 584, and 589 of the Code of Federal Regulations. These regulations are available on the Internet at http://www.gpoaccess.gov/cfr/index.html.

As with human food, pet foods may not be adulterated or misbranded. Pet foods may not contain any poisonous or deleterious substances or residues of pesticides in excess of established tolerances. They may not be stored in any containers that may render the contents injurious to health because of any poisonous or deleterious substance and may not contain any color additives or food additives that are unsafe. To ensure safety, canned pet food must be manufactured and registered in accordance with the FDA regulations for low-acid canned foods. Pet food labeling may not be false or misleading in any way. Damage or inferiority may not be concealed in any manner. Pet food may not be sold under the name of any other food and may not have any valuable constituents omitted or extracted.

Although pet food products do not need to have premarket approval by FDA, these products are subject to the requirements of the act, and pet food manufacturers are subject to individual annual product registration in most states.

State laws may require that pet food labels bear, in addition to the mandatory information required by federal law, a label statement of “guaranteed analysis” for minimum protein and fat content and maximum fiber and moisture content, a nutritional adequacy statement, and feeding directions. Additional information concerning state registration and labeling requirements may be obtained from the individual states where the products will be distributed or from the Official Publication of the Association of American Feed Control Officials, Inc. c/o Sharon Krebs, Assistant Secretary, AAFCO, P.O. Box 478, 104 East McConnell Street, Oxford, Indiana, 47971. AAFCO’s website is http://www.aafco.org/.

Pet foods are also subject to the labeling requirements of the Fair Packaging and Labeling Act, which governs certain aspects of consumer product labeling. AAFCO has developed definitions for certain nutrient content claims, such as “lite” or “light.”

Animal medical devices

A medical device, as defined in the act [Section 201(h)], is:

“An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory, which is … intended for use in the diagnosis of disease, or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.”

There are currently no requirements for FDA pre-market approval of medical devices intended for animal use. Animal medical devices and diagnostic aids are, however, subject to the general provisions of the act that relate to misbranding and adulteration. For example, an animal medical device is misbranded if the labeling is false or misleading. (21 U.S.C. 352(b)). An animal medical device may be considered misbranded if the labeling fails to bear adequate directions for use by the layperson (21 U.S.C. 352(f)(1)). An animal device is misbranded if it is dangerous to animal or human health when used in the manner prescribed, recommended or suggested in labeling (21 U.S.C. 352(j)). The FDA relies on veterinarians and other users to report unsafe animal medical devices.

Articles such as screening test kits for drug residues are regulated as animal medical devices. One example of screening tests is the test used to screen milk for the presence of drug residues. As with other animal medical devices, screening tests must bear adequate directions for use, the labeling may not be false or misleading and the manufacturer should have data adequate to demonstrate that use of the screening kit in accord with label directions will yield consistent and reliable results. If adequate directions cannot be written for lay use, the animal medical device is deemed unsafe for use except under the supervision of a licensed veterinarian. The FDA, therefore, requires that the label bear the statement: “Caution: Federal law restricts this device to sale by or on the order of a licensed veterinarian” (21 CFR 801.109). Examples of animal medical devices that are required to bear the prescription legend include transcutaneous electronic nerve stimulators, pulse magnetic field devices and lasers.
Animal grooming aids

The animal counterpart of a cosmetic is commonly referred to as a “grooming aid.” The act defines a cosmetic as pertaining only to human use (21 U.S.C. 321(i)). Therefore, products intended for cleansing or promoting attractiveness of animals are not subject to FDA control. However, if such products are intended for any therapeutic purpose or if they are intended to affect the structure or function of the animal, they are subject to regulation as new animal drugs under the act.

Drug approval process

Under the act, the term “drug” means articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary; 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. It also includes articles intended for use as a component of a drug.

Once a product is determined to be a drug for animal use, the next step is to determine whether it is a new animal drug. The act 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.” By virtue of Supreme Court interpretations of the necessary basis for general recognition, there are, for all practical purposes, no animal drugs that are not also new animal drugs. The green book, accessible from the CVM home page on the Web, contains a searchable database of all FDA-approved animal drugs.

An unapproved new animal drug may be distributed in accordance with 21 CFR Part 511 if the drug will be used for research, i.e., for the collection of data intended to be submitted in support of an NADA approval. Investigational New Animal Drug (INAD) regulations provide that such drugs may be distributed for use only by experts, qualified by scientific training and expertise, to investigate the safety and effectiveness of animal drugs.

Before a new animal drug may receive FDA approval, the sponsor must establish that the new animal drug is safe and effective.

- **Safe** includes safety to the animal, safety of food products derived from the animal, safety to persons administering the drug or otherwise associated with the animal, and safety in terms of the drug’s impact on the environment.
- **Effective** means that the product will consistently and uniformly do what the labeling claims it will do.

Drug sponsors submit a new animal drug application (NADA) along with supporting data, including all adverse effects associated with the drug’s use. The application must also include information on the drug’s chemistry; composition and component ingredients; manufacturing methods, facilities, and controls; proposed labeling; analytical methods for residue detection and analysis if applicable; an environmental assessment; and other information. The sponsor of a new animal drug is responsible for submitting all appropriate data to establish effectiveness and safety. If the drug product is intended for use in a food-producing animal, residues in food products must also be established as safe for human consumption.

FDA review of the application submitted by drug sponsors is very detailed and comprehensive. FDA scientists will determine whether the data have been developed in accordance with either Good Laboratory Practice Regulations or clinical trial guidance. If the studies were conducted properly, the data are evaluated with respect to drug safety and effectiveness. The animal safety data for a drug product must relate to the dosage levels and routes of administration proposed in the labeling. The primary objective is to determine the safety of the product relative to labeled usage.

At the conclusion of the animal safety review, a summary is prepared that explains why the product is safe or not shown to be safe. If the product has been shown to be safe but some restrictions or constraints on use are needed, all warning and precaution statements to be placed on the label must be enumerated and included in the summary, as well as any expected side effects.

All effectiveness data submitted must relate either directly or indirectly to the specific label and labeling claims made for the product. The sponsor must demonstrate that the product produces the claimed effect.

With respect to human food safety, it is the responsibility of the producer or sponsor of the animal drug to furnish FDA with the scientific information and experimental data that demonstrate that the presence of residues of the animal drug in the edible food products of the animal are safe for the consumer of the food product. The term “residues” applies to the parent drug and/or its metabolites. Detailed guidance on the studies required for animal drug approval is available from the Center for Veterinary Medicine (CVM). To assure that human food of animal origin can be monitored for the presence of drug residues, FDA requires sponsors of drugs for food animal use to provide acceptable analytical methods capable of determining and confirming the animal drug or its metabolites in the animal tissue.

Classifying Rx and OTC animal drugs

FDA is responsible for determining the marketing status (prescription, over-the-counter, or VFD [3]) of animal drug products based on whether it is possible to prepare “adequate directions for use” under which a layperson can use the drugs safely and effectively. Prescription (Rx) products can be dispensed only by or upon the lawful written order of a licensed veterinarian. Safe use includes safety to the animal, safety of food products derived from the animal, safety to the persons associated with the animal, and safety in terms of the drug’s impact on the environment.

Effective use of a drug product assumes that an accurate diagnosis can be made with a reasonable degree of certainty, that the drug can be properly administered, and that the course of the disease can be followed so that the success or lack of success of the product can be observed.

The same drug substances can be marketed in a number of different dosage forms, intended for use by different routes of administration and in different species of animals. Thus, these drug products may be appropriately labeled Rx in some cases and OTC in others. Rx products must bear the legend:

“Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

Dispensing veterinary prescription drugs

Since adequate directions for safe and effective lay use cannot be written for animal prescription drug products, such products can only be sold on the prescription or other order of a licensed veterinarian [Section 503(f)]. Prior to being sold or dispensed, they must remain
in the possession of a person or firm regularly and lawfully engaged in the manufacture, transportation, storage or wholesale or retail distribution of animal prescription drug products. The drug products may be distributed only by persons or firms authorized by state and local laws.

Sale (dispensing, shipping, or otherwise making available for use in animals) of an animal prescription drug product to the layperson may be made only by or on the bona fide prescription or other order of a licensed veterinarian. Sale of an animal prescription drug product to a layperson, except on a prescription or on order of a licensed practitioner, causes the product to be misbranded and subjects the seller to civil and/or criminal provisions of the act.

A licensed veterinarian may legally use or dispense an animal prescription drug product only within the course of his/her professional practice where a valid veterinarian-client-patient relationship [4] exists. Veterinarians employed by drug manufacturers or distributors may not legally dispense prescription drug products to laypersons unless they meet the above criteria. Similarly, practicing veterinarians or their employees may not legally sell animal prescription drug products to walk-in customers unless the same criteria are met. Federal regulations require that drug manufacturers provide at least the following information on the label of the finished package form of animal prescription drug products:

**Drugs in animal feeds (medicated feeds)**

Anyone who adds drugs to feed is subject to the act. Just as each label claim for a new animal drug must be approved, a drug must be specifically approved for administration in animal feed. When the new animal drug application for use of the compound in animal feed is approved, a notice is published in the Federal Register [2]. The medicated feed must be labeled in accordance with the approved labeling.

A drug may be mixed into feed only for uses and at potency levels specifically permitted in the regulations (21 CFR Part 558.) The person or firm mixing a medicated feed containing a category II, Type A medicated article (21 CFR Part 558.4) must be registered with the FDA as a drug manufacturer and hold an approved medicated feed mill license.

It is a violation of the act for drugs to be added for uses or at levels not specified in the regulations. Any individual authorizing the violation as well as the individual illegally mixing the feed may be subject to regulatory action. Additionally, the feed itself may be subject to seizure. The agency will ordinarily allow off-label use of drugs in the feed of minor species provided certain conditions are met, including the involvement of a licensed veterinarian. See Compliance Policy Guide 615.115 (http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg615-115.html).

**Veterinary feed directives**

The Animal Drug Availability Act of 1996 (ADAA) amended the act to establish a new category of drugs, veterinary feed directive (VFD) drugs. A drug intended for use in or on feed, which is limited by an approved application to use under the professional supervision of a licensed veterinarian, is a VFD drug. Final regulations covering the use and distribution of VFD feeds (medicated feeds containing VFD drugs) were published in the Federal Register on December 8, 2000.

The VFD process is straightforward in practice. A veterinarian, operating within the confines of a valid veterinarian-client-patient relationship, examines and diagnoses animal conditions and determines whether a condition warrants use of a VFD drug. If it does, the veterinarian will issue a signed VFD containing information specified by regulation. Extra-label use of a VFD drug is not permitted by anyone, including the veterinarian. The veterinarian keeps a copy of the VFD and provides the completed and signed original and a copy to the client. The client keeps the copy and gives the original VFD to the feed manufacturer. The VFD authorizes the VFD feed to be shipped to the client’s animal feeding operation.

Anyone intending to distribute VFD feeds must notify CVM prior to beginning distribution. Distributors include the VFD feed manufacturer or anyone in the distribution chain who ultimately supplies VFD feed to an animal producer. This could include the veterinarian if he/she is the source of VFD feed. A VFD feed may not be distributed to a client without a signed VFD. However, VFD feed may be sent down the distribution chain if the consignee provides the distributor with a signed acknowledgment letter affirming that it will only ship the VFD feed to a VFD holder or to another distributor who supplies a similar acknowledgment letter.

**Responsibility for illegal residues in meat, fish, milk, and eggs**

FDA is responsible for programs and regulatory actions aimed at preventing illegal drug residues in human food products derived from treated animals. (For regulatory purposes, live animals are considered unprocessed food.) Illegal drug residues in edible products can constitute a hazard to the health of persons consuming such food. Failure to observe label withdrawal periods before slaughter or processing or
failure to withhold milk is the principal cause of illegal drug residues. Other causes may include failure to follow other label directions, poor feed manufacturing practices and human negligence.

FDA is also responsible for ensuring that contaminants of feed origin do not result in unsafe contamination in human food of animal origin. Regardless of the cause, it is FDA's policy to hold responsible any individual in the production and marketing chain who can be shown to have caused (by an act of commission or omission) illegal residues

or other contaminants in edible animal products [5]. If a veterinarian prescribes, dispenses or treats an animal(s) with a drug that results in the occurrence of an illegal drug residue in edible products from the treated animal, the veterinarian may be held responsible for having caused a violation of law.

Additional information on residue avoidance and withdrawal times can be found in the Food Animal Residue Avoidance Databank (FARAD).

Compounding of animal drugs

In general, compounding an animal drug from an active pharmaceutical ingredient (bulk drug) is not permitted by the act unless covered by an approved new animal drug application. This is true even if the compounder is a veterinarian or a pharmacist. However, CVM acknowledges the medical need for compounding may exist within certain areas of veterinary practice. The contemporary practice of veterinary medicine requires products to treat hundreds of conditions and diseases in dozens of species. Business and market realities in the animal health industry can only provide a fraction of products necessary for these indications. Consequently, veterinarians continue to require products to treat diseases or conditions in animals for which no FDA-approved product is available. Veterinarians must by necessity

on occasion utilize products that are compounded to meet a specific patient’s medical need. Thus, the agency may exercise its enforcement discretion in not objecting to compounding from bulk drugs under certain conditions. Additional information on the FDA policy regarding animal drug compounding can be found in Compliance Policy Guide, Section 608.400, “Compounding of Drugs for Use in Animals,” (http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg608-400.html).

Animal drugs may be legally compounded from FDA-approved animal drugs and FDA-approved human drugs if the compounding practices are in conformance with the provisions of the regulation on the extra-label use of FDA-approved drugs (See next section).

Extra-label use of FDA-approved drugs in animals

“Extra-label use” is defined as:

“Actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease and other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from labeled withdrawal time based on these different uses.”

Under the provisions of the Animal Medicinal Drug Use Clarification Act of 1994, the FDA recognizes the professional judgment of veterinarians, and allows the extra-label use of drugs by veterinarians under certain conditions (21 CFR 530). Any drug used in an extra-label manner is by definition a prescription drug since the involvement of a veterinarian is required. Extra-label use of drugs may only take place within the scope of a valid veterinarian-client-patient relationship (VCPR) [4]. In the absence of a valid VCPR, if an approved new animal drug is used for a use for which it is not labeled, such use has caused the drug to be deemed unsafe and therefore adulterated under the act [21 U.S.C. 351(a)(5)].

An approved new animal drug or human drug intended to be used for an extra-label purpose in an animal is not unsafe under the act (21 U.S.C. 360b) and is exempt from the labeling requirements of the act [21 U.S.C. 502(f)], if such use is by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and such use complies with the extra-label use regulation (21 CFR Part 530). Extra-label use is limited to circumstances when the health of an animal is threatened, or suffering or death may result from failure to treat. This means that extra-label use to enhance production is prohibited. Extra-label use of drugs may be considered by food animal veterinarians only when:

- There is no approved new animal drug that is labeled for such use and that contains the same active ingredient in the required dosage form and concentration, except where a veterinarian finds, within the context of a valid veterinarian-client-patient relationship,
Labeling of drugs prescribed for extra-label use

At a minimum, the following label information is recommended:

1. The name and address of the prescribing veterinarian.
2. The established name of the drug (active ingredient), or if formulated from more than one ingredient, the established name of each ingredient.
3. Any directions for use specified by the practitioner (including class/species or identification of the animals; dosage, frequency, and route of administration; and duration of therapy).
4. Any cautionary statements provided by the veterinarian.
5. The veterinarian’s specified withdrawal/discard time(s) for meat, milk, eggs or any food that might be derived from the treated animals.

Because extra-label use of animal and human drugs in nonfood-producing animals (companion, sporting, exotic, etc) does not ordinarily pose a threat to the public health, extra-label use of animal and human drugs is permitted in nonfood-producing animals except where the public health is threatened.

Extra-label use of drugs in treating animals is allowable only by licensed veterinarians within the context of a valid veterinarian-client-patient relationship, and does not include drug use in treating animals by the layman (except under the supervision of a licensed veterinarian).

Lay persons cannot be expected to have sufficient knowledge and understanding concerning animal diseases, pharmacology, toxicology, drug interactions and other scientific parameters to use drugs in any way other than as labeled.

Limitations to extra-label use provisions of AMDUCA

In addition to uses that do not comply with the provision set forth in Sec. 530.10, the following specific extra-label uses are not permitted and result in the drug being deemed unsafe within the meaning of section 512 of the act:

1. Extra-label use in an animal of an approved new animal drug or human drug by a lay person (except when under the supervision of a licensed veterinarian).
2. Extra-label use of an approved new animal drug or human drug in or on an animal feed.
3. Extra-label use resulting in any residue that may present a risk to the public health.
4. Extra-label use resulting in any residue above an established safe level, safe concentration, or tolerance.

Prohibitions under AMDUCA

FDA may prohibit the extra-label use of an approved new animal or human drug or class of drugs in animals if FDA determines that:

1. An acceptable analytical method needs to be established and such method has not been established or cannot be established.
2. The extra-label use of the drug or class of drugs presents a risk to the public health.

A prohibition may be a general ban on the extra-label use of the drug or class of drugs or may be limited to a specific species, indication, dosage form, route of administration or combination of factors.

The following drugs are prohibited for extra-label animal and human drug uses in food-producing animals:

1. Chloramphenicol.
2. Clenbuterol.
3. Diethylstilbestrol (DES).
4. Dimetridazole.
5. Ipronidazole.
6. Other nitroimidazoles.
7. Furazolidone.
8. Nitrofurazon.
9. Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypridazone).
10. Fluoroquinolones.
12. Phenylbutazone in female dairy cattle 20 months of age or older.

The following drugs or classes of drugs that are approved for treating or preventing influenza A are prohibited from extra-label use in chickens, turkeys and ducks:

1. adamantanes.
2. neuraminidase inhibitors.

Extra-label use of drugs in treating food-producing animals for improving rate of weight gain, feed efficiency or other production purposes is prohibited under AMDUCA. A drug (including a bulk drug) may not be mixed into feed for any use or at a potency level not specifically permitted by the regulations in 21 CFR Part 558, even if prescribed by a veterinarian.

Compounding under AMDUCA

The extra-label drug use regulation also provides for the legal compounding of animal drugs from approved animal drugs and approved human drugs. The compounding must be in compliance with the provisions of the regulation as presented above. The regulation provides additional requirements for extra-label compounding (21 CFR 530.13).

The extra-label drug use regulation does not allow for legal animal drug compounding from active pharmaceutical ingredients (bulk drugs). This type of compounding is addressed in the previous section on Compounding of animal drugs.

Reporting adverse drug reactions

Users of new animal drug products are encouraged to notify the product’s sponsor of any unexpected or adverse reactions resulting from the use of that product. Among the data that must be submitted by the sponsor to FDA are reports of injury, toxicity, sensitivity reaction, unexpected incidence or severity of side-effects associated with use or failure of the drug to exhibit expected pharmacological action. FDA scientists analyze these data to determine whether any modifications are needed in the drug’s labeling, dosage level and so on to mitigate future adverse reactions. In extreme instances, the adverse
reactions may be so severe as to request withdrawal of approval of the drug.

FDA also encourages veterinarians to report adverse drug reactions directly to the agency. The reports should be submitted on Form FDA 1932a, Veterinary Adverse Reaction, Lack of Effectiveness, or Product Defect Report. This is a pre-addressed, postage-paid form that is filled out and dropped in the mail by the veterinarian. This form is available at http://www.fda.gov/cvm/adereporting.htm. Copies of the form are also usually available from state veterinary medical associations, clinics of colleges of veterinary medicine, USDA Extension Service veterinarians and FDA offices. FDA may occasionally need more detailed information about an incident, and the veterinarian may be called by an FDA staff veterinarian.

Adverse reactions may be reported by telephone during normal working hours (7 a.m. to 4 p.m. Eastern standard/daylight time) by calling 888-FDA-VETS (888-332-8387) or after hours by dialing 888-FDA-VETS (888-332-8387) and leaving a message. In the second case, a message is recorded and the call is returned by a veterinarian the following working day.

**Types of FDA regulatory actions**

The objective of FDA regulatory programs is to assure compliance with the federal Food, Drug, and Cosmetic Act (the act). Specific enforcement activities include actions to correct and prevent violations, remove violating products or goods from the market, and punish offenders. The type of enforcement activity FDA uses will depend on the nature of the violation. The range of enforcement activities include issuing a letter notifying the individual or firm of a violation and requesting correction, to criminal prosecution of the individual or firm. Adulteration or misbranding is usually the result of an individual failing to take steps to assure compliance with the law. Such an individual may be liable for a violation of the act and, if found guilty, be subject to the penalties specified by the law. Actions include:

- **Warning letters** – Sent to the individuals or firms, advising them of specific, noted violations. These letters request a written response as to the steps that will be taken to correct the violation. The letters constitute one form of warning that can be issued under current agency policy.
- **Seizure** – An action brought against an FDA-regulated product because it is adulterated and/or misbranded within the meaning of the act. The purpose of such an action is to remove specific violating goods from commerce.
- **Injunction** – An order by a court that requires an individual or corporation to do or refrain from doing a specific act. FDA may seek injunctions against individuals and/or corporations to prevent them from violating or causing violations of the act.
- **Criminal prosecution** – May be recommended in appropriate cases for violation of Section 301 of the act; misdemeanor convictions, which do not require proof of intent to violate the act, can result in fines and/or imprisonment up to one year. Felony convictions, which apply in the case of a second violation or intent to defraud or mislead, can result in fines and/or imprisonment up to three years.

FDA field offices have primary responsibility for conducting inspections or investigations and collecting samples that may lead to recommendations for enforcement/regulatory action. The type of action recommended will depend upon the nature of the violation and the public health concern, agency policy, previous history of violations by the firm, and other factors.

**Criminal fines for Food, Drug and Cosmetic Act violations**

Misdemeanor fines under the act may reach $500,000 under some circumstances. The Criminal Fine Enforcement Act of 1994 (Public Law 98-596) provides for fines for violations of federal law. Although it is not part of the act, the Criminal Fine Enforcement Act of 1994 applies to all fines levied under the act, as well as other statutes that contain provisions enforced by FDA.

The following fines are applicable for each offense:

- Up to $100,000 for a misdemeanor by an individual that does not result in death.
- Up to $200,000 for a misdemeanor by a corporation that does not result in death.
- Up to $250,000 for a misdemeanor by an individual that results in death, or a felony.
- Up to $500,000 for a misdemeanor by a corporation that results in death, or a felony.

The maximum imprisonment for a misdemeanor under the act remains a year for each offense.

**Interaction with the Food and Drug Administration**

The Food and Drug Administration is most effective in carrying out its mission under a policy of openness and free communication. Everyone is best served when there is clear understanding of the FDA's regulations and policies and how they are administered. FDA seeks to create confidence in, and support for, programs that are intended to promote and protect the health and well-being of all.

FDA encourages anyone to contact the agency for assistance, to supply information, or to report a problem with a product. To help direct requests to the proper location for a rapid response, it offers the following guidance:

Information on approved drugs, regulations, policies, copies of guidelines, or CVM publications can be found on the CVM website at: http://www.fda.gov/cvm.
## FDA Field Offices

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## Glossary

**Adulteration:** A violation of the Federal Food, Drug, and Cosmetic Act that includes products that are defective, unsafe, not shown to be safe, filthy, or produced under unsanitary conditions. It also includes products that are manufactured under procedures and controls which do not comply with current good manufacturing practice regulations as well as new animal drug products that are not the subject of a New Animal Drug Application approval process. Detailed definitions of adulteration are in the act itself and have been developed in regulations and by the courts.

**Adverse drug experience:** An unexpected side effect, injury, toxicity, sensitivity reaction or unexpected incidence or severity of side effects associated with use of a new animal drug product. The failure of a new animal drug product to exhibit expected pharmacological action also is an adverse drug reaction.

**Animal feed:** An article that is intended for use for food for animals other than man and that is intended for use as a substantial source of nutrients in the diet of the animal. It is not limited to a mixture intended to be the sole ration of the animal.

**Biologics:** see Veterinary biologics.
Device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals, and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Drug: means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient or dietary supplement for which a truthful and non-misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

Electronic animal identification products: Implantable transponders that contain unique information for use in animal identification; a reader compatible with the transponder is used to make the final identification. These transponders are implanted into inedible portions of the animal (e.g., ear), and if the implant is rendered for animal feed, the center is regulating the transponder as a food additive.

Extra-label use: Refers to the actual or intended use of an approved new animal drug in a manner that is not in accordance with the approved label directions.

Food additive: Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, processing, preparing, treating, packaging, transporting or holding food, and including source of radiation intended for any such use), if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use. (See 21 U.S.C. 321(s) for complete definition.)

Labeling: All labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article.

Medicated animal feed: An article intended for use as food for animals, other than man, bearing, containing or purporting to bear or contain any kind of animal drug/drug combination.

Misbranding: A drug or device shall be deemed to be misbranded (a) if its labeling is false or misleading in any particular; (b) if in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; (c) if any word, statement or other information required by or under authority of the act to appear on the label is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. (The complete definition of misbranding can be found in the act 21 U.S.C. 502.)

New animal drug: Any drug intended for use for animals other than man which, among other things, is not generally recognized by qualified experts as safe and effective for use under the condition prescribed, recommended or suggested in the labeling thereof.

Veterinary biologics: Vaccines, bacterins, diagnostics and so on that are used to prevent, treat or diagnose animal diseases. These products generally work through some immunological method or process.

Endnotes

- A drug intended for use in or on an animal feed which is limited by an approved application to use under the professional supervision of a licensed veterinarian is a veterinary feed directive (VFD) drug.
- A valid veterinarian-client-patient relationship (VCPR) is defined by the American Veterinary Medical Association as: “A VCPR exists when all of the following conditions have been met: The veterinarian 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 veterinarian’s instructions.
- The veterinarian 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 veterinarian 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 premises where the animal(s) are kept.
- The veterinarian 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.”
- Copies of Compliance Policy Guides 7125.37 Proper Drug Use and Residue Avoidance by Non-Veterinarians (7/99/91), and 7125.95 Responsibility for Illegal Drug Residues in Meat, Milk and Eggs (7/01/82) are available from Communications Staff, HFV-12, Center for Veterinary Medicine, 7519 Standish Place, Rockville, MD 20855. CPGs are also available on the FDA website (http://www.fda.gov/cvm/cpgdirectory.htm).
11. Topically applied flea control products are usually regulated by the EPA.
   ○ True  ○ False

12. Canned pet food must be manufactured and registered in accordance with the FDA regulations for low-acid canned foods.
   ○ True  ○ False

13. Products intended for cleansing or promoting attractiveness of animals as “grooming aids” are subject to FDA control.
   ○ True  ○ False

14. The FDA conducts scientific tests and experiments to ensure that animal drug residues in food products from a treated animal are safe for consumers.
   ○ True  ○ False

15. FDA rules allow practicing veterinarians or their employees to legally sell animal prescription drug products to all walk-in customers.
   ○ True  ○ False

16. A serial number and date of the order or its filling, needs to be included in the veterinarian’s prescription and included on the label of the dispensed product.
   ○ True  ○ False

17. Veterinary feed directive (VFD) drugs are intended for use in or on feed, limited by an approved application to use under the professional supervision of a licensed veterinarian.
   ○ True  ○ False

18. Failure to observe label withdrawal periods before slaughter or processing or failure to withhold milk is the principal cause of illegal drug residues.
   ○ True  ○ False

19. A veterinarian who prescribes, dispenses or treats an animal cannot be held responsible for causing a violation of law if an illegal drug residue is found in edible products from the animal.
   ○ True  ○ False

20. Extra-label use of drugs in treating food-producing animals for improving rate of weight gain, feed efficiency or other production purposes is prohibited.
   ○ True  ○ False