FDA VETERINARIAN
Center for Veterinary Medicine
2006 Vol. XXI, No. IV

CVM Posts Page on Web Site About Veterinary NSAIDs

The Center for Veterinary Medicine (CVM) has posted information on its Web site about veterinary non-steroidal anti-inflammatory drugs (NSAID), which are in a class of drugs that are effective in controlling pain and inflammation in dogs. The page, "Veterinary Non-Steroidal Anti-Inflammatory Drugs," is on CVM's Web site at *http://www.fda.gov/cvm/nsaids.htm*.

In veterinary medicine, approved veterinary NSAIDs are used to control the pain of osteoarthritis in dogs, and some are approved for the control of postoperative pain in dogs. NSAIDs also control inflammation—the body's response to irritation or injury and is characterized by redness, warmth, swelling, and pain—by blocking the production of prostaglandins, the body-generated chemicals that cause inflammation.

Although NSAIDs can give dogs significant relief from pain and inflammation, like all commonly prescribed drugs, they can present risks, and dog owners need to be aware that problems can arise from these drugs.

According to information CVM obtained from post-marketing surveillance, some dog owners are inadequately informed about the dosage and administration of the drugs, known risks, and clinical signs to watch for in their pets taking NSAIDs.

All NSAIDs approved for oral use in dogs come with a Client Information Sheet (also known as the Information for Dog Owner Sheet) that provide dog owners with important information in a user-friendly manner regarding what can be expected from use of the drug and what side effects to look for. These information sheets are intended for distribution by the veterinarian to the client at the time an NSAID is prescribed for a dog.

CVM has received reports indicating that veterinarians are not always providing dog owners with Client Information Sheets. Consequently, some dog owners might not know the common side effects of the drugs or what to do if their pets experience side effects.

CVM's new NSAID Web page provides consumers with links to package inserts and Client Information Sheets for NSAIDs that are approved for oral use in dogs. Those specific links can be found at *http://www.fda.gov/cvm/currentlabels.html*.

The page also has links to other information about NSAIDs, including:

- CVM public statements to reporters and others, labeled "CVM Updates";
- Guidance Documents; and
- Adverse Drug Experience report information.

Any questions or comments about this page may be directed to the CVM Web Manager, Deborah Brooks. Direct an e-mail to: Deborah.Brooks@FDA.HHS.GOV.

NARMS 2004 Annual Report Notes Enhanced Meat Sampling

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has posted the National Antimicrobial Resistance Monitoring System – Enteric Bacteria (NARMS) Retail Meat Annual Report for 2004 on its Web site at: *http://www.fda.gov/cvm/NARMSReport2004.htm*. The primary purpose of the NARMS retail meat surveillance program is to monitor the prevalence of antimicrobial resistance among foodborne pathogenic and commensal organisms, in particular, *Salmonella*, *Campylobacter*, *Enterococcus* and *E. coli*. The project includes both active surveillance for foodborne diseases and related epidemiologic studies designed to help public health officials better understand foodborne diseases in the United States.

The results generated by the NARMS retail meat program establish a reference point for analyzing trends of antimicrobial resistance among these foodborne bacteria.

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In This Issue

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

CVM Reminds Consumers: Small Turtles Carry Risks of Salmonellosis

by Joseph Paige, D.V.M., MPH, Office of Surveillance and Compliance; Jon F. Scheid, Editor

In the United States, reports of human salmonellosis from pet turtles continue to be received, despite the fact that pet turtles less than 4 in. in length were banned in 1975. The resurgence in illegal sales of these pet turtles and subsequent consumer complaint reports have again raised concerns about the risks to public health from handling these turtles.

Researchers were first able to establish the link between human salmonellosis and turtles in 1962. A more recent report from the Centers for Disease Control and Prevention (CDC) confirms that the threat of contamination continues.

Recent evidence has again demonstrated that baby turtles with a carapace (or shell) of less than 4 in. in length can infect people with the organism *Salmonella*, which can result in invasive illness salmonellosis, a potentially serious, even fatal, disease especially in children younger than 5 years old, who are the ones who most often receive the small turtles as pets.

Symptoms of salmonellosis infections in people include diarrhea, cramps, and fever. The symptoms can show up between 6 and 72 hours after exposure, and can last 2 to 7 days.

For healthy adults, the illness is usually little more than an inconvenience. However, young children (5 years old or younger), older adults, and any individual with a compromised immune system are especially vulnerable to severe illness following infection.

Turtles normally carry *Salmonella* bacteria. The smaller turtles, which are often sold, illegally, as pets for younger children, often infect the children. Infection is normally through the fecal-oral route. In other words, younger children do not know enough to keep their hands away from their mouths and face after handling the turtle or touching the aquarium or the water that makes up the turtles environment.

The types of *Salmonella* found on turtles are not pathogenic to the turtles. The turtles can carry the *Salmonella* with no ill effects. However, some types of *Salmonella* found on turtles are especially virulent for humans.

The Salmonella from baby turtles can also contaminate areas of a home other than the aquarium, thus making individuals sick even if they never touched the animal.

FDA scientists point out that turtles can release, or shed, *Salmonella* intermittently. Therefore, even if a turtle shows no sign of contamination after it is tested, there is no guarantee that the turtle will remain free of *Salmonella*. Currently, no one has been able to demonstrate that a turtle that tests negative for *Salmonella* will not recolonize. It is likely a subsequent test may reveal *Salmonella* contamination.

The CDC presented six case studies in *Salmonella* transmission from turtles in its Morbidity, Mortality Weekly Report (MMWR) issued in March 2005. Four of the cases were in Wisconsin and two were in Wyoming. All were linked to small, pet turtles. One of the cases involved an elderly woman and the rest involved small children. All were sick for several days, and several required hospitalization.

The *Salmonella* from baby turtles can also contaminate areas of a home other than the aquarium, thus making individuals sick even if they never touched the animal. One of the cases documented in the CDC's MMWR report described an 80-year-old woman who was hospitalized for 5 days, then kept in transitional care unit for another 9 days, due to salmonellosis that came from a baby turtle. One of the family members where she lived washed the turtle's bowl in the kitchen sink. Scientists found *Salmonella typhimurium* from the turtle's habitat and from the sink. The isolates recovered from the woman and from the sink were matched through the use of pulsed-field gel electrophoresis, a sophisticated process that creates images of unique patterns from the bacterial isolates, thus revealing the type of *Salmonella* and giving researchers something to compare different isolates.

These reports demonstrate that turtle-associated salmonellosis continues to pose a substantial threat to human health. In addition, either direct or indirect contact with infected turtles and their environments can cause human illness.

FDA VETERINARIAN

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FDA Extends Comment Period for MUMS Indexing Rule

The Food and Drug Administration (FDA) has announced that it is extending the period for comments on the proposed rule for establishing a drug "Index" under the Minor Use and Minor Species Animal Health Act (MUMS Act).

The 30-day extension means that the comment period will extend until December 20, 2006.

The indexing proposal, which FDA released for comment in August, would permit drug companies to legally market unapproved new animal drugs mostly for minor species that are not used for food. (Exceptions are possible in cases in which a drug could be used for early life stages of food animals, e.g., fish eggs, oyster spat).

The rule will primarily help drug manufacturers legally market drugs sold in pet stores and drugs intended for use in wildlife and zoo animals.

Interested persons may submit to the Division of Dockets Management written or electronic comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number 2006N-0067. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

NARMS 2004 Annual Report *(Cont.)*

Food animal products destined for human consumption are known to harbor enteric bacteria, including zoonotic foodborne pathogens. Antimicrobial resistance among these organisms may be associated with the use of antimicrobial agents in food animals. Retail meats represent a point of exposure close to the consumer and, when combined with data from slaughter plants and on-farm studies, provide insight into the prevalence of antimicrobial resistance in foodborne pathogens originating from food animals. To gain a better understanding of antimicrobial resistance among enteric bacteria in the food supply, the NARMS monitors antimicrobial susceptibility/resistance phenotypes in bacteria isolated from retail meats.

Retail meats are collected at the 10 FoodNet sites and cultured for the presence of the selected organisms. Bacterial isolates are sent to FDA/CVM for confirmation of species, antimicrobial susceptibility testing, and genetic analysis. A total of 4,699 meat samples were collected in 2004 as part of the NARMS retail meat surveillance program, which represents an increase of 1,166 samples over the total collected in the previous year. The increase in the number of samples collected in 2004 was due to the addition of FoodNet laboratories in Colorado and New Mexico, increasing the number of test sites from 8 to 10; the other 8 States are California, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, and Tennessee. FoodNet is the principal foodborne disease component of the Centers for Disease Control and Prevention (CDC) Emerging Infections Program (EIP) (*http://www.cdc.gov/foodnet/*) and is a collaborative project of CDC, the 10 EIP sites, the U.S. Department of Agriculture, and FDA.

A notable change in 2004 was the adoption by FDA/CVM of a broth microdilution antimicrobial susceptibility testing method for *Campylobacter* that also increased the number of agents tested to nine from five. The nine antimicrobials tested in 2004 were: azithromycin, ciprofloxacin, clindamycin, erythromycin, florfenicol, gentamicin, nalidixic acid, telithromycin, and tetracycline; ciprofloxacin, erythromycin, and gentamicin were also tested in 2003. Meropenem and doxycycline were dropped from the list of *Campylobacter* agents tested.

Comings and Goings

New Hires

OFFICE OF NEW ANIMAL DRUG EVALUATION

- Charli Long, Staff Fellow
- Dorothy Baily, Staff Fellow
- James Rice, Staff Fellow
- Lynn Oliver, Staff Fellow

OFFICE OF SURVEILLANCE AND COMPLIANCE

- Cathie Marshall, Consumer Safety Officer

OFFICE OF RESEARCH

- Shani Smith, Biologist

Departures

OFFICE OF NEW ANIMAL DRUG EVALUATION

- Anne Edelson, Consumer Safety Technician

OFFICE OF SURVEILLANCE AND COMPLIANCE

- Neal Bataller, Veterinary Medical Officer

OFFICE OF RESEARCH

- David Wagner, Research Animal Scientist
- Tom Chiller, Medical Officer, Epidemiology

How FDA Protects the Safety and Quality of Your Pet's Food

by Suzanne Sechen, Ph.D., Office of New Animal Drug Evaluation

The growing popularity of pets in U.S. households has led to an enormous increase in varieties of pet foods available at grocery and convenience stores and especially in stores dedicated solely to pet needs. Pet owners may be aware that the Food and Drug Administration (FDA) is responsible for protecting the safety of the food they themselves eat, but they may not know that FDA also makes sure that animal foods, including pet foods, are safe and properly labeled. FDA's regulation of pet food includes not just the classic canned cat and dog food, but also the flakes sprinkled in an aquarium, chow for hamsters, seeds for pet canaries, and even the coating on packaged crickets to be fed to pet reptiles.

FDA enforces the Federal Food, Drug, and Cosmetic Act (FFDCA), which defines foods as "articles used for food or drink for man or other animals…and articles used for components of any such article." The FFDCA requires that pet foods, like human foods, be pure and wholesome, contain no harmful or deleterious substances, and be truthfully labeled. The responsibility for regulation of animal foods, including pet foods, is handled by FDA's Center for Veterinary Medicine (CVM).

Under the FFDCA, drugs and food are defined and regulated differently. The Act defines drugs, in part, as articles intended to diagnose, cure, mitigate, treat, or prevent disease, or to affect the structure or function of the body in a manner other than food. Drugs, including drugs intended for use in animals, must be approved by FDA before they can be marketed.

Based on the FFDCA definition, "food" is 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, food may provide nutrients such as protein and calcium for proper muscle and bone structure. There is no requirement that pet foods have pre-market approval by FDA. However, FDA regulates the ingredients that may be used in pet foods and works collaboratively with State regulators to ensure that products are safe and accurately labeled.

Pet food ingredients

Pet food manufacturers may only use ingredients that are deemed wholesome and safe for their intended use. Ingredients become acceptable for use in pet food via several different routes. Many ingredients used in pet foods, such as meat, poultry, grains, and their byproducts are considered traditional and safe "foods." Manufacturers may use these ingredients in pet foods with no premarket approval. Manufacturers of pet foods may also use ingredients "generally recognized as safe" (GRAS) for their intended purposes. Substances are classified as GRAS after consensus determinations by experts, qualified by training to make such determinations about the safety of substances added to foods, based on data published in the scientific literature, or in some cases because of a long history of safe use in foods. Substances that are GRAS for specific purposes in the manufacture of animal foods are listed in the Code of Federal Regulations, Title 21 (21 CFR), Part 582. They include ingredients such as mineral and vitamin sources, flavorings, spices, and essential oils. Also listed are general purpose food additives and agents that provide nutrients or serve as anticaking or emulsifying agents, sequestrants, stabilizers, or preservatives.

Sponsors may gain approval to use a new food additive not considered GRAS by submitting to FDA a Food Additive Petition (FAP). FDA reviews the petition to determine whether the new food additive is safe for its intended use and has "utility," meaning that it performs its intended use. As described in 21 CFR 571, a FAP must contain a description of the chemical identity, manufacturing process and controls, analytical methods, utility data, human food safety data, target animal safety data, product labeling, and in some cases an environmental assessment. If the FAP is approved by FDA, the additive is listed in 21 CFR 573, which describes the intended use of the additive and the specific conditions under which the additive may be safely used. Once listed, any manufacturer may use the food additive for its intended purpose unless the sponsor of the FAP has patent protection for use of the additive.

In addition to the GRAS and FAP routes for allowing food additives to be used in animal food, CVM uses regulatory discretion to permit the use of substances that do not raise any safety concerns. Rather than requiring a FAP for these substances, the new ingredient is permitted to be used in animal feed if sufficient information is available to establish a definition in the *Official Publication of the Association of American Feed Control Officials* (AAFCO). This includes information

(Continued, next page)

...Safety and Quality of Your Pet's Food *(Continued)*

on the safety and utility of the ingredient for the intended purpose and manufacturing process and control. If the information is acceptable and no safety or utility questions are raised, the ingredient is listed in the *Official Publication* for AAFCO. AAFCO is an association of Federal and State regulatory officials that provides a forum to deliberate and discuss issues affecting the sale and distribution of animal feed. CVM provides the scientific review for the new ingredients on behalf of AAFCO. A substance accepted through this AAFCO "Ingredient Definition Process" is still considered to be an unapproved food additive. However, under FDA regulatory discretion, it may be used for the intended purpose by any manufacturer.

Regardless of how a potential pet food ingredient becomes acceptable for use, it may only be used for its intended purpose. Manufacturers may not use the ingredient for a different purpose unless it first becomes GRAS, approved via a FAP, or listed by AAFCO for the new intended use.

Regulation of Pet Food Labeling

With so many products available, accurate labeling of pet foods is important so that consumers can best choose an economical product appropriate for their pet. In fact, pet food labeling is regulated at both the Federal and State level so that consumers can make accurate decisions.

CVM regulates pet food labeling at the Federal level. Federal regulations apply to all animal feeds and establish standards for proper identification of the product, the net quantity statement, proper listing of ingredients, and the manufacturer's name and address.

Some States also enforce their own labeling regulations. Many of these are adapted from model pet food regulations established by AAFCO. These regulations are more specific than the Federal ones and cover aspects of labeling, such as the product name, the guaranteed analysis, the nutritional adequacy statement, feeding directions, and calorie statements.

The AAFCO rules dictate the **product name** of the pet food based on the percentage of ingredients. The "95 per cent rule" typically applies to canned foods that contain primarily meat, poultry or fish. The name of the pet food is simple, such as "Beef for Dogs" or "Tuna Cat Food," and the primary ingredient (beef or tuna, respectively) must make up at least 95 per cent of the product, excluding water added for processing, and at least 70 per cent of the total product weight (including water). The "25 per cent rule" applies to many canned and dry products. Excluding water added for processing, the named ingredient comprises at least 25 per cent, but less than 95 per cent, of the pet food, and at least 10 per cent of the total product weight (including water). The name of the product in this case will state the ingredient, followed by terms such as "dinner," "platter," "entree," or "formula," such as "Beef Dinner for Dogs." The "3 per cent rule" allows manufacturers to add a sidebar or include in the product name the term "with" followed by an ingredient comprising 3 to 25 per cent of the product, excluding water added for processing, for example, "Beef Dinner for Dogs, with Cheese" or "Cat Food with Chicken." Finally, under the "flavor rule," a flavoring must be detectable, typically by using trained animals, although a specific percentage of the flavoring is not required. The "flavor" may actually be the stated ingredient (e.g., "beef flavor") or a substance that mimics the stated flavor.

Despite these rules on naming a pet food, consumers should still carefully read the **ingredient list** to be aware of all ingredients in the pet food and their relative predominance in the product. Regulations require that ingredients be listed in order of predominance by weight. With the "95 per cent naming rule," the main ingredient included in the product name is usually the first one listed in the ingredient list. However, with the remaining naming rules, the ingredient stated in the name may not be the primary component of the pet food. Carefully reading the ingredient list will prevent pet owners from purchasing a product with an ingredient that their pet does not like or tolerate or that pet owners do not wish to feed.

State feed regulations generally require a pet food label to have a "**guaranteed analysis**" for certain nutrients, specifically the minimum percentage of crude protein and crude fat, and the maximum percentages of crude fiber and moisture. (The term "crude" refers to a specific method of testing, not the quality of the nutrient.) Some manufacturers also will include guarantees for other nutrients. Pet food manufacturers may voluntarily include the **calorie content** per kilogram of product on labeling. Consumers should bear in mind that the guaranteed analysis and calorie content are presented on an "as-fed" or "as-is" basis, meaning that they are not corrected for moisture content. Canned pet foods tend to have about four times more moisture than dry foods. Consequently, nutrient percentages will be lower for canned (moist) pet foods versus dry products.

Savvy shoppers should pay attention to the "**net quantity statement**" on pet food labels. A 14-ounce can may look identical to a 16-ounce can, and similar

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...Safety and Quality of Your Pet's Food *(Continued)*

sized bags may contain different weights of dry food. Consumers can make a more accurate comparison of cost per unit of product by checking the net quantity statement on product containers. FDA regulations dictate the format, size, and placement of net quantity statements.

The AAFCO model pet food regulations also cover the "**nutritional adequacy statement**" on pet food labels. If the label states that the product is "complete," "balanced," "100% nutritious," or similar, the statement must be supported either through feeding trials using AAFCO protocols or through formulation with ingredients to provide levels of nutrients that meet a nutritional profile recognized by AAFCO for the species that the product is intended. The product label must indicate which method was used to substantiate nutritional adequacy. The nutritional adequacy statement may also state for which life stage(s) of the animal the product is suitable, such as "for maintenance" or "for growth."

Pet foods that are identified as being intended as snacks, treats, or feed supplements do not need to include a nutritional adequacy statement. Dog "chews," which are typically made from rawhide, bone or other animal materials, are generally exempt from all AAFCO model labeling regulations. However, FDA labeling regulations still apply, including the need for an ingredient list, net quantity statement, and manufacturer's name and address.

Consumers should not be misguided by terms such as "premium" or "gourmet" often seen on pet food labels. Feed regulations do not require that these products contain any higher quality ingredients or hold them to any higher nutritional standards compared to other pet foods. AAFCO has defined the term "natural" and published guidelines on its use in labeling pet and specialty pet products. The term "organic" refers to the conditions under which the ingredients used in products, and the product itself, were produced and must be consistent with regulations developed by U.S. Department of Agriculture. Current regulations covering organic products do not apply to pet foods, but USDA is developing regulations for the labeling of pet foods as organic.

Health information in pet food labeling

Manufacturers of pet foods are not allowed to include drug claims in product labeling, such as stating that their product will prevent or reduce the risk of a disease. This is because feed products have not undergone the rigorous testing for safety and effectiveness required for the approval of new animal drugs. However, CVM is permitting some meaningful health-related information on pet food labels. For example, Feline Lower Urinary Tract Disease is a concern for cat owners. CVM allows the labeling on cat food products to bear claims such as "to reduce urine pH to help in maintaining urinary tract health" if the sponsor provides data to demonstrate that consumption of the product is safe for cats and results in an appropriately acidic urine.

With the increased problem of obesity in pets, AAFCO model regulations permit terms such as "lite" or "low calorie" based on standard calorie references for the specific pet food product, species, and life stage. Products labeled as being lite or low calorie also must state how many calories are contained in a kilogram of food and may also list the number of calories in a familiar household measure, such as a cup or can of the product. Also, if a company makes a high calorie product and a lower calorie alternative, it may make statements such as "25% less calories than our regular product." There are also specific model regulations setting standards for pet food products claiming to be "low" or "reduced" fat products. Low or reduced fat products must provide both minimum and maximum guarantees for crude fat, and the maximum guarantee cannot exceed specified standards for specific product types. However, the model regulations do not require that calorie content be declared on low or reduced fat products.

Claims to treat or prevent gingivitis or periodontal disease are drug claims and should not appear on pet food labels. However, CVM has allowed plaque and tartar control claims for products that achieve their effects by mechanical actions, such as dry biscuits.

Pet food labels often promise "healthy skin" or a "glossy coat." Although these claims are not officially validated, they should be true for any complete and balanced product that provides adequate nutrition for a normal animal. However, statements that a pet food will benefit the skin and coat beyond normal nutritive value or is "hypoallergenic" are considered drug claims.

Regulatory action

Both FDA and State regulators monitor marketed pet food products for unacceptable ingredients, untruthful labeling, drug claims, and other violations. If violations are found, the manufacturer may receive an untitled or Warning Letter from FDA or State regulators or the product may be refused entry or distribution in a particular State or the United States until the manufacturer corrects any violations to the product's formulation

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Centennial Bike Ride Brought Out CVM's Best Spokes Folks

by Walt Osborne, M.S., J.D., Assistant Editor

A slight chill was in the morning air that hovered over the assembled cyclers that Sunday morning, September 17, when most of us were either sleeping in late or perhaps just stumbling from the coziness of our beds. But for hundreds of the more intrepid types, this would be a day to put their cycling prowess to the test: tours of 13, 25, 50, 62, and 100 miles were offered as part of FDA's Centennial Bike Ride Event in the rolling, verdant hills surrounding Berryville, VA. As the morning mist started to burn off, riders were busy stretching, checking their bikes and equipment, chatting about the day ahead, with some seeking introspection and wondering either aloud or to themselves, "Again, why am I doing this?"

The town of Berryville, located in Clarke County, with a population of about 3,000, is usually quite sleepy itself on any given Sunday morning, but not this day. Bicyclers of all ages and riding abilities had descended on this suburban jewel to take part in a Food and Drug Administration celebration to mark the 100th anniversary of the passage on June 20 of its founding law—the 1906 Pure Food and Drugs Act. The Centennial is a major milestone in FDA's history, and the 1906 law transformed FDA into a scientific regulatory agency, making it the oldest consumer protection agency in our nation.

The bike ride, which was just one in a series of events being held during 2006 to commemorate FDA's Centennial, brought together almost 1,200 riders and was held in partnership with the Potomac

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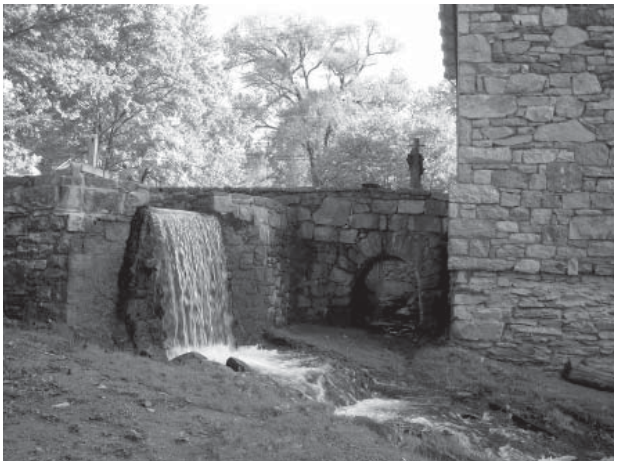


One of the scenic stops on the FDA Centennial Bike Ride Event.

Vashti Klein of CVM's Communications Staff tended the CVM booth, answering questions about the Center and explaining how it works to protect public and animal health.

...Safety and Quality of Your Pet's Food *(Continued)*

or labeling. Persistent, egregious violations that pose health and safety risks to pets could also result in court proceedings against the manufacturer.

Although pet foods do not need pre-market approval by FDA, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. This law also defines the types of records these facilities must establish and maintain.

If consumers have questions or problems concerning a pet food, they may contact the manufacturer listed on product labeling or their FDA Consumer Complaint Coordinator. The contact information for the FDA Consumer Complaint Coordinator in a person's state can be found on the internet at *http://www.fda.gov/opacom/backgrounders/complain.html*. CVM also has information on the regulation of pet food at its Web site *http://www.fda.gov/cvm/petfoods.htm*.

The combined efforts of FDA and State regulators help ensure that pet foods are safe and accurately labeled. By carefully reading pet food labeling, consumers can make informed decisions in choosing the best products for their pets.

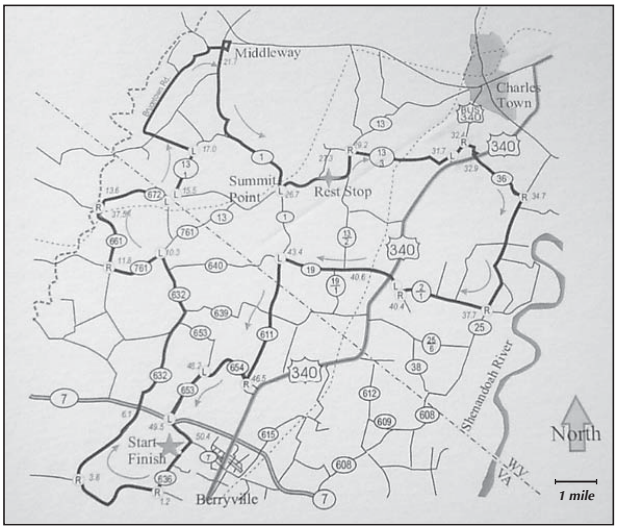
Centennial Bike Ride... *(Continued)*

Pedalers Touring Club in its annual Historic Back Roads Tour. The Club's partnership proved valuable to all the participants, lending its great reputation for a well-planned and marked route, lots of great food, and plenty of friendly volunteers to the event. But the credit must go to CVM staffers Drs. Jean-Michel Campagne, Joseph Cormier, James Nitao, and Bernadette Dunham who came up with the novel concept of a Centennial bike tour, funding sources, and lots of willing hands to fully execute the concept (not to mention donning spandex and helmets and putting pedals into action themselves!).

Clarke County High School's lobby area was the site that day of a Health Fair, coordinated by Dr. Rebecca Owen, with assistance from Drs. Bharati Dhruva, Carmen Stamper, Norman Gregory, and Michael Popek, all from CVM. The fair proved to be a great success and provided a venue for information about most of FDA's Centers (CVM, CDRH, CDER, and CFSAN, which were represented by Ms. Nancy Wynne, Mr. Louis Kaufman, and Dr. Hesha Duggirala), as well as numerous community and public health groups representing such health disciplines as Alzheimer's disease, the Amyotrophic Lateral Sclerosis (ALS) Association, hemophilia, women's health (FDA Office of Women's Health), kidney disease (the American Kidney Association), the American Lung Association, the Berryville Police Department, and veterinary medicine (Mr. Peter Schmidt represented VA-MD Regional College of Veterinary Medicine). FDA's History Office, represented by Ms. Cindy Lachin, had set up a special display on CVM's history that was very informative. It included examples of old veterinary products from other eras. A favorite was a box of "Dr. LeGear's Poultry Prescription—The Laying Tonic, a Tested Poultry Remedy." CVM's information booth was managed by communications staff member and CVM Centennial coordinator, Ms. Vashti Klein, whose boundless energy and creativity contributed to the success of the event. The booth provided visuals to depict CVM's role in drug review, monitoring and enforcement, feed safety, research and communications, and education. Traffic at the booth was brisk throughout the day, and several copies of the following CVM flyers were distributed: "Taking Care of Pets During a Disaster or Emergency," "Caution to Pet Owners—Pet Treats and Toys May Cause Problems for Your Pet," "Alert to Parents—Pet Turtles May Be Harmful to Your Children's Health," and "Selecting Nutritious Pet Foods."

A tip of the biking helmet to all of the organizers and all of the riders who gave up many hours to organize and participate in the event and color the Virginia landscape with good old fashioned FDA pride and enthusiasm. The ride provided an opportunity for FDA to lead by example through FDA employee participation in activities that encourage exercise, fitness, and overall personal health. As CVM biologist and ardent bike rider, Dr. Dragan Momcilovic, so aptly wrote on his blog site, "This ride was a great experience for me in particular because it gave me an opportunity to honor the 100th anniversary of my agency, the Food and Drug Administration." Could there be a better "spokes" person?

Dr. Elizabeth Cormier and husband Dr. Joseph Cormier, who both work at CVM and participated in the FDA Centennial Bike Ride. Dr. Joseph Cormier helped organize the ride. They are wearing the FDA bike jersey created for this event and are standing in front of the CVM exhibit booth. Several FDA Centers had booths set up at the headquarters for the bike ride, the Clarke County High School, Berryville, VA, to tell the public event participants more about FDA.



A map of the course laid out for the FDA Centennial Bike Ride Event, held September 17, 2006, in Berryville, VA, a small town across the Potomac from CVM's headquarters in Rockville, MD. The most intrepid bicyclists traveled the entire 100-mile route.

FDA Addresses Questions Under Bioterrorism Rule About Recordkeeping for Hay Sales

The Food and Drug Administration (FDA) recently addressed questions raised by farmers and livestock feeders concerning the requirements for keeping records under Federal bioterrorism rules relating to sales of hay.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorized FDA to issue regulations that require persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States to establish and keep records identifying the immediate previous sources and the immediate subsequent recipients of the food.

The provisions of the recordkeeping rule are intended to ensure that, in the event of an outbreak of foodborne illness, FDA and other authorities will be able to determine the source and cause of the event as quickly as possible. In addition, the information will improve FDA's ability to quickly notify the consumers or facilities and transporters that might be affected by the outbreak.

The regulation requires persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records. These records identify the immediate previous source of all food received, as well as the immediate subsequent recipient of all food released. Records for animal food, including pet food, must be retained for one year.

Records must be retained at the establishment where the activities covered in the records occurred or at a reasonably accessible location. Companies may keep the required information in any format, paper or electronic.

The text of the final rule and information about recordkeeping and other aspects of the rule are available at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

The definition of "food" includes animal feed, such as hay, and the recordkeeping requirements can apply to persons who handle hay. However, persons involved in operations that meet the definition of a "farm" are exempt from all of the recordkeeping requirements in the final rule. (Commodity brokers and commercial trucking operations that ship commodities, for example, are required to keep records, because they do not fall within the farm exemption.) The final rule defines a farm to include not only the growing of crops or animals, but also includes traditional farming activities that are incidental to the growing of crops and animals, such as harvesting and transporting the food to buyers. The definition of farm, as it is presented in 21 CFR 1.328 is presented below, in the answer to question 4.2.

Questions about the rule

Hay is widely produced and sold throughout the United States. When FDA released the rule about recordkeeping, it heard questions from farmers and ranchers about the rule.

The rule affects many entities and all food and animal feed under FDA's jurisdiction. Thus, FDA's Center for Food Safety and Applied Nutrition (CFSAN), which has the overall lead for developing the bioterrorism regulations under the Act, has posted a "Question and Answer" guidance document on its Web site that explains all of the bioterrorism rules as they apply to food. CFSAN worked closely with FDA's Center for Veterinary Medicine in formulating answers to the questions involving animal feed, including questions involving hay distribution. The guidance document has been updated four times, and the most recent update, issued in September, includes a full explanation of the recordkeeping requirements as they apply to hay.

Below is an excerpt of the questions and answers in the guidance document that pertain to hay. The entire question and answer document is available at *http://www.cfsan.fda.gov/~dms/recguid4.html*.

4.2 A farm grows, dries, and chops alfalfa before releasing it to another person for use as animal feed. Is the farm still exempt from this regulation?

A: FDA considers harvesting of grains and hay to be traditional farming activities covered under the farm exemption. The final rule defines a "farm" in 21 CFR 1.328 as a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting. **The term "farm" includes**: (1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. (*Emphasis added.*)

The answer to the question depends on whether the drying and chopping of the alfalfa is part of traditional harvesting activities that is within the farm exemption, or a post-harvest manufacturing/processing activity that is subject to the rule. FDA considers "harvesting" as encompassing those activities traditionally performed during the removing of a crop from the field through the safe storage of the crop. Thus, drying and chopping activities that are an essential

(Continued, next page)

...Recordkeeping for Hay Sales *(Continued)*

part of the harvest process and which are traditional farming operations for a particular crop are activities covered by the "farm" definition, as long as all other conditions of the "farm" definition are met. For example, the harvesting of hay typically includes the cutting in the field, drying, baling, and storage of the hay. (With hay, drying is particularly important to prevent spontaneous combustion from occurring.) If, however, a farmer were to remove cut hay from storage and chop the hay to make hay cubes to sell, then establishment and maintenance of records would be required, as FDA considers this activity manufacturing/processing of the already stored hay. (This is similar to chopping carrots into 3-inch slices after they are harvested for sale as snack foods; such activity is not integral to harvesting the carrots and is a post-harvest manufacturing/processing activity subject to the rule, unless the carrots are consumed on the farm on which grown or another farm under the same ownership.)

"Manufacturing/processing" as defined in Sec. 1.328 means "making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging." As stated above, under Sec. 1.328 of the final rule, a farm can manufacture/process food and retain its exemption under the rule, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

4.5 I am a hay grower that will bale some of my hay and make ensilage out of the rest. What does FDA consider as "harvesting" as it is used in the definition of "farm" in 21 CFR 1.328? Does drying my hay naturally in the field versus drying my baled hay artificially with blower fans in my barn prior to storage make a difference in whether I am considered exempt as a farm under the final rule?

A: FDA interprets harvesting as the activities traditionally performed during the removing of a crop from the field through the safe storage of the crop. As stated in the answer to Question 4.2, the harvesting of hay includes the cutting, drying, baling, and storage of the hay. Whether the hay is dried naturally in the field or on racks in front of fans before being placed in storage does not change the status of a "farm" since the harvesting of hay requires proper drying before it can be safely stored. However, if you were to remove the hay from storage and chop the hay to make hay cubes to sell, then establishment and maintenance of records for the hay cubes would be required for this activity (but not the growing and harvesting of the hay), since this activity is considered manufacturing/processing of the already stored hay. Further, the ensiling process of cutting grass off the field and blowing the wet grass into a silo for preservation is a traditional harvesting activity that falls within the farm exemption.

4.6 If I sell hay that I grow on my farm to another farm, am I subject to the establishment and maintenance of records provisions in the final rule?

A: No, you do not have to establish and maintain records for the hay you grow and sell to another farmer or to a direct consumer, such as a person that owns pleasure horses. Harvesting also includes releasing the crop to another person. Thus, activities associated with the selling of the crop, such as transportation of the hay by the farmer either directly or through a third-party transporter to a buyer is included within the farm exemption. As discussed in the response to Comment 67 in the final rule preamble, a farm that transports its products from the field does not cease to be a "farm" because such transportation is considered incidental to traditional farming activities. However, if you purchase hay from another farm under different ownership to resell, then you have to establish and maintain records related to the hay you receive and release in accordance with 21 CFR 1.337 and 1.345, respectively.

For example, if Abe, a farmer, grows hay on his farm and feeds it to his livestock on that farm or another farm under the same ownership, he does not need to establish and maintain records. Or, if Abe sells the hay that he grew and harvested to Betty who has another farm for her use to feed livestock on her farm, neither Abe nor Betty have to establish and maintain records regarding the hay, provided each meets the definition of farm in 21 CFR 1.328. On the other hand, if Abe sells his hay to Charlie, who runs a brokerage company and has bought the hay to resell it, then Charlie must establish and maintain records of the hay he receives and releases in accordance with 21 CFR 1.337 and 1.345, respectively. For example, if Abe sells his hay to Charlie, who in turn sells it to Betty to feed her cattle, Charlie must establish and maintain records to identify the immediate previous sources (including Abe) and immediate subsequent recipients (including Betty) of the hay. Brokering hay is not a normal farm activity, and Charlie would be considered a distributor of the hay subject to the rule. Under 21 CFR 1.326(a), persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in Subpart J, unless they qualify for one of the exclusions in 21 CFR 1.327. Abe and Betty do not need to establish and maintain records as long as they meet the definition of a farm.

4.7 Does a farm have to keep records of who transported hay that was bought or sold?

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Ask CVM

Q: Does CVM have specific information about dog products for specific breeds of dogs? Also, if my pet is allergic to brewer's yeast, would an ingredient referred to as "yeast culture" yield the same allergic reaction?

A: CVM regulates the manufacture and distribution of food additives and drugs that will be given to animals. As a regulatory agency, FDA cannot recommend any one pet product over another. Specific questions should be presented to a veterinarian who knows the pet's specific health and nutritional needs. Information is also available on CVM's Pet Food Page (*http://www.fda.gov/cvm/petfoods.htm*) and CVM's Information for Consumers fliers posted on *http://www.fda.gov/cvm/consumer.html*.

Q: We are an overseas firm seeking to market a pet enzyme product in the United States and need to obtain an FDA certificate. What do we need to do?

A: In order to receive permission to import this product into the United States, you will need to send a letter describing your product and include copies of all labels and other promotional materials so that CVM can determine the regulatory status of your product (whether it is a food or a drug). Do not send a sample of the product. Send your letter to:

Division of Compliance (HFV-230)
Center for Veterinary Medicine/FDA
7519 Standish Place
Rockville, MD 20855

Q: I want to export to Japan a pet food product made by a U.S. firm and need to know the meat grading system used by FDA to ensure quality.

A: All meat grading is under the jurisdiction of the U.S. Department of Agriculture/Agricultural Marketing Service (USDA/AMS). You should contact them directly for additional information on meat grading (see *http://www.ams.usda.gov/*). CVM would also recommend that you contact the manufacturer and ask for documentation of the grade of the product being used.

Q: We are starting a pet food home delivery business and are also experimenting with making homemade dog biscuits and marketing them as dog treats. What needs to be on the package label? Also, can you recommend a good food manufacturer for private labeling?

A: CVM has information on its homepage that should answer many of your questions—*http://www.fda.gov/cvm/petfoods.htm*. You also may be interested in looking at the Web sites of the American Feed Control Officials at *www.aafco.org* and the Pet Food Institute at *www.petfoodinstitute.org*. As a regulatory agency, FDA cannot recommend a manufacturing company for you.

Q: Are there Recommended Daily Allowances (RDAs) for dogs, particularly for sodium?

A: There are no RDAs yet for dogs. There will be an equivalent if/when the "new" Nutrient Requirements for Dogs and Cats publishes. The minimum daily sodium (Na) requirement for dogs is rather low and not particularly challenging to meet. The 1985 National Research Council Nutrient Requirements of Dogs listed the minimum requirement as 11 milligrams (mg) Na per kg body weight for adult maintenance in a 10 kg dog eating 742

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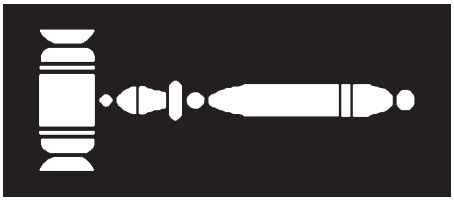
...Recordkeeping for Hay Sales *(Continued)*

A: No. If the hay was transported by the farm/seller (Abe in the example above) or farm/buyer (Betty), no transportation records are needed. Trucks used as part of a farm operation fall within the definition of farm in 21 CFR 1.328, and are exempt from all of the requirements in Subpart J. However, if the hay was transported by a person that does not meet the definition of a farm, such as a commercial trucking operation, then the transporter must establish and maintain records as provided in 21 CFR 1.352.

4.8 I mix my corn and haylage with a commercial protein supplement to feed my cattle. Do I need to keep records?

A: No. The definition of farm, 21 CFR 1.328, includes "facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership." As discussed in the response to Comment 67 in the preamble to the final rule, to ensure that FDA is fulfilling Congress's intent to exempt "farm," FDA revised the definition of a farm in the final rule to include manufacturing/processing activities as long as all food used in such activities is consumed on that farm. Therefore, establishment and maintenance of records is not required for this on-farm mixed feed, as long as the mixture is fed to animals on the farm or another farm under the same ownership. However, records would need to be kept if the mixed feed is released to someone other than a farm under the same ownership. Mixing the corn and haylage with a commercial supplement constitutes manufacturing/processing and falls outside the traditional farming activity once the feed is distributed to anyone other than another farm under the same ownership.

Regulatory Activities for August and September 2006



The offering for sale of animals adulterated under sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FFDCA) has led to the issuance of a WARNING LETTER to Todd R. Meech of Sebeka, MN. The action follows an investigation that also revealed the new animal drugs penicillin G procaine, tylosin, oxytetracycline, and lincomycin were adulterated and unsafe, pursuant to provisions in the FFDCA. The adulteration was caused by the presence of neomycin in amounts that exceeded the established tolerance of 7.2 ppm by as much as 100 percent. The investigation revealed that animals were being held under conditions that were so inadequate that medicated animals bearing potentially harmful drug residues were likely to enter the food supply. The animal drugs mentioned above were being used "extralabel" in that they were not being used in accordance with the approved labeling. Specifically, the drugs were not administered by a licensed veterinarian.

The identical provisions of the FFDCA were cited in a WARNING LETTER issued to Steven L. VanderHoff, member/owner of Vreba-Hoff Dairy, LLC, Hudson, MI. An inspection of this dairy operation revealed that a dairy cow that was offered for slaughter for human food contained residues of penicillin in kidney tissue that exceeded the established tolerance as set forth in Title 21, Code of Federal Regulations, Part 556 (21 CFR 556.510). Similarly, another dairy cow had been offered for slaughter for use in human food bearing residues of oxytetracycline in the liver and the muscles in excess of the established tolerance as set forth in 21 CFR 556.500. In addition, an approved animal drug was administered via a route—intrauterine—that was not indicated in the labeling, without benefit of a valid veterinarian-client-patient relationship, and adequate treatment records were not maintained.

Significant deviations from the Current Good Manufacturing Practice (cGMP) regulations for Medicated Feeds (21 CFR 225) were noted in a WARNING LETTER issued to Steve J. VanRoekel, president & CEO of Ridley, Inc., the parent company of Hubbard Feeds, Mankato, MN. These deviations caused the feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the FFDCA. The investigation found that the firm's continued use of the Type A medicated article, oxytetracycline, in the manufacture of medicated feeds after the drug had reached its labeled expiration date caused the drug to be deemed unsafe within the meaning of section 512(a)(1) of the FFDCA and adulterated within the meaning of section 501(a)(5) of the FFDCA. Additionally, the use of oxytetracycline to produce medicated feed caused the product to be unsafe under section 512(a)(2) of the FFDCA.

A WARNING LETTER was issued to Kent W. Pulfer, DVM, managing partner of MPM Farms, Wayne, NE, because an investigation of the dairy operation confirmed that animals being offered for sale for slaughter as food were adulterated under section 402 of the FFDCA. In addition, the investigation revealed that MPM Farms caused Quartermaster® Dry Cow Treatment brand of penicillin and dihydrostreptomycin to become adulterated and unsafe under sections 501 and 512, respectively, of the FFDCA. Specifically, one dairy cow contained residues of ampicillin in the kidney tissue exceeding the established tolerance set forth in 21 CFR 556.40. A second dairy cow offered for slaughter and use as food was found to contain residues of dihydrostreptomycin in the kidney tissue exceeding the established tolerance set forth in 21 CFR 556.200. In both instances, the firm failed to maintain treatment records. The Quartermaster® Dry Cow Treatment brand of penicillin was found to be adulterated because it was being used extralabel in a manner that did not comply with specific provisions of the FFDCA that address the appropriate withdrawal period.

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Ask CVM *(Continued)*

kcal or metabolizable energy (ME) per day and 30 mg Na per kg body weight for growth in a 3 kg Beagle puppy eating 600 kcal ME per day. For growth, this translates into about 0.15 grams (not milligrams) per 1000 kcal ME or about 0.09% Na on a dry matter basis. AAFCO's Dog Food Nutrient Profiles, which might be viewed as somewhat representative of an RDA, list a recommended Na-content of 0.2% on a dry matter basis for both growth and adult maintenance, and 0.86 grams per 1,000 kcal ME for growth and 0.17 grams per 1000 kcal ME for adult maintenance.

If you would like to know about all of the vitamins and minerals, you should purchase an AAFCO *Official Publication* from AAFCO (located at the following url: *http://www.aafco.org/OrderAAFCOPublications/tabid/75/Default.aspx*) and/or a Nutrient Requirements of Dogs publication from the National Academy Press (located at the following url: *http://www.nap.edu/bookstore.html*).

Regulatory Activities... *(Continued)*

An adulterated slaughter dairy cow that was offered for sale as food in violation of sections 402 and 512 of the FFDCA was cited as the basis for a WARNING LETTER issued to Calvin and Mike Berwald, partners in Berwald Dairy, Toronto, SD. Specifically, the cow in question contained residues of tilmicosin in liver and muscle tissue exceeding the established tolerance set forth in 21 CFR 556.735. In addition, the firm was cited for holding medicated animals under conditions that could have resulted in potentially harmful drug residues entering the food supply; treatment records were also lacking. The firm was also in violation of section 512 of the Act in that tilmicosin was being used extralabel because a licensed veterinarian was not administering the drug.

Residues of sulfadimethoxine in a dairy cow's liver and muscle tissues exceeding established tolerances have led to the issuance of a WARNING LETTER to Timothy M. Potter, owner of John Potter Farm, LLC, Washington, CT, because the cow was offered for sale as human food. The high levels of the drug in the animal's tissues caused it to be adulterated within section 402 of the FFDCA. FDA investigators determined that the firm: (1) failed to maintain an adequate recordkeeping system for determining the medication status of animals offered for slaughter; (2) failed to maintain an adequate record system for ensuring that animals receiving medication were withheld from slaughter for appropriate periods of time; and (3) failed to maintain an adequate system for ensuring that drugs were used in a manner not contrary to the directions contained in the labeling.

Flunixin residues in a dairy cow offered for slaughter as food exceeding established tolerances set forth in 21 CFR 556.286 served as the basis for a WARNING LETTER issued to Louis and Carol Calcagno, co-owners of Moon Glow Dairy, Moss Landing, CA. The presence of flunixin at inappropriate levels caused the animal to be adulterated within the meaning of section 402 of the FFDCA. The investigation also revealed that medicated animals were being held under conditions that would likely lead to the drug residues entering the food supply. Complete treatment records and an adequate inventory system for determining the quantities of drugs to medicate the dairy's animals were lacking. In addition, flunixin was being used extralabel in violation of 21 CFR 530 and section 501(a)(5) of the FFDCA. Other violations revealed in the investigation included the routine, extralabel administration of penicillin G procaine and the use of the drug Baytril 100 (enrofloxacin); enrofloxacin is not approved for use in cattle intended for dairy production of calves to be processed for veal, and its use by the firm was in violation of 21 CFR 530.41.

A WARNING LETTER was issued to Lloyd North, Stanley, NY, for offering a dairy cow for slaughter as food in violation of section 402 of the FFDCA because it contained residues of flunixin in the liver tissue that exceeded the established tolerance set forth in 21 CFR 556.286. In addition, the operation lacked complete written treatment records and documentation showing route of administration and withdrawal times for milk and beef. In addition, the flunixin used was found to be adulterated under section 501(a)(5) of the Act because it was used extralabel; specifically, the wrong route of administration was used, and it was not administered under the supervision of a licensed veterinarian as required by 21 CFR 530. Because of this extralabel use, the drug was also found to be unsafe under section 512(a) of the FFDCA.

Neomycin residues in the tissues of a bull calf offered for sale as human food exceeding the established tolerances set forth in 21 CFR 556.430 resulted in the issuance of a WARNING LETTER to William W. and Barbara L. Young, majority partners and Principal Operators of Will-O-Crest Farms, LP, Clifton Springs, NY. The presence of neomycin at higher levels than authorized caused the animal to be adulterated under section 402 of the FFDCA. The firm used a calf milk replacer (medicated feed) that contained neomycin and oxytetracycline in calves to be processed for veal, contrary to the warning on the label. The extralabel use of the drugs caused the medicated feeds to be unsafe under section 512 and adulterated under section 501 of the FFDCA. Earlier violations included the use of flunixin in a slaughter cow destined for food use at a level exceeding the established tolerance set forth in 21 CFR 556.286. In addition, the drug was not used in conformance with approved labeling.

False and misleading claims in promotional materials for Heartgard® Plus (ivermectin/pyrantel) products for dogs and cats led to the issuance of a WARNING LETTER to Liubov Skibo, Director of Regulatory Affairs at Merial Limited, Duluth, GA. Heartgard® Plus is an oral chewable formulation approved for the prevention of canine heartworm disease and the treatment and control of ascarids and hookworms. In previous letters, FDA had requested that the firm stop claiming 100 percent effectiveness for heartworm prevention. This request was based on the post-approval adverse drug event reports received concerning lack of effectiveness for heartworm prevention. However, the requests were ignored by the firm and the claim continued to be made. As a result, the promotion of the products bearing this claim rendered them false, misleading, and misbranded under section 502(a) of the FFDCA. The Warning Letter requested that the firm immediately cease disseminating the violative promotional materials.

Approvals for New Animal Drugs for August and September 2006

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

ZILMAX (zilpaterol hydrochloride 4.8%) Type A medicated article (NADA 141-258), filed by Intervet Inc. The NADA provides for the use of this Type A medicated article to formulate Type B (liquid and dry) and Type C medicated cattle feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed. Notice of approval was published September 8, 2006.

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

NEOMIX 325 (neomycin sulfate) Soluble Powder (ANADA 200-378), filed by Sparhawk Laboratories, Inc. The ANADA provides for the use of neomycin soluble powder in cattle, swine, sheep, goats, and turkeys for the treatment and control of bacterial enteritis. Based on the formulation characteristics of the generic product, Sparhawk Laboratories, Inc., was granted a waiver from the requirement of an in vivo bioequivalence study for the generic product, Neomycin Sulfate 325 (neomycin sulfate). The generic product is administered as a soluble powder, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, NEOMIX 325 (neomycin sulfate) Soluble Powder was the subject of NADA 011-315, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. Notice of approval was published September 28, 2006.

AMPROLIUM 9.6% Oral Solution (ANADA 200-389), filed by IVX Animal Health, Inc. The ANADA provides for the use of Amprolium 9.6% Oral Solution to make medicated drinking water or as a drench for the prevention or treatment of coccidiosis in calves. IVX Animal Health's Amprolium 9.6% Oral Solution is approved as a generic copy of Merial Limited's CORID (amprolium) 9.6% Solution, approved under NADA 13-149. Notice of approval was published September 27, 2006.

LINCOMED 100 and LINCOMED 300 (lincomycin hydrochloride) (ANADA 200-368), filed by Cross Vetpharm Group Ltd. The ANADA provides that both products are approved as generic copies of LINCOMIX 100 Injectable and LINCOMIX 300 Injectable, sponsored by Pharmacia & Upjohn Co., a division of Pfizer, Inc., under NADA 034-025. Lincomycin hydrochloride is used in swine for the treatment of infectious arthritis caused by staphylococci, streptococci, Erysipelothrix, and Mycoplasma spp., and for the treatment of mycoplasma pneumonia. Notice of approval was published on September 1, 2006.

GENTAMICIN SULFATE SOLUTION filed by Sparhawk Laboratories (ANADA 200-395). The ANADA provides for the use of the product for the control of bacterial infections of

(Continued, next page)

Approvals for August and September 2006 *(Continued)*

Abbreviated New Animal Drug Applications (Continued)

the uterus (metritis) and as an aid in improving conception in mares with uterine infections cause by bacteria sensitive to gentamicin. The sponsor's gentamicin sulfate solution is approved as a generic copy of Schering-Plough Animal Health Corporation's Gentocin (gentamicin sulfate) Solution Veterinary, approved under NADA 46-724. Notice of approval was published August 31, 2006.

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

DRAXXIN (tulathromycin) injectable solution filed by Pfizer, Inc. (NADA 141-244). The supplemental NADA provides for the addition of a pathogen, Mycoplasma bovis, to the indication for use of tulathromycin solution in cattle, by subcutaneous injection for the treatment of bovine respiratory disease. This supplemental approval qualifies for 3 years of marketing exclusivity, beginning August 18, 2006. Notice of approval was published September 29, 2006.

BOVATEC 91 (lasalocid) Type A medicated article (NADA 141-171), filed by Purina Mills, Inc. The supplemental NADA provides for the use of a lasalocid Type A medicated article containing 20 percent lasalocid activity per pound for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). Notice of approval was published September 26, 2006.

AUREOMYCIN 90 Granular (chlortetracycline) Type A medicated article to formulate a free-choice loose mineral Type C medicated feed for beef and nonlactating dairy cattle (NADA 48-761), filed by Alpharma Inc. The supplemental NADA provides for the use of chlortetracycline as an aid in the control of active infection of anaplasmosis caused by Anaplasma marginale susceptible to chlortetracycline. Notice of approval was published September 13, 2006.

TERRAMYCIN 100MR (oxytetracycline dihydrate) Type A medicated article (NADA 95-143), filed by Phibro Animal Health. The supplemental NADA provides for the revision of labeling of the product, which is approved for treating various bacterial diseases of livestock, with the current genus for the causative bacteria for American foulbrood of honeybees. Notice of approval was published September 8, 2006.

CORID (amprolium) Type A Medicated Article 25% (NADA 12-350), filed by Merial Ltd. The supplemental NADA provides for formulation of Type C medicated calf feeds used for the prevention and treatment of coccidiosis caused by Eimeria bovis and E. zurnii at a broader range of concentrations. Specifically, it was determined that the original feeding range of amprolium of 0.05 to 1.25 percent was too narrow to encompass all calves at the range of body weights and different possible dry matter intake levels. Therefore, the minimum allowable concentration of amprolium in Type C medicated feed has been lowered from 0.05 percent to 0.0125 percent amprolium making the feeding range 0.0125 to 1.25 percent (113.5 g/ton to 11,350 g/ton). Notice of approval was published September 6, 2006.

(Continued, next page)

Approvals for August and September 2006 *(Continued)*

Supplemental New Animal Drug Applications (Continued)

TERRAMYCIN (oxytetracycline dihydrate) for Fish Type A medicated article filed by Phibro Animal Health (NADA 38-439). The supplemental NADA provides for the approval of the dihydrate salt of oxytetracycline, a change of oxytetracycline concentration in the Type A medicated article, and the addition of an indication for the control of gaffkemia in lobsters. Notice of approval was published August 8, 2006.

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

TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP ointment) (ANADA 200-287), filed by IVX Animal Health, Inc. The supplemental ANADA provides for a new container size, a 40-gram dropper bottle, to administer the drug, which is approved for the treatment of acute and chronic canine otitis externa. Notice of approval of the supplemental ANADA was published September 28, 2006.

NOVOX (carprofen) caplets (ANADA 200-366), filed by IMPAX Laboratories, Inc. The supplemental ANADA provides for the use of Novox caplets for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs. Notice of approval was published September 1, 2006.

DEPARTMENT OF
HEALTH & HUMAN SERVICES

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07-0096