FARAD Digest

Update on drugs prohibited from extralabel use in food animals

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Extralabel drug use encompasses the use of a drug in an animal in a manner that is not in accordance with the FDA-approved label. This includes use in a species or for a disease or condition not listed on the label; use at dosages, frequencies, or routes of administration that differ from those stated on the label; or deviation from the labeled withdrawal time. Extralabel drug use in veterinary species was made legal by the passage of AMDUCA in 1994.[1] However, there are restrictions to AMDUCA, particularly with reference to ELDU in food-producing animals.

The information reported here is intended to outline the guidelines pertaining to legal ELDU in food animals and to update readers on drugs that are prohibited by the FDA from ELDU in these species. Readers should use this information in conjunction with the information on prohibited drugs contained in a 1999 FARAD Digest.[2]

Guidelines for Legal ELDU

Limitations described in AMDUCA for ELDU in food animals include restrictions on which drugs can be used, the conditions for their use, and who can legally use them. When considering the need for ELDU, it must be remembered that the prime consideration should be to provide treatment to an animal in cases in which the health of the animal is endangered and suffering or death of the animal may result from lack of treatment. Also, there must be no licensed or marketed drug for that species that would be considered effective, and preference should be given for use of veterinary drug formulations, rather than human drug formulations.

A valid VCPR must exist prior to prescription of ELDU. This would assume that a veterinarian has examined the animal or group (herd or flock) of animals, has discussed the condition with the owner, and has sufficient information to make a preliminary diagnosis. Extralabel drug use by a layperson, such as a producer or farm worker, is prohibited, except when under the supervision of a licensed veterinarian.

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Abbreviations

CPG	Compliance Policy Guide
DES	Diethylstilbestrol
ECP	Estradiol cypionate
ELDU	Extralabel drug use
FARAD	Food Animal Residue Avoidance Databank
MUMS	Minor Use and Minor Species Animal Health Act of 2004
VCPR	Veterinarian-client-patient relationship
VRE	Vancomycin-resistant enterococci

Extralabel use of a drug for nontherapeutic purposes is not sanctioned under AMDUCA. This would include, but is not limited to, the use of drugs for growth promotion or reproductive purposes. Extralabel use resulting in any residue that may pose a risk to the public health or that is above an established tolerance is not allowed. In the case of extralabel use of a drug that is not licensed for any indication in that species, the established tolerance is zero or the lower limit of detection for the method used for residue analysis. Thus, any concentration detected in meat, milk, eggs, or honey would constitute a violative residue. Given the advanced methods currently available for detecting drug residues in food and food products of animal origin, miniscule amounts often can be detected.

The use of compounded drugs in food-producing species is allowed by AMDUCA; however, drugs can be compounded only when there is not an approved product available. Thus, compounded drugs, by definition, represent ELDU and are subject to the requirements set forth by AMDUCA. Because they are being used in an extralabel manner, all compounded formulations must have a withdrawal time stated on the label, and this withdrawal time must be specified by the veterinarian, not the compounding pharmacist. As a result of the variability of compounded products, it is difficult to determine an accurate, substantially extended withdrawal period supported by appropriate scientific information. Compounded products must not be used if there is a licensed veterinary drug formulation available, and the prescribing veterinarian must establish the need for the compounded product.

Compounding of drugs from bulk substances is illegal under FDA regulations; therefore, it is also not permissible by AMDUCA. There are a few important exceptions to this rule. One exception is antidotes for use in food animal medicine that would otherwise not

be available because of a lack of products approved for use in humans or other animals. The FDA has stated that regulatory discretion will be used for compounded antidotes, including ammonium molybdate, ammonium tetrathiomolybdate, ferric ferocyanide, methylene blue, pilocarpine, picrotoxin, sodium nitrite, sodium thiosulfate, and tannic acid.[3]

Consider the example of ECP. This drug was previously available for use as an estrogenic hormone for reproductive treatment in food animals, despite the fact that there are no FDA-approved products available for use in human or veterinary medicine.[4] Estradiol cypionate was used primarily for estrus synchronization in cattle. It was subsequently removed from the market, and the only way for practitioners to obtain ECP is through compounding from bulk substances. Although the drug is not specifically prohibited from use in food-producing animals, its use is illegal because it constitutes compounding of an unapproved animal drug and also extralabel use for nontherapeutic purposes. The example of ECP highlights the need for veterinary practitioners to understand the limitations involved in ELDU in food animals to protect themselves and their clients from regulatory actions.

In addition to these restrictions and guidelines, there are certain drugs and drug classes that the FDA has prohibited from use in food-producing animals, regardless of need or indication (**Table 1**). These are drugs for which no acceptable analytic method can be established or for which extralabel use poses a risk to public health. These prohibitions may be absolute or may be restricted to certain types of food-producing animals, such as dairy cows. For some drugs on this list, approved products are available, but there must be strict adherence to label directions.

A list of these drugs and the explanations behind their prohibition was published in a 1999 FARAD Digest.[2] However, in the past 10 years, several new drugs have been added to the list, and some of the previous prohibitions have been revised. A summary of these prohibitions with special emphasis on new and updated information is provided here.

Review of Prohibited Drugs or Drugs Prohibited From ELDU

The following section deals with drugs that have been on the FDA's prohibited drug list for > 10 years and have not had any revisions to the order of prohibition. A more complete summary can be found in the aforementioned FARAD Digest.[2]

Chloramphenicol—Chloramphenicol has been prohibited from use in food-producing animals since 1984 because of the potential development of an idiosyncratic, non–dose-dependent, irreversible, aplastic anemia that may develop in humans exposed to even small amounts of the drug.[2] The use of this drug in food-producing animals is not legal under any circumstance. Florfenicol is in the same class of antibiotics as chloramphenicol but is available for use in cattle, swine, and some aquatic species. Florfenicol has not been associated with aplastic anemia in humans, and therefore, extralabel use of florfenicol in food-producing animals is allowed.

DES—Diethylstilbestrol was once used as a treatment to prevent miscarriages; however, a link was found between the use of DES in pregnant women and the development of reproductive tract abnormalities and tumors in female offspring of DES-treated patients. Subfertility and infertility have also been detected in male and female offspring of DES-treated patients. Reproductive abnormalities have even been seen in granddaughters and grandsons of treated women.[5] The DES products are no longer marketed in the United States, and their use in food-producing species has been prohibited since 1979.

Nitroimidazoles—Members of this drug class, including metronidazole, dimetridazole, ipronidazole, ronidazole, and tinidazole, have in vitro and in vivo potential for carcinogenesis.[2] Some drugs in this drug class were labeled for the treatment of histomoniasis in turkeys and had been recommended as a treatment for trichomoniasis in bulls. However, approved products have been withdrawn from the market, and there are currently no nitroimidazole products approved for use in food animals. Therefore, any use would be in an extralabel manner and is prohibited in food-producing species.

Clenbuterol—Clenbuterol is a β_2-adrenergic receptor agonist that also has secondary anabolic effects. These anabolic effects have led to the illegal use of this drug in show and sale animals to increase lean body mass and weight gain. High doses of the drug are nec-

Table 1—Drugs currently prohibited from use or extralabel use in food-producing animals.

Drugs prohibited from use in food-producing animals	Drugs prohibited from extralabel use in food-producing animals
DES	Sulfonamides in adult dairy cattle*
Chloramphenicol	Fluoroquinolones
Nitroimidazoles (including metronidazole)	Medicated feeds†
Nitrofurans (including topical use)	Indexed drugs
Clenbuterol	
Dipyrone	
Glycopeptides	
Gentian violet	
Phenylbutazone in adult dairy cattle*	
Antiviral compounds in poultry (including adamantane and neuraminidase inhibitors)	

*Cattle > 20 months of age. †Exceptions may be made for minor species.

essary for these effects, which may have been one of the factors that led to the reported hospitalization of > 1,200 people and the death of 3 people in France and Spain that were linked to clenbuterol residues in the liver of illegally treated animals.[2,6] Similar outbreaks have been reported in other countries, including Italy and Portugal.[6–8] Although concentrations of drug are often highest in the liver, toxic amounts can also be found in non–liver-containing meat from treated cattle and lambs.[9]

Clenbuterol[a] is available in the United States only as an orally administered syrup for the treatment of horses with recurrent airway obstruction (ie, heaves). The FDA has never approved an injectable formulation of clenbuterol, so any importation or formulation of such a product would clearly be prohibited. Practitioners should be careful in prescribing this drug to horses that are housed on the same premises with food-producing animals and ensure that all labeling requirements are met. Albuterol, another β_2-adrenergic receptor agonist, is not strictly prohibited from ELDU; however, it is difficult to establish a withdrawal interval after extralabel use of albuterol because of a lack of pharmacokinetic data.

Dipyrone—Dipyrone is an anti-inflammatory, antipyretic, and analgesic drug previously licensed for use in humans. Concerns over an association with adverse effects in humans that ranged from non–dose-dependent teratogenic effects to prolonged bleeding times and agranulocytosis prompted the FDA to withdraw this drug from the market in 1977. Although no licensed products were available for use in animals, products were still marketed for use in non–food-producing animals, at the regulatory discretion of the FDA. However, the FDA received reports of extralabel use of dipyrone in food-producing species. Thus, since 1995, all dipyrone products have been withdrawn from the market until such time as a licensed product becomes available.[10] It is possible that dipyrone may not be included in official lists of prohibited drugs because there are no marketed products available. However, use of dipyrone in any food-producing animal is illegal.

Glycopeptides—Of the glycopeptide class of antimicrobials, vancomycin is the only one available in the United States. Although the authors are not aware of reports of the use of vancomycin in food-producing animals, it has been prohibited on the basis of its potential to cause development of resistant human pathogens.[11] Of particular concern with glycopeptides is the risk of development of VRE. Several studies[12,13] have revealed that VRE can be found in the feces of farm animals; however, there is little evidence of transmission of VRE from animals to healthy people.[14]

Sulfonamide use in dairy cattle—Sulfonamides have been banned from ELDU in adult dairy cows. For this purpose, adult dairy cows are defined as any dairy cow > 20 months of age, regardless of milking status.[15] This ban was instituted because of the concern over carcinogenic effects detected in laboratory animals, which coincided with reports of sulfonamide residues detected in up to 73% of commercial milk samples. There currently is 1 sulfadimethoxine product marketed for use in dairy cows. Use of this drug in accordance with the label is permitted; however, ELDU is prohibited. Sulfadimethoxine is available to producers as over-the-counter products, and this can lead to extralabel use of a prohibited drug by a layperson. Veterinarians should educate their clients on the gravity and legal ramifications of this practice. Furthermore, veterinarians should be aware that they may still be listed as the veterinarian of record for any animals receiving over-the-counter sulfadimethoxine products and be held responsible for illegal residues. Extralabel use of all other sulfonamides and potentiated sulfonamide products is prohibited in adult dairy cattle.

Questions often arise regarding ELDU of sulfonamides in other dairy animals, such as goats or sheep used for milk production. Although this use is not expressly prohibited by the FDA, it is discouraged on the basis of the likelihood of violative residues in milk from these animals. Sulfonamides, similar to other drugs discussed in this report, are considered to be of high regulatory concern; therefore, use of these drugs in an extralabel manner is not advised.

Drugs with Updated Prohibition Orders

Several drugs discussed in the previous FARAD Digest on prohibited drugs[2] have had modifications to their prohibitions. These include the fluoroquinolones and nitrofurans as well as the ELDU of medicated feeds.

Fluoroquinolones—The fluoroquinolones were the first group of antimicrobials prohibited from extralabel use by the FDA because of their potential for creating antimicrobial-resistant strains that posed a threat to human health. Fluoroquinolones are commonly used as a treatment for multidrug-resistant *Salmonella* spp in humans; therefore, their use in food-producing species has been questioned. Consequently, the FDA banned the extralabel use of fluoroquinolones in 1997.[11] Use of marketed products was still allowed, providing label directions were followed. At the time of the prohibition, the use of these marketed products included sarafloxacin and enrofloxacin in poultry and enrofloxacin in beef cattle.

Surveillance of resistance to fluoroquinolones in bacteria isolated from food-producing animals was continued, and an increase in fluoroquinolone-resistant *Campylobacter* spp in poultry was linked to an increased incidence of infection with resistant *Campylobacter* spp in humans.[16,17] Therefore, the FDA proposed a withdrawal of fluoroquinolone products labeled for use in poultry on the basis of the proposed risk to human health, and sarafloxacin products were voluntarily withdrawn from the market by the sponsor. However, in 2005, the FDA withdrew the approval for enrofloxacin products in poultry and effectively made use of these drugs in poultry species illegal.[18] Despite the fact that fluoroquinolone products for poultry have not been available for several years, resistance to fluoroquinolones persists in *Campylobacter* spp and may actually be increasing.[19] In 1 study,[19] it was reported that fluoroquinolone resistance at 2 major US poultry production

operations increased from 13% in 2004 to 21% in 2006, despite discontinuing the use of these drugs.

Fluoroquinolone products are still available for other food-producing species, and these have not been removed from the market. These products include danofloxacin[b] and enrofloxacin.[c] Danofloxacin is labeled for use in beef cattle (excluding dairy cattle) and calves (excluding veal calves) for the treatment of respiratory disease associated with *Mannheimia haemolytica* and *Pasteurella multocida*. Enrofloxacin was originally approved for use in beef cattle for the treatment of respiratory disease associated with *M haemolytica*, *P multocida*, and *Histophilus somni*. Two times during the past year, the label for enrofloxacin has been expanded: first to add nonlactating dairy cattle and then to include swine for the treatment of respiratory disease associated with *Actinobacillus pleuropneumoniae*, *P multocida*, *Haemophilus parasuis*, and *Streptococcus suis*.

Practitioners are reminded that any use of fluoroquinolones that deviates from the label directions is expressly prohibited. Such prohibitions include use in lactating animals and veal calves and different nonlabeled conditions or diseases, dosages, frequencies, and routes of administrations. Fluoroquinolones must not be stored on dairy farms.[20]

Nitrofurans—Nitrofuran products for systemic administration were banned from use in food-producing species in 1991 because of concerns over carcinogenic effects in laboratory animals and a lack of a reliable detection method in food products. Products for topical use were still available with labels for food animals, which included treatment of surface wounds and infectious keratoconjunctivitis (ie, pinkeye). Studies reporting systemic absorption and detection of nitrofurazone residues in meat and milk from cows administered nitrofurans by the intramammary, intrauterine, or ocular routes prompted the FDA to prohibit topical use of these products.[21] Since 2002, all systemic and topical use of nitrofuran products has been prohibited.[22]

Extralabel use of medicated feeds—Extralabel use of medicated feeds by veterinarians and producers is prohibited. However, there are some exceptions to this rule, and these exceptions are published in the FDA's CPG on extralabel use of medicated feeds for minor species.[23] This policy was developed to aid practitioners in treating minor species that are difficult to medicate in any other way and that have few or no approved drug options for treatment. Although this does not legalize the extralabel use of medicated feeds, the FDA will exercise regulatory discretion with regard to the use of these feeds for minor species. Minor species are defined as any animal other than cattle, horses, swine, chickens, turkeys, dogs, and cats. Similar to AMDUCA, this policy has multiple limitations, including extralabel use of medicated feeds only for instances in which the health or life of an animal is in danger and use only in confined or farmed animals. Additionally, extralabel use of medicated feeds in accordance with the CPG is limited to products that have been approved for use in a major species; for aquaculture, extralabel use is limited to medicated feed products approved for use in aquatic species. These products must not be changed or adulterated in any way. All other tenets of AMDUCA must also be met, including prescription only under a valid VCPR, establishment of an appropriate withdrawal interval, and observance of all appropriate labeling and record-keeping duties. Veterinarians who treat minor species are referred to this CPG for complete details.

Many medicated feeds used for growth-promoting properties are actually subtherapeutic doses of antimicrobials. This restriction on extralabel use of medicated feeds is based on concerns about the development of resistant bacteria in animals exposed to subtherapeutic doses of antimicrobials. Along these lines, the European Union banned the use of all growth-promoting antimicrobials in 1995.[24] This included avoparcin, bacitracin, spiramycin, tylosin, and virginiamycin.

In the previous FARAD Digest on prohibited drugs,[2] it was stated that use of ionophore compounds in lactating dairy rations was prohibited. Although extralabel use of these compounds is still prohibited, a monensin-containing feed premix additive[d] has been approved for use in dairy cattle.

Gentian violet—Gentian violet is a xenobiotic dye that was originally added to poultry feeds as a growth promotant and was thought to increase dietary absorption of methionine and glucose.[25] It was determined that its main effect is more likely attributable to prevention of growth retardation secondary to aflatoxin; therefore, its primary use is as a mold inhibitor. However, the FDA has never approved the use of this product in feeds, and the impact of gentian violet residues on human health has not been fully assessed. As such, the use of gentian violet compounds in feeds constitutes extralabel use of a medicated feed and an unapproved new animal drug, and it is prohibited. Other compounds that are generally regarded as safe by the FDA are available for use as mold inhibitors in poultry feeds and should be used as an alternative. These include propionic acid and other organic acids.

The prohibition on gentian violet is not new. It was originally ordered in 1987, but gentian violet has not typically been specifically included on lists of prohibited drugs. Recently, however, topical products containing gentian violet have been found on the market, and the FDA has reiterated the prohibition order on this compound.[26]

Additions to the List of Prohibited Drugs

Since the publication of the previous FARAD Digest on prohibited drugs,[2] several new drugs or classes of drugs have been added to the prohibited drug list. A discussion of these is included in this section.

Phenylbutazone in adult dairy cattle—Use of phenylbutazone in dairy cattle > 20 months of age was prohibited in 2003.[27] This order was based on the detection of phenylbutazone residues in culled dairy cattle and the discovery of phenylbutazone products on dairy farms. This was of particular concern because there are no phenylbutazone formulations approved for use in any food-producing species.

Phenylbutazone has been used in human medicine as an NSAID in the past, but all human products were

withdrawn from the market for safety reasons. In particular, phenylbutazone at doses of 200 to 800 mg/d can induce blood dyscrasias (such as aplastic anemia, leukopenia, agranulocytosis, and thrombocytopenia) and cause death. It is also considered a carcinogen. Of more concern from a food residue standpoint are the reports of an idiosyncratic serum-sickness–type hypersensitivity reaction for which a threshold exposure concentration has not been determined.[27]

Currently, phenylbutazone use is strictly prohibited only in dairy cattle > 20 months of age; however, its use in other meat- and milk-producing species is discouraged for several reasons. The elimination half-life of phenylbutazone is greatly prolonged in ruminant species, compared with the half-life in monogastrics.[28] Residues may be detectable for extended periods after administration, which requires prolonged withdrawal times associated with its use.[29]

Another reason phenylbutazone should be avoided in food-producing animals is that its use is not covered by AMDUCA because there is an effective approved drug. Flunixin meglumine is an NSAID approved for IV administration to cattle (excluding veal calves) and swine. Phenylbutazone is preferred by some practitioners because of its slow elimination after oral administration, which allows for alternate-day administration. Ease of administration is not a viable reason for ELDU, unless it can be documented that no other route of administration is feasible. Therefore, it is difficult to justify the use of phenylbutazone over flunixin meglumine.

Similar to the situation with sulfonamide products, the use of phenylbutazone products in other milk-producing species is discouraged because of the high potential for residues in milk following administration. Although there are currently no NSAIDs labeled for use in small ruminants or other minor species, flunixin meglumine should be used preferentially over phenylbutazone in these animals because it is labeled for use in food animals in other major species. Phenylbutazone is considered to be a drug of high regulatory concern. As such, monitoring programs for residues of it and other NSAIDs in meat and milk are stringent.

Antiviral drugs in poultry—Two classes of antiviral drugs currently marketed for use in humans have been added to the list of prohibited drugs.[30] These are the adamantane inhibitors, rimantadine and amantadine, as well as the neuroaminidase inhibitors, oseltamivir and zanamivir. These antiviral drugs have been used in countries outside the United States to treat or prevent the development and spread of avian influenza in poultry. None of these drugs is labeled for animal use in the United States. The prohibition extends specifically to chickens, turkeys, and ducks; however, use of these drugs in other food-producing species is not recommended, and the prohibition order may be extended to other species in the future.

The prohibition order is based on the potential for the development of resistance to these compounds.[31–33] This potential is supported by the fact that countries that have made it a practice to use amantadine in poultry have detected the development of resistant strains of avian influenza, most notably the H5N1 subtype. Amantadine is used as a feed or water additive, often for prolonged periods, with a median exposure time of 42 days.[32] Cross-resistance to rimantadine has also been reported.[31] In some countries, amantadine is available as an over-the-counter product and is easily obtained by producers without a veterinary prescription. In the United States, the drug is available (by prescription only) for use in humans for the treatment and prevention of influenza as well as the treatment of Parkinson's disease. Numerous adverse effects are associated with amantadine, including CNS effects and fatalities.

Because of the prohibitively high cost of the neuroaminidase inhibitors, they are not used in poultry; however, they currently remain as the last resort for treatment of adamantane-resistant influenza strains in humans. For this reason, the FDA has added this class of drugs to the prohibited list.

Indexed drugs—When dealing with drugs for use in minor species, the products can be approved, conditionally approved, or indexed. Under MUMS, indexing creates a new category of drug that the FDA allows to be marketed but which does not carry the FDA imprimatur of approval.[34] Drugs that have such a small market as to be added to the index are those not being administered to any animal that will enter the human food chain as well as prohibited from ELDU. An example of such a product is a combination product containing salmon gonadotropin–releasing hormone and domperidone.[e] This product can be legally marketed for use as a spawning aid in ornamental finfish,[35] but the product label clearly states that it is not intended for use in fish intended for human or animal consumption or in fish whose offspring may be consumed by humans or food-producing animals. It also expressly states that extralabel use of this product is prohibited.

The Issue of Cephalosporins

In July 2008, the FDA proposed an order of prohibition on the extralabel use of cephalosporins in food-producing animals. Cephalosporins were considered for prohibition because of the increased emergence of cephalosporin-resistant zoonotic foodborne pathogens, particularly *Salmonella* spp, believed to be associated with extralabel use of cephalosporins. A study[36] conducted as part of the US National Antimicrobial Resistance Monitoring System revealed an increase in resistance of *Salmonella* isolates from both humans and food-producing animals to ceftiofur, a third-generation cephalosporin drug marketed for use in cattle, sheep, dairy goats, and swine as multiple injectable formulations as well as intramammary preparations for lactating and nonlactating cows. Ceftiofur is not used in human medicine; however, concerns about the movement of foodborne bacteria between domestic animals and humans and evidence of cross-resistance among drugs in the cephalosporin class caused the FDA to consider the extralabel use of cephalosporins a risk to public health and safety.

Similar to the situation for other prohibited drugs, the FDA allowed a 60-day comment period before the rule would be in effect. In the case of the cephalosporins, a high response rate resulted in the comment period being extended an additional 60 days so that the

order of prohibition was expected to go into effect on November 30, 2008. Opposition to the order of prohibition was overwhelming, and the FDA opted to revoke the order of prohibition until it could adequately consider the comments received.[37] This should not be interpreted as the order being permanently revoked, however. The prohibition order may be reissued at any time if the FDA considers the evidence for prohibition stronger than the evidence against. We included this discussion of cephalosporins to highlight the process involved in drug prohibitions as well as to stress the need for responsible ELDU in animals.

Consequences of the Use of Prohibited Drugs in Food Animals

In the case of the detection of illegal residues for any drug, certain actions can be taken against the producers and any other individual that is held responsible for those residues, including the prescribing veterinarian.[38] These include condemnation of the animals or animal by-products (ie, milk) involved in the residue violation as well as detention of future shipments, onsite investigation of a suspect producer, and notification and reporting of abusers to state and federal agencies. After the initial violation, a warning letter is sent to the responsible persons. In the instance of repeated or flagrant abuse of the laws, an injunction is placed against the producer until such time as all animals on the premises can be shown to be free of residues. If the animals are not free of residues within 60 days, the injunction may become permanent.

In extreme cases, responsible persons may be fined or imprisoned. This involves cases in which blatant misuse of toxicologically important drugs results in residues substantially above tolerance, false guarantees are issued that animals with violative residues are free of drugs or the appropriate withdrawal period has been maintained, or there are multiple misdemeanor counts or 1 or more felony counts. These consequences also apply to cases in which the residues detected are for drugs prohibited from extralabel use in food animals. In these instances, a warning letter or injunction need not be filed prior to prosecution for criminal actions.[38]

In the case of purposeful or accidental exposure to prohibited drugs, FARAD will decline from providing withdrawal intervals for ELDU. It should be mentioned that FARAD is not a regulatory agency and will work with veterinarians and consumers to solve problems so that the human food chain is protected. If there is doubt as to whether a drug is prohibited, or if the use of a drug in an extralabel manner is covered by AMDUCA, practitioners are encouraged to contact FARAD via the Web submission form that can be found at the FARAD Web site (www.farad.org), via e-mail (usfarad@gmail.com), or via the FARAD hotline (1-888-873-2723). Information is also available at the FDA Center for Veterinary Medicine Web site (www.fda.gov/cvm/).

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c. Baytril 100, Bayer Animal Health, Shawnee Mission, Kan.
d. Rumensin Type A medicated feed article, Elanco Animal Health, Greenfield, Ind.
e. Ovaprim injectable solution, Western Chemical Inc, Ferndale, Wash.

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