

FLOCK HEALTH MANAGEMENT FOR DAIRY SHEEP

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Dairy sheep producers usually have a background of experience with farm management and disease and parasite control in less intensively managed sheep before they develop a commercial dairy operation. This paper will assume knowledge of vaccination protocols and parasite control, abortion diseases, foot diseases, lambing problems and care of the neonate. Emphasis will be placed instead on feed-related problems of the ewe, drug residues, care of the early-weaned lamb, and chronic diseases that are all too often purchased when assembling a dairy flock. Brief mention will be made of udder problems, but mastitis is discussed in more detail elsewhere in this symposium.

Listeriosis

Producers looking for better forages to increase milk production from their dairy ewes sometimes are tempted to try haylage, baylage, or corn silage or to acquire manger sweepings from dairy cattle as a cheap source of feed. One of the greatest hazards of feeding ensiled forages is the presence of *Listeria monocytogenes* in poorly fermented feeds. This organism is ubiquitous in the environment but multiplies at cool temperatures in silages with a pH above 5.5. Silage from Ag Bags or wrapped bales may include deadly amounts of the organism if soil contaminated the forage, holes developed in the plastic wrapper, or the forage was too mature/dry to ferment properly when ensiled. Manger sweepings often include chunks of spoiled silage rejected by the cows. Cows are much more resistant to listeriosis than sheep, so absence of disease on the cattle dairy is no indication that the feed will be safe for sheep.

In a Scottish study, the risk of listeriosis in sheep increased 8 fold with silage feeding. Inoculants and preservatives decrease the risk but are expensive. Wrapping bales where they will be stored instead of spearing the wrapped bale to move it is very critical, and accidental holes in the bale wrapper must be covered with appropriate tape. If silages are fed, spoiled portions should be discarded. The manger should be cleaned daily and the uneaten feed removed from the barn rather than thrown into the pen as bedding. No vaccine is available in the USA to protect against listeriosis.

Listeriosis can appear as a neurologic disease (circling, facial nerve paralysis, dropped jaw, twisted neck) in weaned lambs or adults. This disease is rapidly fatal though some cases respond to high dose penicillin, oxytetracycline, or florfenicol. Listeriosis can also cause abortion in late pregnancy and the diagnosis will depend on laboratory cultures. Some neonatal lambs will be septicemic or found dead with multiple tiny abscesses in the liver. It is also important to realize that silage-fed animals are more apt to shed *Listeria* in their feces and milk than are hay-fed sheep. Fresh cheeses made from raw milk or aged cheeses recontaminated in the cheese cellar or refrigerator can cause serious illness or death in humans.

Copper Toxicity

Copper is a trace mineral that is necessary for the health of the sheep. The actual requirement depends on the level of molybdenum in the diet, and to a lesser extent the calcium and sulfur concentration. According to the NRC's Nutrient Requirements of Sheep, the requirement for copper in the overall diet on a dry matter basis varies with the age and status of the sheep. Lactating ewes will need a lower concentration of copper in their feed than growing lambs.

NRC recommended dietary copper concentration (ppm, dry matter basis)			
	Growth	Pregnancy	Lactation
Molybdenum <1.0 ppm	8-10	9-11	7-8
Molybdenum >3.0 ppm	17-21	19-23	14-17

To avoid both toxicity and deficiency of copper, the copper:molybdenum ratio should be 6:1 to 10:1. Suffolk and Texel sheep absorb copper more efficiently and are at greater risk of toxicity. In a report from Sweden, East Friesian dairy sheep were particularly susceptible to copper poisoning, but it was not clear if this was a breed characteristic or the result of feeding high levels of concentrates to the ewes to support milk production.

A sheep consuming excess copper gradually builds up stores in the liver over several months while appearing healthy. After some stress, acute copper toxicity appears and the sheep is suddenly lethargic and off feed. The sclera (white of the eye) is yellow from jaundice and the urine is coffee colored. Treatment is rarely successful. Some affected sheep die with only hemorrhages in various organs found at gross necropsy. Other suddenly dead sheep have no lesions but histologic examination of the liver reveals severe necrosis and analysis verifies a very high copper concentration in liver or kidney.

Prevention of copper toxicity in dairy sheep should be based on knowledge of the mineral concentrations in forages, grains, and supplements. Trace mineralized salts and concentrate feeds formulated for other species should not be fed unless verified to have a safe copper content. Dairy cattle, swine or horse feeds are sometimes the source of toxic amounts of copper, while in other cases a red salt block is incriminated.

Pregnancy Toxemia and Ketosis

If there is severe undernutrition or just a protein deficiency in late pregnancy, udders will be small and colostrum production decreased at time of parturition. Lambs may die of hypothermia or starvation at about the time the ewe's udder fills with milk. The colostrum antibody production by the ewe and therefore absorption by the lamb will also be adversely affected, potentially leading to higher lamb mortality from infectious diseases.

Late pregnant ewes and heavily lactating ewes that are off feed should be checked for ketones in the urine, using commercial test strips or pills. The pill or strip turns purple when ketone bodies are present. Urine can be collected when the ewe rises as a person enters the pen, or the nostrils can be held closed for up to 45 seconds to induce urination by stressing the ewe. Many animals with pregnancy toxemia are very dehydrated, and in addition the bladder may be empty, so release the sheep before it dies of anoxia. Other signs of pregnancy toxemia include abnormally small fecal pellets (an indication that the animal is eating poorly), reluctance to rise, self-isolation from the flock, or teeth grinding.

Initial treatment of the ewe with pregnancy toxemia includes 2 ounces of propylene glycol orally 2 to 3 times a day, 60 ml of calcium borogluconate subcutaneously divided into 4 sites, mixed B vitamins or thiamine, and intravenous dextrose (60 ml of 50% solution diluted to slightly less than 500 ml in sterile water). Animals that are acidotic and dehydrated will benefit from large volumes of intravenous fluids and sodium bicarbonate. Antibiotics are indicated if the fetuses may have died. If the ewe is unresponsive and unable to rise, the prognosis is grave. If the animal is not eating by the next morning a C section may be attempted to try to save its life. If there is partial response and the last possible breeding date is known, induction of parturition with 20 or 25 mg of dexamethasone may be attempted if the ewe has reached day 139 of pregnancy. Induction requires approximately 48 hours, and will come too late for severely affected animals.

Prevention of pregnancy toxemia in ewes pregnant with two or more lambs is no different for dairy ewes than for ewes that only suckle their young. The protein and energy needs of the dam and the developing fetuses must be met without causing a grain overload/indigestion situation. The secret is good quality forage, with supplementation of perhaps a pound of grain per ewe per day the last 3 to 4 weeks of pregnancy. The grain needs to be introduced gradually and with ample feeder space. Yearling ewes should be fed separately from adults to minimize competition. Older ewes that have lost molars may need a pelleted roughage source to supply their nutritional needs.

Hypocalcemia

Although it is rare for sheep to have a hypocalcemic episode similar to milk fever of dairy cows at the time of lambing, late pregnant and heavily lactating ewes are especially susceptible to calcium deficiency. Dietary oxalates increase susceptibility. Hypocalcemia may be precipitated by exercise, as when the sheep are driven in from pasture or chased by dogs. The sheep becomes too weak to continue or to get up and may lie on its sternum with the hindlimbs extended out behind it. Often the head is held low with neck extended, and the breathing is labored as if pulmonary edema or pneumonia were present. Ewes that have been lactating heavily may be still on their feet but off feed, cool and trembling. Fecal output and rumen contractions are decreased and a mild bloat may be observed. Ewes that are calcium deficient at the time of lambing may be slow to expel their lambs, such that dystocias or stillbirths result.

Treatment of hypocalcemia requires immediate administration of calcium to restore muscle function before the animal dies of heart failure. A commercial 23% calcium borogluconate

solution is used; avoid the combination products with phosphorus and dextrose added. A veterinarian will usually give 60 ml (cc) intravenously to a ewe that is unable to rise, but this must be done very slowly to avoid provoking potentially fatal irregularities of the heart beat. Less severe cases or instances where the diagnosis is not certain are handled with 60 ml of the 23% solution given subcutaneously, in four sites such as high and low behind the shoulders on each side. Goat owners report that Tums™ antacid pills are readily accepted by their animals and provide a calcium source in times of emergency or heavy production, as each pill contains 500 mg of calcium. By comparison, 500 ml of the injectable 23% calcium gluconate solution contains 10.7 g of calcium and the 60 ml sheep dose contains 1284 mg.

Prevention of hypocalcemia in sheep may require supplementing the diet of late pregnant and lactating ewes by addition of dicalcium phosphate to the trace mineral mix offered on pasture. Grain rations formulated for lactating ewes usually contain supplemental calcium. In dairy cattle feeding, alfalfa is often avoided in the diet of dry cows, not because it is too high in calcium but because high potassium levels in heavily fertilized alfalfa interfere with magnesium absorption, and low magnesium then induces hypocalcemia. If dairy sheep are being fed alfalfa hay or haylage from cow dairy farms, avoid feeding forages with a potassium concentration substantially above 1%. Based on recommendations for dairy cattle, the potassium to magnesium ratio in the ration in late pregnancy should not exceed 4:1.

Grain Overload

Consumption of excessive amounts of rapidly fermenting carbohydrates leads to production of acetic and butyric acids in the rumen. As the pH of the rumen contents drops, acid-loving bacteria are favored. Streptococci and lactobacilli overgrow, producing lactic acid and driving the pH even lower. When the rumen pH drops below 5.5 the buffering capacity of bicarbonate in the saliva has been exceeded. The sheep is depressed and off feed. The body temperature can initially be slightly elevated, but drops below normal as the toxic indigestion progresses. Fluid is pulled out of the bloodstream and into the rumen, causing a characteristic splashy consistency that can be heard if the sheep's body wall is succussed (punched rapidly) on the left side. The eyes sink as dehydration increases. If the sheep lives a day it will develop diarrhea. If the animal has not been well vaccinated against enterotoxemia (two doses approximately one month apart followed by boosters at least once if not twice a year and especially 3 to 4 weeks prelambling), the overgrowth of *Clostridium perfringens* bacteria in the intestine will produce a rapidly fatal toxin. Interference with the production of B vitamins by normal rumen bacteria can lead to polioencephalomalacia, which will cause blindness, elevated head, and eventual convulsions as brain cells are deprived of glucose. The off feed situation produced by a mild indigestion can throw a late pregnant ewe into pregnancy toxemia.

Treatment of grain overload begins with removing all grain from the group and offering dry hay. If the sheep is willing to eat the hay, the saliva produced while chewing the hay will help to return the rumen pH to normal. More severely affected animals will need more support from a veterinarian, including intravenous fluids (perhaps 5 liters) with added sodium bicarbonate to correct the acidosis. Calcium (60 ml subcutaneously divided into four sites), thiamine (10 mg/kg

several times a day by any route) and a single oral dose of 500 mg of a tetracycline product to slow bacterial fermentation are typically given. A particularly valuable animal that is not eating hay by the next day can be given a liter of cow or sheep rumen fluid (collected from a fistulated cow or an animal at slaughter) by stomach tube, to reestablish normal rumen flora.

Prevention of grain overload requires careful management of the sheep. The first line of defense is good forage so that large amounts of grain are not needed to support growing fetuses or high milk production. Grain should be coarse rather than finely ground, to slow its digestion. Grain should be introduced gradually over a week, to supply approximately one pound per ewe and a pound per lamb being raised in early lactation. If more grain is needed, buy better hay! Divide the grain feedings into two or more per day if more than a pound is needed per day. Equally important in preventing grain overload is having adequate feeder space so that all ewes can eat their fair share of grain at the same time. Fort Knox level security on the grain storage facility is also mandatory.

Drug Residues in the Milk

Only one antibiotic is labeled for sheep with zero milk and meat withdrawal. That is ceftiofur (Naxcel™) which is a prescription antibiotic specifically labeled for sheep at 0.5 to 1.0 mg/kg (1 to 2 ml/100 pounds) once a day intramuscularly. Reconstituted Naxce™1 can be kept refrigerated for up to 7 days or frozen for up to 8 weeks without loss of potency.

All other antibiotics and most dewormers will cause contamination of the ewe's milk and meat if a withdrawal period is not adhered to. Very few products are labeled for use in sheep (see <<http://www.nrsp-7.org/MUMSRx/>> using Internet Explorer), fewer are currently marketed, and information is not given for milk withdrawal at this website. Labeled meat withdrawals for dewormers include Valbazen™ at 7 days, Ivomec Oral™ at 11 days and Levasole™ at 3 days. Although procaine penicillin G is labeled for sheep with a meat withdrawal of 9 days, this is at a dosage of 1 ml per 100 pounds once a day, and almost no infections of sheep are susceptible to such a small dose. Thus dairy sheep producers must work closely with their veterinarians to establish safe meat and milk withdrawals, to avoid residues in products sold and to avoid interference from antibiotics or anthelmintics (some of which are antifungal) with production of cultured cheeses.

The flock veterinarian, the only person allowed to prescribe extralabel drug use, can obtain guidance in establishing withdrawals from FARAD, the Food Animal Residue Avoidance Database. FARAD has a website at <<http://www.farad.org/>> under revision and a hotline for veterinarians on the east coast at . FARAD has previously published recommendations for extralabel use of oxytetracycline in sheep, indicating that because of rapid elimination of the drug after IV and IM administration, the labeled withdrawal periods for cattle are usually adequate. A milk discard of at least 96 hours (144 hours for multiple or high doses) should be used, followed by residue testing. For Ivomec Oral, FARAD has recommended a 9 day milk withdrawal for goats but has not published a recommendation for dairy sheep. Written records of all extralabel drug use must be kept for 2 years.

Although vaccines typically have a 21 to 60 day meat withdrawal, they have no milk withdrawal.

Increasing numbers of scientists and newsmongers question the use of antibiotics in food producing animals, contending that the practice may favor the development of antibiotic resistance in organisms that cause human diseases. Sheep producers need to adhere closely to the law regarding extralabel drug use. Specifically, any use of drugs not labeled for sheep, or higher dosages of the drugs or a different route of administration is forbidden unless prescribed by a veterinarian familiar with the animal being treated or the health and management of the flock. This veterinarian must either examine the animal or make “regular and timely visits” to the flock. Advice gleaned from a drug catalog or even a sheep conference cannot be translated into extralabel drug use unless this is approved by the flock veterinarian. The aim of the legislation is not to make health care expensive or to support veterinarians but to keep meat and milk free of drug residues. A dairy flock needs to be especially careful of drug residues, to protect the “natural” or “green” associations that consumers make with sheep products. The flock veterinarian also can assist in improving management and nutrition to decrease the need for drug usage.

Certain drugs are absolutely, totally, and unquestionably forbidden in all sheep for any reason, no matter if the animal will be used in the future for production of meat or milk or not. These forbidden drugs include Baytril (enrofloxacin), chloramphenicol, metronidazole, nitrofurazone, and clenbuterol. Sheep producers who obtain veterinary services from small animal practitioners need to be aware of this list, as unfortunately the veterinarian who sees very few food animals or thinks of them as ruminating pets may be unaware of recent changes in the law. It is illegal to mix any extralabel drug into feed. Coccidiostats are not permitted in the feed of ewes producing milk for human consumption. The extralabel use of drugs for production purposes, including estrus control, is also forbidden under the current law.

Skin Diseases of the Udder

Any condition that damages the health of the skin near the teat opening will predispose to colonization with bacteria, notably *Staphylococcus aureus*. Bacteria then travel up through the teat sphincter into the udder, where they cause mastitis. Contagious ecthyma (orf, soremouth) can be easily spread to the teats of a naive ewe from an infected nursing lamb and thence to the hands of the dairymen, where crusts develop and persist for typically 4 or 5 weeks on initial human infection. The milking machine can also spread this virus to additional ewes. Toxic or gangrenous mastitis often results from the scabs on the teats.

If lambs are hungry because the ewe is being asked to raise too many or is not fed properly or because a creep feed is not offered, the lambs may chew on the ewe’s teats. This can cause scab formation and mastitis as described above or painful sores may make machine milking difficult. Bite wounds high on the teat can also result in formation of scar tissue within the teat. The next time the ewe lambs it will not be possible to express milk from the affected teat.

Care of the Early Weaned Lamb

It is common to allow the lambs to nurse for approximately one month in a commercial dairy sheep operation, then to wean them abruptly and milk the ewes in the parlor. The lambs should have had access to a creep feed (preferably with a coccidiostat such as decoquinate or lasalocid) beginning by one week of age. They also need an easily reached palatable and clean water supply. Weaning failure, where the lamb does not drink water or eats only hay after weaning is a common cause of death. Lambs that have been dam reared on pasture may need to be dewormed several weeks after weaning and housing.

The rearing area for weaned lambs needs to be dry, well ventilated, and uncrowded. It is also important that the lambs in a pen vary no more than 2 weeks in age and that the pen be cleaned before younger animals are moved into it. This is for control of coccidiosis, which is otherwise magnified as early born lambs excrete so many oocysts that later born lambs develop diarrhea and illthrift before they can develop immunity. A tight lambing period, obtained by careful attention to the fertility of the ewe and ram, is a major aid in coccidiosis control. Older sick lambs, such as those with chronic pneumonia, should also not be mixed with recently weaned lambs.

An alternative to weaning at a month of age is weaning at 24 hours (after colostrum consumption) and transfer to a lambbar. These lambs need clean dry bedding or an elevated pen with wire flooring. The milk replacer should be one designed for lambs and a starter feed should be offered early on. If coccidiosis is a severe problem, decoquinate can be added to the milk replacer (DeccoxM™), otherwise a coccidiostat should be included in the starter.

Biosecurity on the Sheep Farm

Assembling a dairy flock, purchasing rams or replacement lambs, and showing sheep or showing off the dairy operation to visitors are all very risky ventures. Many diseases of sheep are bought and paid for. Three major chronic diseases with long incubation periods are discussed below, but the owner should not forget about the risks of introducing footrot, pinkeye, soremouth, chlamydial or campylobacter abortions, ram epididymitis, and anthelmintic-resistant parasites. Incoming animals should be quarantined for at least a month, and examined closely for evidence of disease on arrival and at the end of the quarantine period. If possible the newly arrived animals should be managed as a separate group or released into a small subset of the flock for further observation for a year or more.

Trucks should be sanitized before transporting sheep to the farm. Shearing equipment should be sanitized before use, or better yet the flock's own equipment should be used. The flock should not mix with other sheep while on pasture. Visitors should be required to wear disposable boots or boots and coveralls provided by the farm. Animals that leave the farm for a show or exhibition should be quarantined on their return.

Caseous Lymphadenitis (CLA)

Contagious abscesses are caused by the bacterium *Corynebacterium pseudotuberculosis*. The organism has a long incubation period, often of 2 to 6 months or more. Thus it is common to buy animals that have no evidence of the disease, only to find abscesses at the next shearing. Although sheep that only have external abscesses eat and milk normally, the animals that develop abscesses in the lungs and other internal organs commonly develop a wasting disease that leads to death or premature culling. To avoid this risk, buy animals (including rams) only from farms that are believed to be free of caseous lymphadenitis. Additionally, all incoming animals should be palpated for enlargement of external lymph nodes (below the ear, between the lower jaws, in front of the shoulder, on the flank in front of the stifle, at the back of the stifle, and above the udder) on arrival and before release from quarantine. Affordable antibiotics will not successfully resolve these abscesses. Serologic tests currently available are not well validated and furthermore will not distinguish between infected, recovered, and vaccinated sheep.

The infection can be spread by shearing (which opens abscesses and contaminates the blades) or by contact with pus from an abscess that has ruptured spontaneously. Nasal discharges contaminating feed or water will also spread the disease from an animal with lung abscesses. Unthrifty sheep, for whatever reason, should be culled promptly from the flock. If caseous lymphadenitis is already present in the sheep dairy, culling of obviously infected animals and vaccination of replacements will decrease future infections.

Ovine Progressive Pneumonia (OPP)

OPP, referred to in Europe as maedi/visna, is caused by a retrovirus. Viruses of this family (which includes HIV) are never cleared from the infected host. The virus causes a chronic pneumonia in adult sheep, with weight loss, exercise intolerance, and eventually difficulty breathing and death. Many infected ewes live a normal productive life without developing interstitial pneumonia, and the producer may not recognize a major economic loss outside of the occasional young to middle-aged ewe culled as a “lunger”. Some but not all studies have demonstrated a lower milk production in sheep infected with the OPP virus and developing an interstitial mastitis with fibrosis. Arthritis and neurologic disease are less common manifestations of the virus infection.

Sheep infected with the OPP virus are commonly identified by means of a commercial agar gel immunodiffusion (AGID) test. Although the test is specific (animals with a positive test are almost always truly infected), the sensitivity of the test is lower. Thus some animals that carry the virus and can spread it to others in the flock through respiratory secretions, milk, or blood will not produce enough antibodies to give a positive test result. The risk of introducing the virus with a purchased animal will be greatly reduced if the entire source flock has tested negative as opposed to the more dangerous practice of accepting test-negative animals from an infected flock.

Eradication of OPP from a sheep flock has been achieved by testing all ewes before each lambing and promptly culling the seropositive animals. Alternatively, lambs may be removed at birth and fed on cattle colostrum or heat treated sheep or goat colostrum, then milk replacer. A two flock management system is then established, where the artificially reared animals are never allowed to mix with the original, infected flock. Uninfected animals must also be milked before the sheep in the original flock. Serologic testing of the “clean” flock is repeated twice a year for several years, then annually for some years longer if no positive sheep are found.

Paratuberculosis (Johne’s Disease)

Johne’s disease seems to be prevalent in high-producing dairy sheep in this country, partly because source flocks were infected and partly because the disease is more apt to become clinical when sheep are stressed by high production. Sheep over one year of age, and often over two years old lose weight and show decreased production. A small percentage of clinically affected sheep will develop diarrhea, and susceptibility to parasitic infestations is increased. A mild anemia and hypoproteinemia are typical laboratory findings. The causative agent is the bacterium *Mycobacterium paratuberculosis*, more correctly known as *Mycobacterium avium* subspecies. *paratuberculosis*. It can persist in the environment for a year or more.

Sheep strains have traditionally been almost impossible to culture in the laboratory such that diagnosis has depended on demonstration of acid fast staining organisms in histologic sections of intestine or lymph node. Recently the Diagnostic Laboratory at Cornell has acquired new equipment that permits isolation of the sheep strains in just a few weeks. Other laboratory tests allow differentiation of sheep strains from cattle strains of *M. paratuberculosis* and from *Mycobacterium avium*.

Serologic testing is hampered by the late appearance of antibodies to the organism. Even though the young lamb is the most likely animal to become infected, by the fecal-oral route, serum antibodies do not appear until after shedding in the feces has begun, approximately coinciding with the onset of clinical signs. The preferred serologic test for sheep is a small ruminant AGID. ELISA tests designed for cattle, including the recently approved Paracheck™, are not accurate enough in individual sheep to be used alone for diagnosis. Instead they should be used as screening tests and infection of animals with positive ELISA results should be confirmed by fecal culture or necropsy.

If the herd infection status is unknown, serologic and necropsy monitoring should be performed on thin or cull adult sheep. Once the disease has been demonstrated in the flock, management efforts should be directed at limiting fecal oral spread of the agent. This can be accomplished by good feeder design (to keep feet and manure out of the feed), liberal use of bedding, crutching ewes prelambling, avoiding close grazing situations and contaminated water supplies, and timely culling of thin animals and their offspring.

If a dairy sheep flock is to be assembled, seronegative animals should be acquired from flocks that have actively looked for the disease and not found it. Additional biosecurity measures include not grazing lands that have been grazed by infected cattle, sheep, or goats or where

manure from infected flocks has been spread. Trucks should be cleaned and sanitized before use, visitors entering the farm should wear clean boots or disposable foot covering, and colostrum or milk from infected farms should not be fed. Manger sweepings from cattle herds infected with Johne's disease are very apt to spread the infection to sheep, as they do to heifers when fed to youngstock on the cattle dairy.

Selected References and Websites

American Sheep Industry Association. 1996. SID Sheep Production Handbook, 6911 S. Yosemite, Englewood, CO. Phone 303-771-3500 or order from ASI at <http://www.sheepusa.org/> or from various suppliers of sheep equipment.

National Research Council. 1985. Nutrient Requirements of Sheep, 6th ed. National Academy Press, Washington D.C. Available online at <http://www.nap.edu/books/0309035961/html/index.html>

Martin-Jimenez T, Craigmill AL, Riviere JE. 1997. Extralabel use of oxytetracycline. J. Am. Vet. Med. Assoc. 211:42-44.

Baynes RE et al. Undated. Extralabel use of ivermectin and moxidectin in food animals. <http://www.farad.org/vets/digest9.htm>

Food and Drug Administration. Extralabel drug use in animals; final rule. Federal Register 61(217):57731-57746 can be accessed online at <http://www.fda.gov/cvm/index/amducca/amducafr.htm>

A summary of the AMDUCA regulations is available online at <http://www.geocities.com/Heartland/8815/eldu.html>