FDA VETERINARIAN

Center for Veterinary Medicine

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NATIONAL PET WEEK 2002

During the week of May 5-11, veterinarians, veterinary technicians, and pet owners will celebrate "People, Pets, & Veterinarians . . . a Winning Team." National Pet Week 2002 is co-sponsored by the American Veterinary Medical Association (AVMA, *http://www.avma.org*), the Auxiliary to the AVMA, (*http://www.avmaaux.org*) the American Animal Hospital Association (AAHA, *http://www.healthypet.com*), and the North American Veterinary Technician Association (*http://www.avma.org/navta*).

Successful teams are formed through winning partnerships. Each member contributes and benefits. National Pet Week is a mutually beneficial program for pets, their owners and veterinarians. It raises pet owners' awareness of the health issues facing their pets; it helps increase the quality of the care their pets receive; and it highlights the veterinarian as the expert on pet health care. It is a perfect opportunity to educate the public and enhance community outreach.

Pet owners want what is best for the health and welfare of their companion animals. By highlighting specific health issues through National Pet Week, owners are motivated to discuss them with their veterinarian.

Photo by Karen Kandra

"People, Pets, & Veterinarians . . . a Winning Team"

Pets get better care when their owners understand specific health issues. Celebrated in early May, National Pet Week is used to raise awareness of heartworm, fleas and ticks, as well as to provide information about ongoing and preventative care for chronic conditions.

Today's pets are considered important members of the family, and for many persons pets provide emotional stability and improve their quality of life. Pet ownership is a long-term commitment, but the rewards will last a lifetime.

PROTECTING PETS FROM MOSQUITO-BORNE DISEASES

The following is used with permission from www.goodnewsforpets.com (Germinder & Associates, Inc.), and can be found on the web site for the North American Veterinary Technician Association, Inc. at www.navta.net.

Mosquito-borne illnesses are some of the deadliest in the world today, causing more than 300 million clinical cases each year of illness in humans, including encephalitis, malaria, and dengue fever, according to the World Health Organization. But humans are not the only ones who can suffer from the effects of mosquito-borne disease. Mosquitoes can also carry a variety of illnesses that dogs and horses are susceptible to as well, including heartworm, equine encephalitis, and the relatively new but deadly threat of West Nile Virus.

The American Mosquito Control Association says there are more than 2500 different species of mosquitoes throughout the world, with around 150 species living in the United States. As one of the most diverse species on earth, each

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PROTECTING PETS FROM MOSQUITO-BORNE DISEASES (Continued)

species of mosquito is adapted to live in specific habitats, exhibiting unique behaviors and biting different animals. There are species of mosquitoes that bite in the morning, and those that bite after dark. There are mosquitoes that bite in the shade and those that prefer the brightness of day. There are some species that prefer to bite mammals like humans and those that prefer birds, horses, dogs and livestock.

Mosquitoes are found in literally every climate in the world, from the jungles of Africa to the Arctic. And they are not getting any less dangerous or easier to control.

The West Nile Threat

With the emergence of the West Nile Virus in New York in 1999, the common house mosquito known as the Culex pipiens has become a carrier of an exotic, sometimes deadly virus that previously had been unheard of on American shores. The West Nile Virus was first identified in Africa in 1937, and since that time has begun a slow steady spread throughout the world, including the United States. Since the first case of West Nile Virus was identified in New York in 1999, the virus has spread from Maine to Florida, and as far west as Ohio. The West Nile Virus causes West Nile encephalitis in humans, a fatal brain infection, and while the disease in humans has been proven deadly but rare, West Nile has quickly become established as a real threat to horses, with 40 percent of horses that contract the disease dying from the illness.

West Nile is a flavivirus, a member of a large group of viruses that are called arboviruses. Arboviruses are transmitted by blood-sucking vectors, such as a mosquito or even a tick. Arboviruses require a host, which in West Nile's case are birds. Mosquitoes act as a vector, and during periods of adult mosquito blood feeding, mosquitoes become infected when they feed on infected birds. Because birds tend to collect in flocks, it is easy for the disease to quickly spread. After an incubation period of 5 to 15 days, infected mosquitoes can then transmit the virus to humans and animals.

Just as in humans, following a bite by an infected mosquito, the West Nile Virus multiplies in the horse's blood system, and crosses into the brain, where it infects the brain, causing inflammation and interference with the central nervous system. Clinical signs of the disease in horses include fever, stumbling/tripping, muscle weakness/twitching, partial paralysis, inability to stand, convulsions and coma. There is no documented evidence of person-to-person or animal-to-person transmission of the West Nile Virus, so an infected horse cannot infect a human or other horses.

In addition to birds and horses, West Nile Virus has been shown to infect cats, bats, chipmunks, skunks, squirrels, and domestic rabbits, although unlike in horses and birds, it does not appear to cause extensive illness. There is now an equine vaccine for West Nile Virus. Contact your veterinarian for further information to prevent infection of this deadly illness in horses. For other sources of information on the West Nile Virus go to, *www.cdc.gov/ncidod/dvbid/westnile/index.htm* and *www.aphis.usda.gov*.

Contact your veterinarian for a new equine vaccine to protect horses against West Nile Virus.

Heartworm-A Growing Threat?

In addition to being carriers of viruses like West Nile, mosquitoes also carry deadly parasites, or filarial disease, including heartworm, a potentially fatal disease in dogs.

Heartworms live in the heart and pulmonary arteries of infected dogs. A disease that occurs all over the world, heartworm was once thought to be limited to the south and southeast region of the United States, but is now found in most regions of North America, particularly where mosquitoes are prevalent.

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FDA VETERINARIAN

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PROTECTING PETS FROM MOSQUITO-BORNE DISEASES (Continued)

Coinciding with mosquito season, heartworm disease is carried by the mosquito as an intermediate host, who when it bites a dog, transmits the microscopic worm into the dog's bloodstream. Although it takes a number of years before dogs show signs of infection, once infected, it is a particularly deadly and nasty illness, with worms that have grown up to 10 inches in length clogging the heart, causing severely infected dogs to die suddenly during exercise or excitement.

Heartworm preventatives have been available for some time through veterinarians to help prevent the deadly illness. However, these preventatives are only as effective as the pet owners who administer them, and many dogs have become infected due to pet owner noncompliance. A new injectable is now available through a veterinarian that can give a dog complete protection against heartworm for up to six months.

Mosquito Control

One reason mosquitoes are prolific and difficult to control is because of their rapid life cycle, which spans from egg to adult in some species in as little as four days. An adult female (the only mosquito that can draw blood) can lay more than 200 eggs at a time, and in the perfect weather conditions, the eggs will hatch sometimes in as little as four days. Although mosquitoes generally only live a few weeks as an adult, one species of mosquito that has been found to carry West Nile Virus can survive through the winter, hibernating until warmer temperatures to emerge again.

For all mosquitoes, however, water is the critical component of a successful habitat when laying their eggs. For this reason, pet owners should be aware of any sources of stagnant water around their property, in buckets, rain spots, clogged gutters, birdbaths, etc. Because mosquitoes like to rest on weeds and in other vegetation, pet owners can also help reduce mosquitoes by cutting down weeds near their homes' foundations and mowing the lawn regularly. There are also a number of insecticides available that can be applied to trees, shrubs and walls.

Other effective measures include keeping pets inside at dawn and dusk, when mosquitoes are most active, and installing bug tight window and door screens, even on stables, and replacing outdoor lights with yellow "bug" lights.

Mosquito-borne diseases are a serious threat to both pets and humans, but with control and prevention, it is possible to protect our pets from the deadly diseases they carry.

Keep pets away from weeds and water to avoid infection by mosquitoes.

UPDATE ON ANIMAL DIETARY SUPPLEMENTS

by Linda A. Grassie

Part of FDA's responsibility in enforcing the Federal Food, Drug, and Cosmetic Act (the Act) is to ensure that animal food is safe and properly labeled. FDA's Center for Veterinary Medicine (CVM) is responsible for enforcing this part of the Act. Dietary supplements, such as vitamins and minerals, fall into the category of animal feeds.

Dietary supplements for animals such as vitamin and mineral products have been marketed for many years. Most of these products include ingredients that are approved food additives, generally recognized as safe (GRAS) substances, or ingredients listed in the *Official Publication of the Association of American Feed Control Officials (AAFCO).*

Quite a few animal supplement products are being sold as a result of the Dietary Supplement Health and Education Act (DSHEA) passed by Congress in 1994, and these products generally contain similar ingredients to those in human dietary supplements. However, FDA published a notice in the *Federal Register* in 1996 explaining why the Agency believes that DSHEA does not apply to animals. Many of these types of products marketed for animals contain ingredients that may be unsafe food additives or unapproved new animal drugs, making the products unsafe for the animals.

CVM is concerned about these products because we do not have scientific data to show that they are safe or even contain the ingredients listed on the label. This article describes CVM's authority and concerns about certain animal

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UPDATE ON ANIMAL DIETARY SUPPLEMENTS (Continued)

Many of these types of products marketed for animals contain ingredients that may be unsafe food additives or unapproved new animal drugs, making the products unsafe for the animals.

dietary supplements, and what companies can do legally to market their products.

CVM Authority

In addition to enforcing the provisions of the Act designed to ensure that animal food is safe and properly labeled, CVM is also responsible for ensuring that animal drugs are safe, effective, and can be manufactured to a consistent standard. Safety includes drug safety for the animals, environment, and for people who consume animal-derived products. Animal dietary supplements can fit under the definition of food, drug, food additive, or GRAS substance. These terms are defined in the Act as follows:

FOOD – The Act defines food as "articles used for food or drink for man or other animals...and articles used for components of any such article." There is no requirement that animal foods have pre-market approval by CVM. The Act does require that animal foods, like human foods, be pure and wholesome, contain no harmful or deleterious substances, and be truthfully labeled.

DRUG – The Act defines a drug, in part, as "an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or an article intended to affect the structure or function of the body other than food."


Photo by Karen Kandra

DSHEA does not apply to animal supplements.

In the drug definition, the courts have interpreted "food" as something that provides nutrition, taste, or aroma. If a food affects the structure or function of the body, it does so by these properties (for example, a food may provide nutrients such as calcium for proper bone structure). However, if a substance affects the structure or function of the body apart from its nutritive value, such as improvement in joint function, it may be considered a drug. Structure/function effects extending beyond the "food" umbrella also include claims for improved or increased production and performance, or alteration or improvement in function.

When a substance, including one considered food, is intended to be used for the treatment or prevention of disease or for a "non-food" structure/function effect, FDA considers it a drug. Under the Act, a new animal drug must be shown to be safe and effective for its intended use by adequate data from controlled scientific studies as part of a New Animal Drug Application (NADA). If a product on the market is not approved, it may be deemed an adulterated drug and subject to regulatory action.

FOOD ADDITIVE – In 1958, Congress amended the Act to require the pre-market clearance of additives whose safety was not generally recognized. The Act was also amended to deem food unsafe and adulterated if it contains an unapproved food additive. A food additive petition is the pre-clearance mechanism developed by the FDA for demonstrating that a food additive is safe for its intended use and has utility. If the FDA agrees with the petition, a regulation is published in the *Federal Register* and the additive is added to the *Code of Federal Regulations*.

GRAS SUBSTANCE – The Act also states that substances added to food that qualified scientists generally recognize as safe (GRAS) under the conditions of the intended use are not "food additives" and as such are exempt from pre-clearance approval. A GRAS substance is GRAS only for an intended purpose. For example, sodium aluminosilicate is GRAS as an anticaking agent. It has been purported to bind mycotoxins and prevent absorption from the intestinal tract, but is not GRAS for this use. A food substance also cannot be GRAS for the prevention, treatment, or mitigation of a disease. So, chondroitin sulfate cannot be GRAS to prevent or treat arthritis. For this use this ingredient would be a drug.

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UPDATE ON ANIMAL DIETARY SUPPLEMENTS (Continued)

CVM has used regulatory discretion and has not required food additive petitions for some substances that do not raise any safety concerns. In these cases, we ask the company to submit the information needed to be listed in the *AAFCO Official Publication*. AAFCO is an association that includes officials from all States, Canada, Costa Rica, and the Federal government who are responsible for enforcing the laws regulating the production, labeling, distribution, and/or sale of animal feeds. One of AAFCO's main goals is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards, definitions, and enforcement policies for animal feeds. In regulating animal feeds, CVM often works with AAFCO.

CVM has used regulatory discretion and has not required food additive petitions for some substances that do not raise any safety concerns.

AAFCO INGREDIENT DEFINITION – This ingredient definition process is done to conserve CVM resources, as food additive approval is time-consuming. CVM reviews the data to ensure the ingredient has utility and can be manufactured consistently to meet product specifications. Although ingredients used under regulatory discretion are still unapproved food additives, CVM agrees that it will not take regulatory action as long as the labeling is consistent with the accepted intended use, the labeling or advertising does not make drug claims, and that new data are not received that raise questions concerning safety or suitability.

DSHEA: Does Not Apply to Animal Supplements

When Congress enacted the DSHEA in 1994, it created a new category of substances and new regulatory scheme. The Act was amended to define a dietary supplement as a product intended to supplement the diet and that contains at least one or more of the following ingredients: a vitamin; a mineral; a herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of the previously mentioned ingredients. The main effect of DSHEA was to remove certain dietary ingredients from regulation as food additives, which require pre-market approval.

As mentioned above, in April 1996, CVM published a notice in the *Federal Register* outlining the reasons why FDA believes that DSHEA does not apply to substances for use in animals. This has been upheld in at least one court case. Thus, substances marketed as dietary supplements for humans still fall under the pre-DSHEA regulatory scheme when marketed for animals; that is, they are considered food, food additives, new animal drugs, or GRAS depending on the intended use. Most of these types of products on the market would be considered unapproved and unsafe food additives or new animal drugs based on current intended uses. While these products are technically in violation of the law, they are of low enforcement priority except for when public or animal health concerns arise.


Photo by Donna Ross

Supplements must be shown to be safe to the animals.

Why is CVM concerned about some dietary supplements marketed for animals?

CVM's concerns about certain dietary supplements focus on three main areas:

- Human food safety – supplements that are used in food animals, including horses that are used for food, must be shown to be safe for people who consume products from the animals. Without these data, there is no assurance that animal-derived food is safe.
- Animal safety – supplements must be shown to be safe to the animals. CVM and AAFCO have not received data showing that these products have actually been tested on animals to show that a particular level is appropriate or safe for the animals.
- Manufacturing quality – supplements must be shown to be manufactured to a consistent standard (for example, shown to contain a given amount of the ingredient).

In addition, some of these products are being marketed to treat or prevent disease. This moves them from the supplement category into the drug category. CVM is concerned that these products have not been shown to be safe and effective. And, some owners may be using these products in lieu of obtaining appropriate veterinary treatment for their animals.

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UPDATE ON ANIMAL DIETARY SUPPLEMENTS (Continued)

How can companies legally market animal dietary supplement products?

- They can check the list of approved food additives and GRAS substances in Title 21, Part 570 – 584 of the *Code of Federal Regulations.* (*http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfrv6_01.html*)
- They can check the list of ingredient definitions in the *Official Publication of the Association of American Feed Control Officials*.

If the ingredient they propose to use in their product is not on either list, they can submit a Food Additive Petition (*http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr571_01.html*) or the information needed to list the ingredient in the *AAFCO Official Publication*. Companies may visit the AAFCO web site (*http://www.aafco.org/*) and contact the appropriate AAFCO investigator. Another option would be for them to contact the control officials within their State. Contact information for the AAFCO investigators and State Feed Control Officials may be found on the AAFCO website.

If companies wish to market a new animal drug, they can submit a New Animal Drug Application (NADA) with CVM. Information on submitting NADAs may be found on the CVM Home Page at: *http://www.fda.gov/cvm/index/other/nadaappr.htm*.

Linda Grassie is the Deputy Director of CVM's Communications Staff.

SWINE MYCOPLASMAL WORKSHOP HELD

by LCDR Princess R. Campbell, DVM

The Division of Therapeutic Drugs for Food Animals, in the Office of New Animal Drug Evaluation, Center for Veterinary Medicine (CVM) held a Swine Mycoplasmal Workshop following the annual conference of the American Association for Swine Veterinarians (AASV), on March 6 and 7, 2002. The workshop was an information gathering forum with attendees from academia, the pharmaceutical industry, and veterinarians, and producers involved in swine production. Dr. Naba Das representing CVM presented the opening remarks followed by the President of the AASV, Dr. Lisa Tokach, who welcomed the FDA's efforts to involve outside experts in this collaborative effort. The two-day event featured speakers representing the top experts in the field. The speakers included Drs. Brad Thacker (Associate Professor in the Department of Veterinary Diagnostic & Production Animal Medicine, Iowa State University), Monte McCaw (Associate Professor of Swine Medicine, North Carolina State University, College of Veterinary Medicine), Eric Bush (epidemiologist, USDA Centers for Epidemiology and Animal Health), Kent Schwartz (Adjunct Assistant Professor of Department of Veterinary Diagnostic & Production Animal Medicine, Iowa State University), Chris Minion (Associate Professor in the Department of Veterinary Microbiology and Preventive Medicine, Iowa State University), Eileen Thacker (Assistant Professor in the Department of Veterinary Microbiology and Preventive Medicine, Iowa State University), Carlos Pijoan (Professor in the Department of Clinical & Population Sciences, University of Minnesota College of Veterinary Medicine), John Kolb (Boehringer Ingelheim Vetmedica, Inc.), John Korslund (hog producer and veterinarian, Indiana), Bill Hollis (swine practitioner, Illinois), and James Bradford (Pharmacia Animal Health).

Photo by Karen Kandra

Coordinators of the Swine Mycoplasmal Pneumonia workshop include Dr. Michelle Stull, Dr. Princess Campbell, Dr. Julia Punderson, Dr. Susan Storey, Dr. Janice Derr, Dr. Janis Messenheimer, Ms. Irma Carpenter, Dr. Cindy Burnsteel, Dr. Gillian Comyn, Dr. Nabil Anis, and Ms. Sharon Wanamaker.

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SWINE MYCOPLASMAL WORKSHOP HELD (Continued)

The discussion was confined to the effects of *Mycoplasma hyopneumoniae* in swine respiratory disease. The presentations reflected each speaker's area of expertise and views on this topic. Both Drs. Brad Thacker and Monte McCaw spoke on disease presentation on the farm, while Dr. Eric Bush spoke on the epidemiology of the disease from the NAHMS perspective. Dr. Eileen Thacker addressed the effect the organism had on the immune system and discussed a research induced infection model being developed at Iowa State University. Dr. John Kolb presented immunological considerations, Dr. Kent Schwartz addressed diagnosis from pathological signs, and Dr. Carlos Pijoan presented some new diagnostic tools for the disease. Dr. Chris Minion gave a very interesting talk on the genome sequencing for *M. hyopneumoniae*. Dr. John Korslund expounded on the economic effect of the disease. Dr. Bill Hollis gave a practitioner's perspective and Dr. James Bradford discussed the only drug approved for reduction in the severity of *M. hyopneumoniae* in the United States. He discussed all the data his company generated for substantial evidence of effectiveness for the approval.

Dr. Gillian Comyn was CVM's chairperson for the committee that produced the workshop. Dr. Janice Derr and Dr. Cindy Burnsteel of CVM gave presentations on Statistical Considerations and Substantial Evidence of Drug Effectiveness, respectively. Other committee members from CVM not previously mentioned that assisted in the preparation and actual presentation of the workshop are Dr. Nabil Anis, Dr. Princess Campbell, Ms. Irma Carpenter, Dr. Janis Messenheimer, Dr. Julia Punderson, Dr. Susan Storey, and Dr. Michelle Stull. The task remains for the Division of Therapeutic Drugs for Food Animals along with the Biometrics Team to assimilate the information and knowledge gained at this beneficial workshop with the goal of determining the information needed to support substantial evidence of effectiveness for a drug against *M. hyopneumoniae.*

Dr. Campbell is a veterinary medical officer in CVM's Division of Therapeutic Drugs for Food Animals.

CONTAMINATED ANIMAL FEED SUPPLEMENTS RECALLED

The Food and Drug Administration is announcing the voluntary recall of several animal feed products produced by Quali Tech Inc., a manufacturer based in Chaska, Minnesota. These products are protected minerals and mineral pre-mixes. These products are added to feed to provide cattle, pigs, and other livestock with necessary micronutrients.

This action was taken as a response to a joint investigation conducted by FDA, the Minnesota Department of Agriculture, Minnesota Department of Health, and Minnesota Pollution Control Agency. The operators of Quali Tech have been cooperating fully with the investigation and recall.

Quali Tech voluntarily recalled these products after laboratory data from several sources indicated that they contained dioxin. In addition, Quali Tech discontinued production of the contaminated products on February 28, and will not resume production until the source and cause of the dioxin can be identified.

Quali Tech discontinued production of the contaminated products on February 28, and will not resume production until the source and cause of the dioxin can be identified.

The only products subject to this recall are the Sea-Questra-Min and Carbosan products in their original packaging and any premix manufactured by Quali Tech containing these trace minerals. All other mixes containing these trace mineral products are not subject to the recall. For the purpose of this recall a premix is defined as "a uniform mixture of one or more micro-ingredients with diluent and/or carrier."

Dioxin is a broad family of chemical compounds that can be produced by a broad range of common human activities. It is released into the environment through burning of various materials including municipal waste, household trash, and fuels like oil, coal, or wood. The manufacture of paper and chemicals, as well as other industrial processes, can also produce dioxin.

Some amount of dioxin is naturally present in the environment and the above activities have caused background levels of dioxin to increase over time. Recently, the efforts of State and Federal environmental agencies have served to reduce these non-natural sources of dioxin. As a result, background levels of dioxin have begun to drop.

Addressing the problem of dioxin resulting from the use of the protected minerals and mineral premixes which are the subject of this recall is an important part of the overall effort to reduce dioxin levels in the food chain and environment.

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CONTAMINATED ANIMAL FEED SUPPLEMENTS RECALLED (Continued)

Dioxin compounds are commonly found, at very low levels, in food, particularly in foods containing meat or animal fat. FDA routinely surveys for dioxin as part of its' Market Basket survey. FDA continues to survey for dioxin in the Agency's Market Basket survey and through a directed survey of animal products.

Dioxin compounds are commonly found, at very low levels, in food, particularly in foods containing meat or animal fat.

The low levels of inclusion of the above mineral products in feed and the normal background levels would make it difficult if not impossible to determine whether these products would increase the low level of dioxin in food.

A complete list of recalled products is available by contacting Quali Tech spokesman Jim O'Neal at 612-766-8420.

PENTOBARBITAL IN DOG FOOD

by Linda Bren

This material appeared in the May/June 2002 issue of the ***FDA Consumer****.*

The low levels of sodium pentobarbital that dogs might receive through their food are unlikely to cause any health problems, according to an FDA study.

Pentobarbital is an anesthetizing drug used for dogs and other animals, such as horses and cattle. Because it is also widely used for humane euthanasia of dogs, cats and other animals, the most likely way that pentobarbital could get into dog food would be in rendered animal products. Rendered products come from a process that converts animal tissues to feed ingredients.

During the 1990s, the FDA's Center for Veterinary Medicine (CVM) received reports from veterinarians that pentobarbital seemed to be losing its effectiveness for anesthesia in dogs. Based on these reports, the Center decided to investigate the theory that the dogs were exposed to pentobarbital through dog food, and that this exposure was making them less responsive to pentobarbital when it was used as a drug.

Low levels of sodium pentobarbital that dogs might receive through their food are unlikely to cause any health problems.

CVM developed and used a sophisticated process to detect and quantify minute amounts of pentobarbital in dog food. Upon finding pentobarbital residues in some samples of dry dog food, CVM scientists conducted further tests that led them to conclude that dogs eating dry dog food are unlikely to have any adverse health effects from the low levels of pentobarbital found in the dog food samples tested.

During the 1990s, the FDA's Center for Veterinary Medicine (CVM) received reports from veterinarians that pentobarbital seemed to be losing its effectiveness for anesthesia in dogs.

CVM scientists also developed a test to detect dog and cat DNA in the protein of dog food. Since pentobarbital is used to euthanize dogs and cats at animal shelters, finding pentobarbital in rendered feed ingredients could suggest that pets were rendered and used in pet food. Test results indicated a complete absence of protein material that would have been derived from euthanized dogs or cats. As a result of their study, CVM scientists assume the source of the pentobarbital in dog food is cattle or horses euthanized and then rendered.

After finding that the low levels of pentobarbital that dogs might receive through food are unlikely to cause them any adverse health effects, FDA officials did not think that further research into the issue was necessary. CVM officials say they plan to publish the study findings in peer-reviewed scientific journals.

CVM's studies and a summary report of the results are available at *www.fda.gov/cvm/efoi/efoi.html*.

Linda Bren is a Writer-Editor with the ***FDA Consumer****.*

FDA CONTINUES WORK TO HELP PREVENT MAD COW DISEASE

by Linda Bren

This article appeared in the May/June 2002 issue of the ***FDA Consumer****.*

The prevention of bovine spongiform encephalopathy (BSE), commonly called mad cow disease, remains a top priority for the Food and Drug Administration and other government agencies.

BSE is a chronic, degenerative disorder affecting the central nervous system (brain and spinal cord) of cattle. A similar disorder in people, called variant Creutzfeldt-Jakob disease (vCJD), is believed to be caused by eating certain tissues from BSE-affected cattle. Both BSE and vCJD are fatal. Neither disease has ever been found in the United States.

A recent study by Harvard University gave high marks to government efforts to keep BSE out of the United States and to prevent its spread if it is ever found here.

The Harvard risk assessment study, released in November 2001, determined that the chances of BSE entering the United States and posing a risk to consumers and the agricultural industry are "extremely low." This three-year landmark study, commissioned by the U.S. Department of Agriculture (USDA), concluded that the joint efforts of the USDA and the FDA have been largely responsible for keeping BSE out of the country. Further, in the unlikely event that BSE would appear in U.S. cattle herds, the government's "multiple firewall" system would keep the disease from spreading so that it would eventually die out, according to the study. This firewall consists of a feed ban, import controls, and a surveillance program.

The Harvard study identified the feed ban as the linchpin of protection against the spread of BSE. Established in 1997 by the FDA's Center for Veterinary Medicine (CVM), the animal feed regulation prohibits feeding to cattle and other ruminants (such as sheep and goats) most mammalian protein, including a feed supplement known as meat-and-bone meal (MBM). Feeding cattle MBM that is contaminated with BSE is believed to be the most likely way for BSE to spread throughout a cattle herd.

Import controls are the critical safeguard against BSE being introduced into the United States. Since 1989, the USDA has banned the import of live ruminants and most ruminant products from the United Kingdom and other countries where BSE has been reported and from countries thought to be at high risk for BSE. The ban was expanded to include most of Europe in 1997 and Japan in 2001.

The third essential component of the firewall system of BSE prevention is the USDA's active surveillance program. The USDA has tested more than 21,000 cattle brains for BSE in the United States and Puerto Rico during the program's 11 years of operation and has found no evidence of BSE in American cattle.

Photo by Karen Kasmauski

Feeding cattle meat and bone meal contaminated with BSE is believed to be the most likely way for BSE to spread throughout a cattle herd.

"There are many places where one could intervene along the food chain to help prevent BSE," says Murray M. Lumpkin, M.D., the FDA's senior associate commissioner. "From the conception of the animal, through its raising and feeding, through the slaughtering and processing, to the marketplace, and to the preparation. Controlling all of these steps and the many people involved in them would be logistically impossible," says Lumpkin. But the Harvard study factored them all into their model to help determine which interventions have the greatest potential impact and what further actions the government could take to make the present very small risk of BSE in the United States even smaller. By using this simulation model and running dozens of hypothetical scenarios and many variations of each main scenario, the Harvard researchers concluded that compliance with the feed rule is one of the important keys to minimizing the risk of BSE.

Another study, released by the General Accounting Office (GAO) in February 2002, also noted the importance of feed rule compliance. The GAO study cited deficiencies in the FDA's oversight and enforcement of the feed rule.

"The FDA was well aware of these areas before the GAO report and was already making significant progress in addressing areas of concern so that we could strengthen further our public health protections," says Stephen Sundlof, D.V.M., Ph.D., director of the FDA's CVM.

The FDA's feed ban compliance and education efforts include a rigorous program to inspect establishments involved in the production of animal feed. With state feed inspectors, whom the FDA has under contract to help with these inspections, the FDA has completed initial inspections of all known animal renderers and commercial feed mills. Only about 4 percent of these entities were out of compliance with the feed rule.

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FDA CONTINUES WORK TO HELP PREVENT MAD COW DISEASE (Cont.)

"With an additional $13 million allocated to the FDA this fiscal year to oversee and enforce the feed regulation, the agency will hire 115 more people to expand BSE inspection efforts," says Sundlof. "This means we'll have an ongoing program to inspect and re-inspect every establishment that handles the prohibited material," he says. "We'll also increase our inspection coverage at the borders to help keep potentially BSE-tainted materials from entering our country."

"With an additional $13 million allocated to the FDA this fiscal year to oversee and enforce the feed regulation, the agency will hire 115 more people to expand BSE inspection efforts," says Sundlof.

The FDA has also implemented a new inspection tracking database, allowing the agency to record inspection results and track compliance more effectively.

Along with escalating its inspection program, the FDA plans to increase its sampling of domestic and imported feed to test for the presence of the prohibited protein. After holding a public meeting in Kansas City, Missouri, in October 2001, CVM is now reevaluating its feed rule to determine how to strengthen it to further reduce the risk of BSE. The Center will be issuing an advance notice of proposed rulemaking in the near future regarding possible changes in the feed ban rule.

"An important message from both the Harvard and the GAO studies is that we still need to be very vigilant, now and for a long time to come," says Lumpkin. "We must continue to work hard to make a good system even better. The FDA and the states will continue their aggressive inspection program and will continue to work closely with all components of the cattle and feed communities to help make a, thankfully, low public health risk even lower."

The latest information on BSE and the full report of the Harvard risk assessment study are available at *www.fda.gov/oc/opacom/hottopics/bse.html*.

Linda Bren is a Writer-Editor with the ***FDA Consumer***.

RUMINANT FEED (BSE) ENFORCEMENT ACTIVITIES

To help prevent the establishment and amplification of BSE through feed in the United States, FDA implemented a final rule that prohibits the use of most mammalian protein in feeds for ruminant animals. This rule, Title 21 Part 589.2000 of the *Code of Federal Regulations*, became effective on August 4, 1997. To date, active monitoring by the U.S. Department of Agriculture (USDA) has found *no cases* of bovine spongiform encephalopathy (BSE) in U.S. cattle. This is an update on FDA enforcement activities regarding the ruminant feed (BSE) regulation.

FDA's enforcement plan for the ruminant feed regulation includes education, as well as inspections, with FDA taking compliance actions for intentional or repeated noncompliance. FDA's Center for Veterinary Medicine (CVM) has assembled data from the inspections that have been conducted AND whose final inspection report has been submitted to CVM (i.e., "inspected/reported") as of March 11, 2002. There is a lag time between the completion of an inspection and the submission of a final inspection report to CVM. This lag period includes the time required to conduct quality assurance on the report and to evaluate the findings before a final report is submitted.

As of March 11, CVM had received inspection reports covering inspections (both initial inspections and re-inspections) of 10,458 different firms. The majority of these inspections (around 80%) were conducted by State officials under contract to FDA and the remainder by FDA officials.

Various segments of the feed industry had different levels of compliance with this feed ban regulation. The results to date are reported here both by "segment of industry" and "in total".

RENDERERS

(These firms are the first to handle rendered protein and send materials to feed mills and ruminant feeders.)

- **NUMBER OF FIRMS WHOSE INITIAL INSPECTION HAS BEEN REPORTED TO CVM** – 239
- **NUMBER OF FIRMS HANDLING MATERIALS PROHIBITED FOR USE IN RUMINANT FEED** – 171 (72% of those firms inspected/reported).
- Of the 171 renderers handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 4 (2%) had products that were not labeled as required
  - 3 (2%) did not have adequate systems to prevent comingling
  - 1 (1%) did not adequately follow record keeping regulations

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RUMINANT FEED (BSE) ENFORCEMENT ACTIVITIES (Continued)

– 4 (2%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

FDA LICENSED FEED MILLS

(FDA licenses these mills to produce medicated feed products. This licensing has nothing to do with handling prohibited materials under the feed ban rule: 21 CFR 589.2000. A license from FDA is not required to handle materials prohibited under 21 CFR 589.2000.)


Photo by Karen Kandra

- **NUMBER OF FIRMS WHOSE INITIAL INSPECTION HAS BEEN REPORTED TO CVM** – 1,203
- **NUMBER OF FIRMS HANDLING MATERIALS PROHIBITED FOR USE IN RUMINANT FEED** – 370 (31% of those firms inspected/reported)

A license from FDA is not required to handle materials prohibited under 21 CFR 589.2000.

- Of the 370 licensed feed mills handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 8 (2%) had products that were not labeled as required
  - 2 (1%) did not have adequate systems to prevent co-mingling
  - 3 (1%) did not adequately follow record keeping regulations
  - 10 (3%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

FEED MILLS NOT LICENSED BY FDA

- **NUMBER OF FIRMS WHOSE INITIAL INSPECTION HAS BEEN REPORTED TO CVM** – 4,867
- **NUMBER OF FIRMS HANDLING MATERIALS PROHIBITED FOR USE IN RUMINANT FEED** – 1,224 (25% of those firms inspected/reported)
- Of the 1,224 feed mills not licensed by FDA handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 55 (4%) had products that were not labeled as required
  - 28 (2%) did not have adequate systems to prevent co-mingling
  - 28 (2%) did not adequately follow record keeping regulations
  - 86 (7%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

OTHER FIRMS INSPECTED

(Examples of such firms include: ruminant feeders, on-farm mixers, protein blenders, and distributors.)

- **NUMBER OF FIRMS WHOSE INITIAL INSPECTION HAS BEEN REPORTED TO CVM** – 4,710
- **NUMBER OF FIRMS HANDLING MATERIALS PROHIBITED FOR USE IN RUMINANT FEED** – 565 (12% of those firms inspected/reported)
- Of the 565 such firms handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 17 (3%) had products that were not labeled as required
  - 2 (less than 1%) did not have adequate systems to prevent co-mingling
  - 7 (1%) did not adequately follow record keeping regulations
  - 25 (4%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

TOTALS (as of March 11, 2002)

- **NUMBER OF FIRMS WHOSE INITIAL INSPECTION HAS BEEN REPORTED TO CVM** – 10,458
- **NUMBER OF FIRMS HANDLING MATERIALS PROHIBITED FOR USE IN RUMINANT FEED** – 2,153 (21% of those firms inspected/reported)
- Of the 2,153 firms handling prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):
  - 77 (4%) had products that were not labeled as required
  - 34 (2%) did not have adequate systems to prevent co-mingling
  - 35 (2%) did not adequately follow record keeping regulations
  - 113 (5%) firms were found to be out of compliance

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. . . (BSE) ENFORCEMENT ACTIVITIES (Continued)

RE-INSPECTIONS

When firms are found to be out of compliance with the feed ban rule, FDA lists them for a re-inspection. As of March 11, 2002, reports of 2,185 re-inspections have been submitted to CVM. On re-inspection of these 2,185 firms, 32 (1%) were found still to be out of compliance with this rule. Firms previously found to be not in compliance have corrected problems through a variety of ways, including further training of employees about the rule, developing systems to prevent co-mingling, re-labeling their products properly, and adhering to record keeping regulations. Other firms have achieved compliance by eliminating prohibited materials from their operations.

DATABASE CHANGE

After March 11, 2002, FDA discontinued the database that was used to compile these numbers. The Agency is starting a new database on April 15, 2002, and future updates on BSE enforcement will draw from it.

A NEW LOOK!

The *FDA Veterinarian* has a new look! Since being introduced in September, 1986, the newsletter has been a black and white publication with three columns of text. We hope you like this fresh, updated format. We want it to be inviting and easy to read while providing a valuable source of CVM's current news and information concerning regulations governing animal drugs and feeds. We invite your comments.

COUNTER-TERRORISM TRACKING SYSTEM LAUNCHED

by Karen Oliver

The Counter-terrorism (CT) Programs Staff launched the intranet-based Counter-terrorism Tracking System (CTTS). The March 11, 2002 launch of the CTTS occurred six months after the worst terrorist attack in our country's history.

The events of September 11, 2002, the subsequent anthrax outbreak, and the deployment of U.S. troops in the war on terrorism have resulted in a rapid expansion of Food and Drug Administration's (FDA) counter-terrorism efforts. In the course of meeting its counter-terrorism mandate, FDA works with many agencies of Federal, State, and local governments, consumers, industry, academia, and foreign governments. These wide-ranging activities have been coordinated centrally since the latter part of 2000 by the Counter-terrorism (CT) Programs Staff, Office of Science Coordination and Communication (OSCC), Office of the Commissioner (OC). Working with representatives from Centers and Offices throughout FDA, the CT Programs Staff serves as the FDA point of contact for all counter-terrorism activities both inside and outside the agency.

In an effort to enhance timely communication and inter-agency collaboration and cooperation, the CTTS was designed to be a single source for capturing all of FDA's CT activities including workload, accomplishments, planning, archiving documents, and generating reports. Further, the CTTS will guide budget planning in the coming years. Due to the urgent need to coordinate and track counter-terrorism efforts, the current system is a pilot tracking system that can be accessed by authorized users across the agency. It will be migrated to a permanent system over the next year.

There are three different permission levels for authorized users of the tracking system. The different permission levels are viewers, users, and administrators. Viewers have permission to view data, query the database, and generate reports. Users have permission to input and view data, query the database, and generate reports. Administrators have permission to input data, query the database, generate reports, and modify the system. Each of the five Centers within the FDA (CDER, CBER, CDRH, CFSAN, CVM) as well as the OC and National Center for Toxicological Research (NCTR) have designated users and viewers of the system.

The Counter-terrorism Programs Staff, under the direction of Dr. Andrea Meyerhoff, has the lead responsibility for CTTS. Mary Dempsey and Karen Oliver, the Health Science Administrators within this office, have administrative permission. They are the appropriate contacts for problems, questions, suggestions, and comments. The Counter-terrorism Programs Staff is located in the Parklawn Building, and can be reached by telephone 301-827-4067, fax 301-827-5671, and e-mail Counterterrorism@oc.fda.gov.

Karen Oliver is a Health Science Administrator in the Office of Counter-terrorism Programs, Office of the Commissioner.

FROM FDA'S OFFICE OF CRIMINAL INVESTIGATIONS

The FDA's Office of Criminal Investigations (OCI), Chicago Field Office initiated an investigation into Gerald L. HERRELL and his business, B & H VEAL, as a result of a referral from the FDA Minneapolis District Office. Allegations included that HERRELL/B & H VEAL caused the feeding of the unapproved new animal drug nitrofurazone (NFZ) to veal calves intended for human food. In addition, HERRELL and B & H VEAL allegedly sold veal calves fed NFZ to a meat packing company for slaughter as human food. The sale of animals fed NFZ for human food is a violation of the Federal Food, Drug, and Cosmetic Act (FD&CA).

Special agents of the FDA's Office of Criminal Investigations, the U.S. Department of Agriculture, Office of Inspector General, Office of Investigations (USDA/OIG/OI), and CSOs from the FDA, Minneapolis District Office, executed federal search warrants at B & H VEAL and at HERRELL's residence, where empty NFZ packets and NFZ labeling were seized.

On March 14, 2001, in U.S. District Court, Milwaukee, WI, HERRELL was convicted of violating Title 21, U.S.C., § 331(a) and 333(a)(1) for his introduction into interstate commerce of an adulterated food, namely veal calves for human consumption that had been treated with NFZ, after the January 1992 NFZ ban. The District Court Judge admonished HERRELL for putting the human food supply at risk and sentenced HERRELL to one year probation and ordered HERRELL to pay a $3,000.00 fine.

On October 23, 2001, FLAV-O-RICH DAIRY entered into an Agreement for Pre-Trial Diversion with the U.S. Attorney's Office for the Western District of Virginia in Roanoke, VA. The agreement holds criminal charges regarding the introduction of adulterated milk into interstate commerce in abeyance, pending successful completion of a twelve-month period of supervised probation. The agreement also requires FLAV-O-RICH to implement an intensive monitoring and education program to ensure that antibiotic tainted milk is detected and destroyed.


Photo by Karen Kandra

The sale of animals fed NFZ for human food is a violation of the Federal Food, Drug, and Cosmetic Act.

This case originated when it was determined that the FLAV-O-RICH plant in Bristol, VA was not properly testing for the presence of antibiotics in bulk milk tanker trucks that delivered raw milk for processing. As a result, 2% and whole milk products containing antibiotics were shipped in interstate commerce. Random sampling conducted by the Tennessee Department of Agriculture detected the presence of antibiotics in milk packaged by FLAV-O-RICH. The company initiated a voluntary recall of 2% milk products, but failed to recall all of the adulterated whole milk products.

CONSENT DECREE IN TISSUE RESIDUE CASE

On December 18, 2001, in the United States District Court for the Northern District of Ohio, Eastern Division, a Consent Decree of Permanent Injunction was signed by Martin D. Yoder, doing business as Martin D. Yoder Livestock. Mr. Yoder was enjoined from introducing adulterated food into interstate commerce because he sold for slaughter cattle that contained unsafe new animal drugs.

During the period January 1998 to February 2001, Mr. Yoder was responsible for delivering to slaughter 38 animals with excessive levels of new animal drugs in their edible tissues. Some of the drugs found included flunixin meglumine, tetracycline, penicillin, streptomycin, sulfadimethoxine, and gentamicin sulfate. Under the consent decree, Mr. Yoder must establish and implement a system that identifies each animal that he purchases for delivery to slaughter with an appropriate tag number. He further must obtain signed written statements from the sellers of the animals as to whether the animal is "medicated". In addition, he must establish and implement a written record-keeping system documenting any drugs that are administered to the animals, when administered and by whom, the withdrawal period of each drug, and the date the animal is sold or delivered for sale or slaughter. These records must be maintained for at least two years.

REGULATORY ACTIVITIES

by Karen A. Kandra

The following firms/individuals received warning letters for offering animals for slaughter that contained illegal drug residues:

- Loren A. Duescher, Co-Owner, Duescher Hilltop Jerseys, Kewaunee, WI
- Richard L. Hayes, Owner, Richard Hayes Cattle Company, Hereford, TX
- Case B. Vlot, Owner, Case Vlot Cattle, Chowchilla, CA
- Walter DeJong, Owner, DeJong Dairy, Monroe, WA
- Greg T. Troost, Owner, T & T Cattle, Parma, ID
- George Kasbergen, Co-Owner, Spring Grove Dairy, Mira Loma, CA
- Cornell Kasbergen, Co-Owner, Spring Grove Dairy, Tulare, CA
- Wayne L. Jones, President, Jones Brothers Dairy, LLC, Mount Horeb, WI

These violations involved illegal residues of neomycin in a dairy cow, multiple residues of tilmicosin, penicillin, sulfadimethoxine, and gentamicin in steers, gentamicin in a calf, sulfamethazine in a bob veal calf, penicillin in a culled dairy cow, penicillin in a cow, and sulfadimethoxine in a dairy cow.

A warning letter was issued to John Tyson, Chairman of the Board and CEO, Tyson Foods, Springdale, AR, for violations related to 21 CFR Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE).

Violations included failure to label the organ slurry product with the required cautionary statement "Do Not Feed to Cattle or Other Ruminants". The FDA suggests the statement distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by a purchaser.

Doug Robertson, Owner, Equine Serum Products, Inc., Lamar, MO, received a warning letter for marketing and distributing the product "Cycle Pro Pregnant Mare Serum" without an approved New Animal Drug Application.

NEW ANIMAL DRUG APPROVALS

Company	*Generic and (Brand) Names*	*Indications*	*Routes/Remarks*
Schering-Plough Animal Health Corp. (NADA 141-192)	Zeranol (Ralgro® LA)	Cattle. For increased rate of weight gain.	**SUBCUTANEOUS**—The NADA provides for an ear implant containing 138 mg zeranol used for increased rate of weight gain for up to 210 days in pasture cattle (slaughter, stocker, and feeder steers, and heifers). Additionally an ADI of 0.00125 mg per kilogram body weight per day for total residues of zeranol is created. *Federal Register* 02/14/02
Boehringer Ingelheim Vetmedica, Inc. (NADA 141-180)	Albuterol Sulfate (Torpex™) Rx	Horses. For the relief of bronchospasm and bronchoconstriction.	**INTRANASAL**—The NADA provides for an aerosol for the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction. Not for use in horses intended for food. *Federal Register* 02/15/02

SUPPLEMENTAL NEW ANIMAL DRUG APPROVALS

Company	*Generic and (Brand) Names*	*Indications*	*Routes/Remarks*
Pfizer, Inc. (NADA 141-111)	Carprofen (Rimadyl® Chewable Tablets) Rx	Dogs. For the relief of pain and inflammation associated with osteo-arthritis.	**ORAL**—The supplement provides for a once daily, 2-milligram per pound dosage of carprofen, by oral chewable tablet. *Federal Register* 02/14/02

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SUPPLEMENTAL NEW ANIMAL DRUG APPROVALS (Continued)

Company	Generic and (Brand) Names	Indications	Routes/Remarks
Alpharma, Inc. (NADA 141-085)	Bacitracin Methylene Disalicylate, Zoalene BMD® Zoamix®	Chickens. For the management of coccidiosis and necrotic enteritis.	**MEDICATED FEED**—The supplemental NADA provides for using approved single-ingredient bacitracin methylene disalicylate and zoalene Type A medicated articles to make two-way combination drug Type C medicated feeds used for the management of necrotic enteritis and coccidiosis in replacement and broiler chickens. *Federal Register* 02/14/02
Schering-Plough Animal Health Corp. (NADA 141-063)	Florfenicol (Nuflor®)	Cattle. For treatment of Bovine Respiratory Disease and foot rot.	**SUBCUTANEOUS**—The supplement provides for changing a pathogenic genus from Pasteurella to Mannheimia on labeling of florfenicol injectable solution. *Federal Register* 02/14/02
Boehringer Ingelheim Vetmedica, Inc. (NADA 139-472)	Tiamulin (Denagard®)	Swine. For the control of porcine proliferative enteropathies in swine.	**MEDICATED FEED**—The supplement provides for use of tiamulin Type A medicated articles to make Type B and Type C medicated feeds used for control of porcine proliferative enteropathies (ileitis) in swine. *Federal Register* 02/19/02
Pharmacia and Upjohn Co. (NADA 111-636)	Lincomycin Hydrochloride (Lincomix Soluble Powder)	Swine. For the treatment of swine dysentery.	**ORAL**—The supplement provides for use of lincomycin hydrochloride soluble powder in the drinking water of swine weighing greater than 250 pounds. The supplement provides for the removal of the label limitation "not for use in swine weighing more than 250 pounds" and replacement of it with "the safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding". *Federal Register* 04/10/02

ABBREVIATED NEW ANIMAL DRUG APPROVALS

Company	Generic and (Brand) Names	Indications	Routes/Remarks
First Priority, Inc. (ANADA 200-301)	Chlorhexidine Acetate (Privasan™ Antiseptic Ointment)	Dogs, cats, horses. For treatment of surface wounds.	**TOPICAL**—The ANADA is a generic copy of Ft. Dodge Animal Health's Nolvasan antiseptic ointment approved under NADA 9-872. *Federal Register* 02/27/02
Blue Ridge Pharmaceuticals, Inc. (ANADA 200-270)	Ivermectin (Iverhart™ Tablets) Rx	Dogs. For prevention of heartworm disease.	**ORAL**—The ANADA is a generic copy of Merial Ltd.'s Heartgard Tablets approved under NADA 138-412. *Federal Register* 03/13/02

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ABBREVIATED NEW ANIMAL DRUG APPROVALS (Continued)

Company	Generic and (Brand) Names	Indications	Routes/Remarks
Vetrepharm Research, Inc. (ANADA 200-257)	Ketamine Hydrochloride Rx	Cats and subhuman primates. For restraint.	**INTRAMUSCULAR**—The ANADA provides for veterinary prescription use of an injectable solution of Ketamine HCL in cats and subhuman primates for restraint or in cats as the sole anesthetic agent in diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation. In addition Vetrepharm Research, Inc. is listed for the first time as the sponsor of an approved animal drug application. *Federal Register* 04/10/02

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPROVALS

Company	Generic and (Brand) Names	Indications	Routes/Remarks
Phoenix Scientific, Inc. (ANADA 200-124)	Flunixin Meglumine Rx	Beef and Dairy cattle. For control of fever and inflammation.	**INTRAVENOUS**—The supplemental ANADA provides for use of flunixin meglumine solution by intravenous injection for control of fever and inflammation in beef cattle and non-lactating dairy cattle. *Federal Register* 03/01/02
Phoenix Scientific, Inc. (ANADA 200-123)	Oxytetracycline (Maxim 200)	Cattle. For treatment of various bacterial diseases.	**SUBCUTANEOUS**—The supplemental ANADA provides for subcutaneous administration of OTC injectable solution in beef cattle, non-lactating dairy cattle, and calves, including pre-ruminating (veal) calves. *Federal Register* 03/19/02

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