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FDA Proposes Tighter Feed Ban to Prevent BSE

The Food and Drug Administration on October 6 proposed banning certain high-risk cattle material from all animal feeds, including pet food, to strengthen safeguards against bovine spongiform encephalopathy (BSE).

The proposed rule would add requirements to the 1997 feed rule, which bans most mammalian protein from use in feed for cattle and other ruminants. The rule proposes to eliminate 90 percent of all potentially infectious material from the feed supply.

The proposed rule would ban from all feed:

- Brains and spinal cord of cattle 30 months old or older.
- Brains and spinal cord of cattle not inspected and passed for human consumption.
- The entire carcass of cattle not inspected and passed for human consumption if the brain and spinal cord has not been removed.
- Tallow, if it is derived from the material that would be prohibited under this rule and contains more than 0.15 percent insoluble impurities.
- Mechanically separated beef derived from material that would be prohibited under this rule.

The proposed rule is designed to prevent any possible "leakage" of potential infectious material into cattle feed. The 1997 rule prohibits the use of most mammalian protein in feed for cattle and other ruminants, but allows the use of the protein, including the brain and spinal cord, in feeds for swine and poultry. The proposed rule would prevent the highest risk material from entering any part of the feed chain. Therefore, it is unlikely to find its way, by accident or deliberately, into feed for cattle.

FDA believes that the 1997 feed rule has been extremely effective. However, with the discovery of BSE in the United States, FDA officials decided to further strengthen the measures already in place.

Earlier position

In January 2004, FDA announced it was planning to take other steps to address the BSE situation, including banning the use of poultry litter, plate waste, and blood and blood products in cattle feed. FDA also said it was planning to

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U.S. Completes Investigation of BSE-Infected Cow in Texas

After investigating the report of a cow in Texas found in June to be infected with bovine spongiform encephalopathy (BSE), Federal officials reported that appropriate safeguards were in place and working, which prevented the further spread of the disease.

The infected animal was destroyed and did not get into the food, feed, or pet food supply, officials said. This was the first native born cow in the United States found to be infected with BSE.

The U.S. Department of Agriculture (USDA), which is in charge of tracking and preventing animal disease, reported the infected animal to the Food and Drug Administration (FDA) on June 24, 2005. To determine if any other animals or offspring of animals from the herd of the infected animal were infected with BSE, USDA tracked down as many as it could of the 200 adult and 213 calves associated with the infected animals. No additional BSE was found.

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PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

FDA Proposes Tighter Feed Ban to Prevent BSE *(Continued)*

require dedicated facilities for handling feed and feed ingredients for ruminant animals.

However, after further consideration, including recommendations from an International Review team convened by USDA to assess the controls in place to prevent the spread of BSE, FDA concluded that banning plate waste, poultry litter, and blood and requiring dedicated facilities are not needed if high risk tissues are excluded from animal feed channels. By keeping the high-risk material out of all feed, none could be spilled into poultry litter, so that route would be blocked. BSE rules by USDA's Food Safety Inspection Service (FSIS) and FDA's Center for Food Safety and Applied Nutrition (CFSAN) address food safety by keeping potentially infectious material out of food, thus eliminating plate waste as a possible vehicle. Blood has not been shown to be a vehicle for BSE infection, so it was not included in the proposed rule. (In addition, international standard setting agencies believe blood products are as safe for use in animal feed as milk and milk products.) And separate, dedicated facilities would not be needed because the proposed rule would eliminate the high-risk material, thus eliminating the concern for contamination of cattle feed.

The proposal would cost the industry approximately $14 million to $24 million per year, annualized over a 10-year period. This estimate includes the cost of complying and the cost of substitute feeds.

The comment period for the rule closes December 20, 2005. Comments should be identified by Docket Number 2002N-0273, or RIM 0901-AF46. They can be submitted electronically through the Federal eRulemaking Portal: *http://www.regulations.gov,* or through the Agency website at *http://www.fda.gov/dockets/ecomments*.

Written comments can be submitted via fax at 301-827-6870; or mailed, hand delivered, or sent by courier as a paper copy, on a disk or a CD-ROM, to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, 20852. The comments may be posted publicly on FDA's dockets, including any personal information submitted with the comment.

U.S. Completes Investigation of BSE-Infected Cow in Texas *(Continued)*

Meanwhile, FDA officials, along with the Texas Animal Health Commission and the Texas Feed and Fertilizer Control Service, investigated the sources of feed given the infected animal to see if they could discover the source of the infectious material. In addition, the Federal and State authorities tracked the disposition of all animals associated with the infected cow to be sure the provisions of FDA's 1997 BSE rule were followed.

The investigation concluded that the 1997 feed rule, which prohibits the feeding of most mammalian protein to cattle and other ruminants, was being followed. At an August 30 press teleconference, Dr. Stephen Sundlof, director of FDA's Center for Veterinary Medicine, said that the investigation revealed that all companies involved were complying with the 1997 BSE feed rule.

FDA's investigation identified 21 feed products used on the farm. FDA and State investigators went to three retail feed stores that had supplied the feed, and to nine feed mills that made the feed. According to Dr. Sundlof, "This investigation found no feed products used on the farm since 1997 had been formulated to contain prohibited mammalian protein."

According to Dr. Sundlof, the infected cow, which was approximately 12 years old, had "very likely consumed contaminated feed well before 1997…."

The animals associated with the infected cow were properly handled during slaughter and disposition under the feed rule, Dr. Sundlof said: "The investigation into the disposition of herdmates from this farm involved visits to nine slaughter plants and eight rendering plants. The investigation found that all rendering plants were operating in compliance with the BSE ruminant feed rule. A review of the inspection history of each of these rendering firms found no violation."

On October 6, FDA announced proposed rules to further reduce the risk of BSE in the United States. The proposal would ban certain high risk cattle material from use in all feeds and pet foods. (See related story on page 1, "FDA Proposes Tighter Feed Ban to Prevent BSE.")

FDA VETERINARIAN

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CVM Approves Drug for Catfish; First New Antimicrobial for Finfish in 20 Years

The Center for Veterinary Medicine (CVM) in October approved an antimicrobial drug for use in treating catfish, marking the first new antimicrobial approved in over two decades for use in a finfish species.

The drug sponsor is Schering-Plough Animal Health Corporation, Union, N.J. The product, Aquaflor® Type A Medicated Article (florfenicol), an antibiotic, was approved as a "Veterinary Feed Directive" (VFD) product for the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*.

Enteric septicemia of catfish (ESC) is a serious disease for catfish producers. It has been reported that ESC accounts for 30-47 percent of all cases submitted to fish diagnostic laboratories in the southeastern United States. The disease causes high morbidity and mortality among catfish in infected ponds. Economic losses from ESC are reported to cost the catfish industry millions of dollars each year.

Channel catfish (*Ictalurus punctatus*) are the species most susceptible to infection with ESC, although the disease has been reported in other members of the catfish family Ictuluridae. In addition there are also occasional reports in other species of finfish. Affected fish are sometimes observed swimming in tight circles (related to the presence of intracranial bacteria), and frequently have multiple small red and white ulcers on their skin. Severely affected fish may also exhibit exophthalmia (bulging eyes), and erosions between the eyes, sometimes referred to as "hole-in-head" condition.

Second Veterinary Feed Directive (VFD) Drug Since 1996

Aquaflor® is only the second drug CVM has approved as a VFD. The first was Elanco Animal Health's Pulmotil 90 (tilmicosin phosphate), approved in 1996 as an antimicrobial for control of swine respiratory diseases.

The Animal Drug Availability Act (ADAA) of 1996 established a new category of drugs in addition to those available over-the-counter (OTC) and by prescription. This category of drugs was specifically designed for certain medicated feeds. Prior to ADAA, there were difficulties associated with regulating medicated feeds using only the OTC or prescription categories alone. For more information about the VFD provisions of ADAA see CVM's Guidance for Industry #120, "Veterinary Feed Directive Regulation," at *http://www.fda.gov/cvm/Guidance/guide120.doc*.

***Aquaflor® Type A Medicated Article (florfenicol), an antibiotic, was approved as a "Veterinary Feed Directive" (VFD) product for the control of mortality due to enteric septicemia of catfish associated with* Edwardsiella ictaluri.**

Since Aquaflor® was approved as a VFD drug, it is only available upon the order of a licensed veterinarian. In order to obtain a VFD order from a veterinarian several conditions must be met. The order must be made in the context of a valid veterinarian-client-patient relationship. In other words, the veterinarian must have firsthand knowledge of the fish experiencing the disease condition and be available for follow up, such as in the case of adverse reactions. Copies of the VFD order will then go to a licensed feed mill for preparation and distribution of the medicated feed. A second copy of the VFD order will be kept on the premises by the client to be followed in administering the medicated feed to ponds of affected fish. A third copy of the VFD order will be retained by the veterinarian. Industry guidance "Veterinary Feed Directive Regulation" (Guidance for Industry #120) (*http://www.fda.gov/cvm/Guidance/guide120.doc*) describes in detail the responsibilities of the veterinarian, producer, and the feed mill.

It is important to note that VFD orders can be written only for a single site and contain an expiration date, after which further disease diagnosis must be made prior to writing another order. It is acceptable to write an order for the treatment of multiple ponds located in a single location. It is expected that all medicated feed will be utilized for a particular disease outbreak and that medicated feed will not be stored for future use.

FDA/CVM believes that such control of VFD drugs is critical to reducing unnecessary use of such drugs in animals and to slowing or preventing any potential for the development of bacterial resistance to antimicrobial drugs. Safety concerns relating to difficulty of diagnosis of disease conditions, high toxicity, or other reasons may also dictate that the use of a medicated feed be limited to use by order and under the supervision of a licensed veterinarian.

First Drug Designated Under the MUMS Act

Aquaflor® is the first drug to be designated under the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. Aquaflor® was designated based on the fact that catfish are a minor species. Designation occurs prior to submission of a new animal drug application and provides certain benefits to drug sponsors to encourage them to develop drugs for minor uses and minor species.

The MUMS Act—patterned after the well known and successful human

(Continued, next page)

CVM Releases 2003 NARMS Retail Meat Annual Report

The Center for Veterinary Medicine (CVM) has recently published its 2003 National Antimicrobial Resistance Monitoring System (NARMS) Retail Meat Annual Report, which reports on the prevalence of antimicrobial resistance among zoonotic foodborne bacteria.

According to the report, which was posted on CVM's website (*http://www.fda.gov/cvm/coversheet2003.htm*) September 30, the goal of the retail meat surveillance program is to determine the prevalence of antimicrobial resistance among foodborne bacteria that are pathogenic to humans, and among commensal organisms, which are not pathogenic to humans, but can pass resistance traits to bacteria that are. In particular, the survey looked for resistance in *Salmonella*, *Campylobacter*, *Enterococcus* and *E. coli*.

The NARMS retail meat surveillance program is a collaboration that includes the Food and Drug Administration, the Centers for Disease Control and Prevention (CDC) and 10 participating FoodNet laboratories in the United States.

FoodNet is a component of the CDC's Emerging Infections Program, which CDC created as an active surveillance program to help public health officials understand the epidemiology of foodborne diseases in the United States.

The report states that retail meats are a point of potential bacterial exposure to consumers, and are therefore of public health importance. The information generated from the retail meat program will be compared with data from the U.S. Department of Agriculture and the CDC components of NARMS to ascertain the prevalence of *Salmonella* serotypes and the antimicrobial resistant patterns of the four bacterial species throughout the food production environment.

The data from the retail meat program will establish a "reference point" to allow scientists to analyze trends of antimicrobial susceptibility and resistance phenotypes among foodborne human pathogens and selected commensal

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CVM Approves Drug for Catfish... *(Continued)*

Orphan Drug Act of 1983 – is another provision of ADAA. The MUMS Act was a response to the lack of economic incentive for drug sponsors to develop drugs for minor species and for minor uses (rare diseases) in major species. Minor species are defined as any animal other than dogs, cats, horses, swine, cattle, chickens, or turkeys.

The MUMS Act contains three key provisions to assist in the development of drugs for minor uses and minor species: designation, conditional approval, indexing. For more information on these provisions and about the MUMS Act go to CVM's website at *http://www.fda.gov/cvm/minortoc.htm*.

Designation of a new animal drug, prior to its approval, provides incentives to the drug sponsor to continue its development and to seek eventual approval. The MUMS Act makes the drug eligible for grants to support safety and effectiveness testing.

Additionally, sponsors who gain approval for designated new animal drugs will be granted seven years of exclusive marketing rights, which means the sponsor will face no competition in the marketplace for the approved use of the drug for that time period.

Evaluated for Antimicrobial Resistance Risk Management Strategy

Aquaflor® is among the first new antimicrobial approvals in food-producing animals that have been evaluated under CVM's Guidance for Industry #152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern" (*http://www.fda.gov/cvm/Documents/fguide152.doc*).

The safe use of antimicrobials in the production of food-producing animals is an important public health issue. The Guidance for Industry about evaluating the safety of antimicrobial new animal drugs (#152) provides a regulatory pathway sponsors can use to show how a new antimicrobial drug can be used in a food-producing animal without endangering public health. CVM has determined that antimicrobial resistance risk management strategies (as described in the Guidance for Industry) in place for Aquaflor® are appropriate for its proposed conditions of use in pond culture systems.

New Horizon for Aquaculture Drugs

The approval of Aquaflor® signals a new horizon for drugs for finfish and minor species. Previously, treatments for the diseases of these species have languished for lack of economic incentives to encourage drug sponsors to pursue their approval. The hurdles have been high and the path uncertain. Now, under the provisions of ADAA and MUMS together with the guidance for addressing key issues such as antimicrobial resistance, drug sponsors have a clearer path for pursuing these approvals. The Center is pleased that sponsors are pursuing approvals for drugs to treat important diseases in minor species and for minor uses (rare diseases) in major species.

Taking Care of Pets During a Disaster or Emergency

To be sure you can properly take care of your pet during an emergency, like Hurricane Katrina, or during an evacuation, you must plan ahead.

If you have to leave your home, take your pet with you if at all possible. You are the best person to take care of your pet. Also, as the American Veterinary Medical Association (AVMA) pointed out in a brochure it issued about preparing for a disaster, if the situation is dangerous for people, it is dangerous for animals, too.

But, before you leave, know where you can take your pet. Find out which motels or hotels are "pet friendly," or which ones will accept pets in an emergency. Or plan to go to the house of a friend or relative who will permit you to bring your pet.

Before you have to travel, get your pet used to a crate. Familiar surroundings might help easy a pet's anxiety. And getting an animal into a crate for travel will be easier once the animal is used to it.

Take pet food, medicines, vaccination records, and information about pet insurance if your have a policy. Assemble all of this into a disaster kit that you can grab as you leave.

Relying on a neighbor

If you get trapped away from your home due to a disaster or other emergency, your pet will be better off if you have already made arrangements with your neighbor or nearby friend to take care of the animal.

The temporary caretaker should have phone numbers to reach you (a cell phone number may be the best), and all the instruction necessary to properly care for the animal. Those instructions should include a signed authorization for veterinary care, and financial limits to the veterinary care.

If you have to leave your home, take your pet with you if at all possible. You are the best person to take care of your pet. Also…if the situation is dangerous for people, it is dangerous for animals, too.

Afterward

Emergencies can make pets display unexpected or uncharacteristic behaviors. Well-behaved animals may become aggressive and defensive after a major disruption in their lives. The animal may not return to more typical behavior for several weeks. Be careful releasing an animal after an emergency, especially in unfamiliar surroundings. Make sure it cannot escape. Do not release the animal outside until you know the area is safe, AVMA said.

Allow your pet plenty of time to rest and get used to new surroundings. Provide familiar toys, if possible.

AVMA has prepared an extensive guide to preparing for emergencies, both for pet owners and livestock owners. It is available on AVMA's website, at *www.avma.org/disaster*. Download a copy of "Saving the Whole Family."

The guide has checklists and helpful tips on preparing for disasters, and it explains the steps you should take once the warning has been sounded.

It has information about taking care of all types of pets, including birds and snakes. It also has information about preparing livestock.

…NARMS Retail Meat Annual Report *(Continued)*

bacteria in meats commercially available to the U. S. consumer.

During 2003, eight CDC FoodNet laboratories collected samples for the NARMS Retail Meat surveillance program (California, Connecticut, Georgia, Maryland, Minnesota, New York, Oregon, and Tennessee). Staff from the participating FoodNet sites visited at least five grocery stores per month, purchasing 40 samples of fresh meat, which included 10 samples each of chicken breast, ground turkey, ground beef, and pork chops (the exception being Connecticut, which collected only five samples each for 2003).

All eight FoodNet sites cultured the meats and poultry for the presence of *Salmonella* and *Campylobacter*. Additionally, the Georgia, Maryland, Oregon, and Tennessee laboratories cultured meat and poultry for the presence of *E. coli* and *Enterococcus*. Once isolated and identified, bacterial isolates were sent to FDA's CVM Office of Research for further characterization including species confirmation, antimicrobial susceptibility testing, and genetic fingerprinting through pulsed-field gel electrophoresis analysis (*Salmonella* and *Campylobacter* only).

The NARMS retail meat component began in 2002 and is the newest addition to the NARMS program. There are currently 10 FoodNet sites participating in the collection and analysis of retail meat samples. This has increased the number of retail meats examined and number of bacterial isolates recovered. The 2004 annual report is currently being developed and should be available in early 2006.

CVM Animal Health Specialists Deployed to Louisiana, Mississippi After Hurricanes

Animal health specialists from the Center for Veterinary Medicine (CVM) participated in the Federal government's response to the damage from hurricanes Katrina and Rita. CVM veterinarians and a veterinary technician were deployed to take care of the thousands of displaced pets, in some cases treating them for exposure and injuries from the storm, and in other cases just keeping them housed and fed.

CVM veterinarians and a veterinary technician were deployed to take care of the thousands of displaced pets, in some cases treating them for exposure and injuries from the storm….

Shortly after Federal Emergency Management Agency officials realized the extent of the damage, the Public Health Service (PHS) began deploying its officers to Louisiana and Mississippi to help protect human and animal health.

Two CVM veterinarians were deployed to the disaster area as members of the PHS's Commissioned Corps. A third CVM employee, a veterinary technician with experience in dealing with emergency situations, was able to go when the Food and Drug Administration (FDA) granted her special permission.

PHS veterinarian CDR Charlotte Spires worked at the largest of the shelters,

(Continued, next page)

Hurricane's destruction: Outside of D'iberville and St. Martin, MS. These were single family houses. (Photo courtesy of LCDR Hall-Robinson.)

CVM Animal Health Specialists Deployed . . . *(Cont.)*

established at the Lamar Dixon Exposition facilities in Gonzales, LA. The 250-acre site was used for several disaster relief functions, including as a staging area for emergency services, as well as shelters for human and animal refugees.

The Lamar Dixon site served as a shelter for a total of nearly 6,400 animals during the emergency. As many as 400 volunteers worked there. The site was set up by the Humane Society of the United States.

Dr. Spires, who works in CVM Office of New Animal Drug Evaluation, worked for much of the time at the Lamar Dixon site as a triage veterinarian, assessing the health of incoming animals to determine which ones needed immediate treatment.

Working conditions were tough, she said. Fans provided the only cooling, but the heat index during the day reached 118°. At midnight, the temperature would drop only to about 90°. Workers were on their feet for far longer than normal eight-hour shifts.

Rescue workers would bring 200-300 dogs a night to the shelter, said Dr. Spires. In some cases, she said, displaced individuals would give rescue workers an address where a pet had been abandoned, so the rescuers could retrieve the animal.

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The remains of an oriental grocery store in D'iberville, MS. LCDR Elivra Hall-Robinson, who not only is a veterinarian, but also a food-safety specialist, was deployed to the area destroyed by Hurricane Katrina to participate on environmental assessment teams, which checked basic sanitation, including food safety. (Photo courtesy of LCDR Hall-Robinson.)

Hurricane Katrina left wide areas of Louisiana and Mississippi flooded, which created problems for pets as well as humans. This is a flooded neighborhood in St. Bernard Parish, MS. (Photo courtesy of LCDR Hall-Robinson.)

CVM Animal Health Specialists Deployed . . . *(Cont.)*

In another case, the rescuers would bring in animals not associated with any owner but found in the flooded area. Some of the animals were hard to handle because of the experience they had been through. Other animals were feral and not used to being handled, Dr. Spires said.

Shelter workers frequently suffered from animal bites and heat exhaustion—the two most common human health issues, Dr. Spires added.

The second largest shelter was set up at Louisiana State University AgCenter's John M. Parker Coliseum, Baton Rouge, LA. It was established by the Louisiana State Veterinary Association.

The Parker Coliseum site processed nearly 2,000 animals. Most animals brought to the Parker Coliseum shelter were "owner identified," meaning that they were placed at the facility until the owners could find someplace to live and then reclaim their pets.

The PHS deployed LCDR Elvira Hall-Robinson, a veterinarian with CVM's Office of Research, to the Parker Coliseum. She conducted environmental and public health needs assessments at animal shelters in New Orleans parishes, collected animal and volunteer data from Parker Coliseum and Lamar-Dixon and made sure local authorities were aware of the situations at these local shelters.

While there, as part of her duties, Dr. Hall-Robinson and other members of the veterinary team contacted other animal rescue shelters that were not affiliated with the State Department of Agriculture to promote outreach to bring these facilities under the State's Incident Command structure. These unaffiliated shelters were set up by many animal rescue support groups. Most did a good job following pet-owner reunification rules.

In addition to that, Dr. Hall-Robinson and other Commissioned Corps veterinarians helped the LA SPCA shelter veterinarian and provided veterinarian care to LA SPCA shelter animals, allowing the shelter veterinarian a chance to rest and start looking for a place to live.

Environmental assessment

Dr. Hall-Robinson's deployment to the Parker Coliseum was actually her second deployment to the Katrina area. Although a veterinarian, she also has a strong background in food safety, and worked in that capacity in the U.S. Army. PHS made use of this background and sent her for her first post-Katrina deployment to serve as part of an environmental assessment team working in Mississippi.

Her work on the environmental assessment team was to check basic sanitation, including the safety of the food available to storm refugees.

Within a few days of the hurricane, the PHS environmental assessment teams were canvassing the areas affected by the hurricane to identify the areas in which storm refugees were sheltered, determine the

(Continued, next page)

Disasters affect people and pets. This dog was at the Muttshake Animal Rescue Foundation in New Orleans, LA. The dog's owner gave the dog up because of the neurological problem (the head tilt) that occurred during the hurricane's disaster. (Photo courtesy of LCDR Hall-Robinson.)

Emergency workers' living conditions. Public Health Service veterinarians and others who traveled to New Orleans to help pets displaced by Hurricane Katrina lived in circus tents. Temperatures during the day topped 100° and at night dropped only to 90°. (Photo courtesy of Sharon Ricciardo.)

CVM Animal Health Specialists Deployed . . . *(Cont.)*

number of people in the shelters, and check out basic sanitation. In addition, the teams were trying to identify individuals who needed medical attention or had special needs.

Site Management

Another CVM employee who was not a PHS member, but was able to travel to Louisiana to help under a special arrangement with FDA, was Sharon Ricciardo, a Consumer Safety Officer in CVM's Office of New Animal Drug Evaluation.

Ms. Ricciardo is a certified veterinary technician, licensed paramedic, and firefighter, and she has received specialized training in disaster response. Within days of the disaster, FDA had granted her administrative leave and CVM excused her from her regular duties, allowing her to travel to the Parker Coliseum site.

The initial challenges at the Parker site were organizing crates, collecting food for the animals, and receiving veterinary medical supplies. (Most supplies at the Lamar-Dixon and Parker sites were donated.) The Parker Coliseum site Incident Commander, a local veterinarian and lead member of the Louisiana Veterinary Medical Association, specifically requested assistance from Ms. Ricciardo to coordinate these logistics, due to Ms. Ricciardo's expertise in disaster relief management.

Approximately 150 individuals worked at the Parker Coliseum shelter daily. Ms. Ricciardo's job was to coordinate the staff, which included veterinarians, veterinary students, technicians, and general volunteers, some of whom had lost their houses in the storm, but still came to the shelter to work. Ms. Ricciardo was also in charge of site safety and security, establishing shift rotations, talking to the press, and overseeing general site operations.

The floor of the LSU AgCenter's John M. Parker Coliseum was arranged with crates to house the animals left there for safe keeping. Most of the pets at this site were "owner-identified," and the owners intended to come back for their pets. (Photo courtesy of CDR Tory Hampshire)

Many of the animals at the Lamar-Dixon Shelter, the largest officially sanctioned shelter, were plucked from the flood waters, and their owners were unknown. When the shelter closed in October, the animals were given to foster homes until the owners could reclaim them. (Photo courtesy of CDR Charlotte Spires.)

Public Health Service's Commissioned Corps was originally organized in the late 1700s to take care of merchant marine sailors. It has a military type organization, and its members hold ranks similar to those of officers in the U.S. Navy.

The Corps is designed to be deployed quickly—possibly within hours—in crisis situations to provide human and animal medical emergency services. The Commissioned Corps includes physicians, nurses, dentists, veterinarians, and others with health specialties.

CVM has several Commissioned Corps members, who, when not deployed, work alongside the Center's civilian employees.

FDA Investigates Illegal Extralabel Use of Sulfonamides (Sulfa Drugs) in Dairy Cows

Some veterinarians have been illegally using sulfonamides (sulfa drugs) in lactating dairy cows, according to information reported to the Center for Veterinary Medicine (CVM).

For example, during a routine inspection of a Wisconsin dairy operation in August, a State inspector found containers of unapproved sulfa drugs in the milk barn—evidence of improper sulfa drug use. The regional milk specialist noticed a box of six tubes marked SXT, indicating a sulfa drug inside. The drug had been prescribed by a veterinarian, who later received a warning against prescribing any sulfa drug that was not specifically approved for use in lactating dairy cattle.

CVM's concern is that the use of a small amount of a sulfonamide drug in a lactating dairy cow can result in the contamination of milk from several hundred cows when mixed in a bulk tank. The contamination levels could be high enough to present a risk to public health.

CVM issued a "CVM UPDATE" in August warning veterinarians that FDA's rules prohibit the extralabel use of sulfa drugs in lactating cows. It also said, "CVM has received some information indicating that sulfonamides, some in combination with trimethoprim, are being prescribed for use in treating conditions in lactating dairy cattle for which they are not approved." The article stated that unapproved use of sulfonamides is a frequent cause of violative residues in food-producing animals.

In some cases, FDA can permit extralabel, or off-label, use of FDA-approved animal and human drugs. The extralabel provisions are part of the 1994 Animal Medicinal Drug Use Clarification Act and its implementing regulation, Title 21, Code of Federal Regulations, Part 530 (21 CFR 530). However, FDA's extralabel drug use rule specifically prohibits the use of some drugs in an extralabel fashion, including sulfa drugs in lactating dairy cows. (See box for other drugs prohibited from extralabel use.)

CVM's concern is that the use of a small amount of a sulfonamide drug in a lactating dairy cow can result in the contamination of milk from several hundred cows when mixed in a bulk tank.

According to Dr. Mike Talley, CVM's milk safety specialist, the only currently marketed drug approved for use in lactating dairy cows 20 months of age or older is sulfadimethoxine as an injectable or oral bolus. Use of the product also carries with it the responsibility to discard the cow's milk for a certain period of time after treatment as prescribed on the labeling.

CVM has also found that veterinarians are misusing the approved injectable product by intramammary infusion to treat mastitis. CVM is also concerned about veterinarians increasing the dose or treating conditions in lactating cattle not on the approved labeling. Administering a drug in an unapproved manner is another form of extralabel drug use and is prohibited in the case of sulfa drugs in lactating dairy cows.

The drug is also approved as a sustained release oral bolus, in beef cattle. However, CVM has received reports that veterinarians use the sustained release boluses to treat lactating dairy cattle.

Drugs prohibited from extralabel use in all food-producing animals:

- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol
- Dimetridazole
- Furazolidone, nitrofurazone, other nitrofurans
- Fluoroquinolones
- Glycopeptides
- Ipronidazole
- Other nitroimidazoles
- Phenylbutazone in female dairy cattle 20 months of age or older
- Sulfonamide drugs in lactating dairy cattle (except approved label use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine)

Ask CVM

Q. My veterinarian has prescribed a human prescription drug for my pet. I found that if I buy the drug from Mexico, I can get it a lot cheaper and without a prescription. I understand that Center for Veterinary Medicine (CVM) will permit individuals to bring limited amounts of drugs into the United States under a personal import policy. So, is it legal for me to buy this drug in this manner?

A. If the same drug you are buying from Mexico is available in the United States, then CVM cannot grant you permission to import it. Our regulations do not recognize cost or different marketing status (over-the-counter versus prescription) as a reason to allow imports of drugs into the United States. However, if the drug you are importing has a necessary attribute not found with the drug available in the United States, such as different dosage forms (e.g., liquid versus tablet) or different strengths/concentrations, then CVM may grant your veterinarian permission to import a small amount of the drug for use with your pet. Requests for drug importation can be made only by veterinarians and are considered on a case-by-case basis by CVM's Division of Compliance. Requests can be addressed to the Food and Drug Administration, Center for Veterinary Medicine, Division of Compliance, 7519 Standish Place, HFV-230, Rockville, MD 20855

Q. Does the Food and Drug Administration (FDA) have jurisdiction over drugs for my aquarium fish?

Yes, and the procedures FDA uses to allow those drugs on the market will be changing. In the past, we made special exceptions to keep certain limited-use drugs available where needed, but now a new law will give us broader authority to make such drugs legally available.

The Minor Use & Minor Species Animal Health Act of 2004 (MUMS Act), among other purposes, was intended to improve FDA's ability to encourage the development of products intended for use in aquarium fish.

The MUMS Act grew out of a concern of Congress and FDA about the lack of legally available drugs for use in minor species (including aquarium or ornamental fish, zoo animals, and many pets, such as guinea pigs or ferrets, as well as animals of agricultural importance such as sheep, goats, and catfish) or for minor use in major species. The primary reason for this lack of drug availability is the cost that potential drug sponsors face to put a drug through the FDA animal drug approval process. The potential market return typically is less than the cost of the approval. The market for aquarium fish products, in many cases, is simply too small to generate enough financial return to warrant the cost of approval.

The MUMS Act grew out of a concern of Congress and FDA about the lack of legally available drugs for use in minor species or for minor use in major species.

FDA approval is currently the only basis for the legal marketing of animal drugs, and FDA has approved only one drug for use in aquarium fish. Therefore, all other aquarium drug products are actually being marketed without FDA approval. FDA could take legal action (if resources permitted) to remove all of these products from the market—leaving no means of treating aquarium fish.

Instead, the Agency has elected to use regulatory discretion to keep products intended for the treatment of aquarium fish available. For those products, FDA requires that they be produced under good manufacturing practices, registered, and listed with FDA. Also, FDA requires the manufacturer to follow drug labeling requirements.

Meanwhile, FDA looked for a better system, which the MUMS Act will offer.

The MUMS Act contains an entirely new basis for the legal marketing of animal drugs intended for use in minor species such as aquarium fish. This process will be considerably less expensive and time-consuming for sponsors than the approval process. This new category will be called the Legally-Marketed Unapproved New Animal Drug Index, or "The Index."

FDA is in the process of writing regulations to implement the indexing provisions of the MUMS Act. The proposed regulations are due to be published by February 2006, and the final regulations are due by August 2007. The option to request indexing of drugs for minor species will be available after the publication of the final regulations.

The new process will be restricted to products that pose no food safety, environmental, or user safety concerns. Most products for aquarium fish should readily meet these requirements.

Under the new process, panels of qualified experts from outside the Agency will assess the available evidence relating to target animal safety and effectiveness of selected drug products. If the panel finds that the evidence supports a conclusion that the benefits of a product outweigh its risks under specified conditions of use, the drug manufacturer will request that the FDA include the product in an

(Continued, next page)

CVM Personnel Comings and Goings

New Hires

OFFICE OF RESEARCH

- Heather Harbottle, Staff Fellow (Microbiologist)

OFFICE OF NEW ANIMAL DRUG EVALUATION

- Joseph Cormier, Staff Fellow (Chemist)
- Tong Zhou, Toxicologist

OFFICE OF MANAGEMENT

- Kristin Cook Program Support Assistant
- Sonia Gallagher, Secretary

Departures

OFFICE OF SURVEILLANCE AND COMPLIANCE

- Sue Ann Williams, Consumer Safety Officer

OFFICE OF MANAGEMENT

- Dawn Calhoun, Program Analyst

Ask CVM *(Continued)*

index of drugs legally available for use in minor species.

If the FDA agrees with the conclusions of the expert panel, it will grant the manufacturer's request and index the product.

Not all such products will be over the counter. The panel may conclude that a product should be available, but restricted to prescription status.

You can find out more about MUMS-related issues at CVM's website *http://www.fda.gov/cvm/minortoc.htm*.

CVM Scientists Develop Nitrofuran Residue Detection Method for Shrimp

Center for Veterinary Medicine (CVM) scientists have developed a method for detecting residues of nitrofurans in shrimp and have created a video to show the process to other scientists so they can check imported foods to detect residues of the illegal drugs.

Nitrofurans are broad spectrum antibiotics that have been used in a variety of species, including chicken, turkey, pigs, cattle, shrimp, and fish. However, the Food and Drug Administration withdrew approval for use of nitrofurans (furazolidone and nitrofurazones) as antiprotozoals in poultry and swine in 1991, because the drugs are considered to be mutagenic and carcinogenic. In 2002, FDA also withdrew approval for remaining topical uses in food-producing animals. FDA has no approved uses of nitrofurans in food-producing animals.

Nitrofurans are broad spectrum antibiotics that have been used in a variety of species, including chicken, turkey, pigs, cattle, shrimp, and fish.

However, nitrofurans are used in other countries. The European Union detected nitrofurans in imported shrimp in 2002, so regulators in the United States developed a method to detect that use.

Nitrofurans are quickly metabolized in animals, so residue detection methods must be able to spot the drug's metabolites. Researchers in CVM's Office of Research, Dr. Pak-Sin Chu and Dr. Mayda Lopez, developed a method for detecting the metabolites in shrimp. It is a modified method based on methods used for land animals. It detects bound residues of nitrofuran drugs, and has a sensitivity of 1 part per billion. The method uses liquid chromatography-tandem mass spectrometry, and was described in an article in an issue of the *Journal of Agricultural and Food Chemistry*.

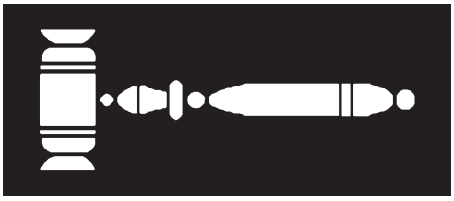
CVM has shared the methodology with the Food and Drug Administration's regulatory enforcement arm—the Office of Regulatory Affairs. A modified version of the methodology can be used in field laboratories, for enforcement actions.

Dr. Chu and Dr. Lopez have developed a written Standard Operating Procedure describing the method. They also created a video that fully describes the steps in the process. The audience for the video is primarily analytical chemists and regulatory scientists.

The 33-minute video includes seven sections: introduction, sample prewashing, hydrolysis and derivatization, sample cleanup, liquid chromatography-tandem mass spectrometry, quantitation, and confirmation. It shows Dr. Lopez performing the steps of the method.

"Lab techniques that are hard to accurately capture with words can be effectively illustrated with the power of visual presentation," Dr. Chu said. The video is a cost-effective option for making such presentations to several labs, he added.

Regulatory Activities



The following individuals and firms received Warning Letters for offering animals for slaughter that contained illegal tissue residues:

- Phillip V. Banks, co-owner, Phillip and Vincent Banks Dairy Farm, Normandy, TN
- Mike D Griffith, partner, G & G Dairy, Twin Falls, ID
- Charles F. Luchsinger and Susan B. Luchsinger, co-owners, Silver Spring Farm, Syracuse, NY
- Kevin R. Martin, owner, Martin-Vue Farms, Goshen, IN
- Marlen L. Martin, owner, Marlen Martin Farm, Goshen, IN
- Melvin Medeiros, owner, Maria Medeiros Dairy, Laton, CA
- Donald N. Pope, owner, Donald Pope Veal Farm, Whitewater, WI
- Samuel O. Smith, owner, Smith Dairy, Cornersville, TN
- George E. Vander Dussen, owner, Providence Dairy, Texico, NM

The above violations involved gentamicin in dairy cows, penicillin in dairy cows, dihydrostreptomycin in a dairy cow, neomycin in a veal calf, and sulfadimethoxine in dairy cows.

A Warning Letter was issued to Eugene R. Anderson, DVM, owner, Morris Veterinary Center, PSC, Morris, MN, because an investigation revealed that the practices of the veterinary center caused animal drugs to be unsafe under Section 512(a) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 360b, and adulterated within the meaning of Section 501(a)(5) of the Act, because drugs were prescribed for use in a manner that did not conform with their approved uses or with regulations for Extralabel Drug Use in Animals, 21 CFR Part 530. The above violations involved sulfadimethoxine and oxytetracycline in lactating dairy cattle.

A Warning Letter was issued to Gary D. Daniels, DVM; Dale A. Timm, DVM; Myron A. Cyphers, DVM; Henry Peeters, DVM, Chosen Valley Veterinary Clinic, Chatfield, MN. An investigation confirmed that the new animal drugs sulfadimethoxine and gentamicin sulfate were caused to be unsafe under Section 512(a) of the Act, 21 U.S.C. 360b, and adulterated within the meaning of Section 501(a)(5) of the Act because the drugs were used in a manner that did not conform with their approved uses or with the regulations for Extralabel Drug Use in Animals, 21 CFR Part 530. In addition, the investigation found that the clinic was compounding and distributing the unapproved new animal drug GM 100. The GM 100 drug product is a new animal drug as defined under Section 201(v) of the Act. The composition is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. The drug is adulterated under Section 501(a)(5) of the Act because it is unsafe within the meaning of Section 512 of the Act. Section 512 in part deems a new animal drug to be unsafe unless an approved new animal drug application (NADA) is in effect for the specific product in question. The Chosen Valley Veterinary Clinic holds no FDA approval of an application for its GM 100 drug product.

The GM 100 drug product is a new animal drug.... The composition is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling.

A Warning Letter was issued to Wendy J. Raak, president, Xtreme Design, Inc., Rosemount, MN, because an inspection revealed that this veterinary product distributing facility is marketing and distributing Xtreme Shampoo and Xtreme Spray. Section 201(g) of the Act defines a drug as an article intended in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals or intended to affect the structure or function of the body of man or other animals. The representations made for the Xtreme products indicate that they are intended for use, among other things, in the cure, prevention, and treatment of disease in horses and/or to affect the structure or function of their bodies. These include statements such as, "Helps on all skin fungus, ringworm, rainrot, girth itch, thrush, proud flesh, greasy heel, cankers and scratches." These products are therefore drugs under the Act. Because they are not the subject of approved new animal applications (NADAs), they are unsafe under Section 512(a) of the Act, and thus adulterated under Section 501(a)(5) of the Act.

Approvals for July through September 2005

CVM has published in the *Federal Register* notice of the approval of this New Animal Drug Application (NADA)

DRAXXIN (tulathromycin) Injectable Solution (NADA 141-244), filed by Pfizer, Inc. The NADA provides for the veterinary prescription use of tulathromycin solution in cattle, by subcutaneous injection, for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella* mulitocida, and *Histophilus somni* (*Haemophilus somnus*); for the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*; and in swine, by intramuscular injection, for the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, P. multocida, Bordetella bronchiseptica,* and *H. parasuis*. The regulations are also amended to add the acceptable daily intake for total residues of tulathromycin and tolerances for residues of tulathromycin in edible tissues of cattle and swine. Notice of approval was published July 12, 2005.

CVM has published in the *Federal Register* notice of the approval of these Supplemental New Animal Drug Applications (NADA)

DECTOMAX (doramectin) Pour-On Solution for Cattle (NADA 141-095), filed by Pfizer, Inc. The supplemental application provides for a period of protection from reinfestation with two species of external parasites following topical administration of doramectin solution on cattle. Specifically, the period of persistent effectiveness is 42 days for *Linognathus vituli* and 77 days for *Bovicola (Damalinia) bovis*. Notice of approval was published July 26, 2005.

TERRAMYCIN-343 (oxytetracycline HCl) Soluble Powder (NADA 8-622), filed by Pfizer, Inc. The supplemental NADA provides for use of the product for skeletal marking of finfish fry and fingerlings by immersion. The approval of this supplemental NADA relied on publicly available safety and effectiveness data contained in Public Master File (PMF) 5667, which were compiled under National Research Support Project-7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses. The supplemental NADA also provides for the addition of statements to product labeling warning against the use of this product in drinking water of lactating dairy cattle. In addition, FDA has found that the regulations contain incorrect statements warning against the use of oxytetracycline soluble powder in calves intended for veal. Accordingly, the regulations in 21 CFR 520.1660d are amended to reflect appropriate warning statements for this product. This action is being taken to improve the accuracy of the regulations. Notice of approval was published July 18, 2005.

(Continued, next page)

Regulatory Activities *(Continued)*

CVM has published in the *Federal Register* notice of the approval of these Abbreviated New Animal Drug Applications (ANADA)

- Phenylbutazone 20% Injection (phenylbutazone) (ANADA 200-371), filed by Sparhawk Laboratories, Inc. The ANADA provides for veterinary prescription use of Phenylbutazone 20% Injection for relief of inflammatory conditions associated with the musculoskeletal system in horses. Sparhawk Laboratories, Inc.'s product is approved as a generic copy of Schering-Plough Animal Health Corp.'s, BUTAZOLIDIN Injectable 20%, approved under NADA 11-575. Notice of approval was published August 17, 2005.

- Tiamulin Liquid Concentrate (12.3% tiamulin hydrogen fumarate) (ANADA 200-360), filed by Phoenix Scientific, Inc. The ANADA provides for use of tiamulin concentrate solution to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia. Phoenix Scientific, Inc.'s Tiamulin Liquid Concentrate is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s DENAGARD (tiamulin) Liquid Concentrate approved under NADA 140-916. Notice of approval was published July 26, 2005.

- Speclinx-50 (spectinomycin dihydrochloride pentahydrate and lincomycin hydrochloride monohydrate) Water Soluble Powder (ANADA 200-380), filed by Cross Vetpharm Group Ltd. This ANADA provides for use of SPECLINX-50 Water Soluble Powder to create a solution administered through the drinking water of chickens. This solution acts as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *M. gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin. Cross Vetpharm Group Ltd.'s SPECLINX-50 Water Soluble Powder is approved as a generic copy of Pharmacia & Upjohn Co.'s L-S 50 Water Soluble Powder, approved under NADA 046-109. Notice of approval was published July 15, 2005.

CVM has published in the *Federal Register* notice of the approval of these Supplemental Abbreviated New Animal Drug Applications (ANADA)

- Flunixin Meglumine (flunixin meglumine) Injection (ANADA 200-124), filed by Phoenix Scientific, Inc. The supplemental ANADA provides for veterinary prescription use of flunixin meglumine solution by intravenous injection in lactating dairy cattle for control of fever associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. Notice of approval was published August 22, 2005.

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