
Chapter 5 – Center for Veterinary Medicine

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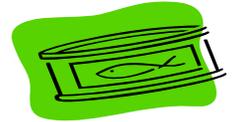
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Animal Feed

Menu Pet Food Recall

FDA Tackles One of the Largest Pet Food Recalls in History

In March of 2007, a massive recall of pet food products manufactured by Menu Foods, Inc., a private-label pet food manufacturer based in Streetsville, Ontario, Canada, was initiated. On March 16, 2007, Menu Foods announced that it was recalling all its "cuts and gravy" style dog and cat food produced at its facility in Emporia, Kansas, between December 3, 2006, and March 6, 2007.



The recall was prompted by consumer complaints received by Menu Foods of kidney failure in a number of cats and dogs. Menu Foods began conducting its own tasting trials and reported instances of kidney failure after the animals ate the affected product. As of March 17, 2007, Menu Foods reported 14 animal deaths to the FDA. Nine cats died during routine taste trials conducted by Menu Foods. The products involved in the recall were sold in the United States, Canada and Mexico.

FDA consumer complaint coordinators nationwide began receiving calls from consumers and veterinarians who reported illnesses potentially associated with the contaminated pet food. In the first three weeks of the recall, FDA received over 12,000 reports – more than twice the number of complaints typically received in a year by the consumer complaint coordinators.

Initially, the recall was limited to "cuts and gravy" style pet food in cans and pouches of dog and cat food Menu Foods manufactured between December 3, 2006, and March 6, 2007.

Recalled pet foods later included cat, dog, and ferret foods. A complete list of pet foods affected by the recall is available on a website at: <http://www.accessdata.fda.gov/scripts/petfoodrecall>. The foods are listed by type of pet food and then alphabetically.

Finding the Cause

In March 2007, FDA learned that certain pet foods were sickening and killing cats and dogs. Analysis by the Agency's Forensic Chemistry Center revealed melamine and melamine analogues in the pet foods and in the wheat gluten used as an ingredient. After FDA traced the suspect wheat gluten to a single supplier in



China, the Agency issued an Import Alert focused on this firm and began sampling 100 percent of all wheat gluten from China. In April 2007, FDA launched an investigation into imported rice protein concentrate that also was used as an ingredient in some pet foods and was found to contain melamine and its analogues. The Agency traced the suspect product to another Chinese supplier. FDA issued an Import Alert focused on this supplier and began sampling 100 percent of all rice protein concentrate from China.

Melamine is a molecule that has a number of industrial uses, including use in manufacturing cooking utensils. It has not been approved for use as an ingredient in human or animal food in the U.S., and it is not permitted to be used as fertilizer in the U.S., as it is in some parts of the world.

Ultimately, Import Alert #99-29 was issued on April 27, 2007, to expand on the previous alerts to cover all vegetable protein products from China. Under the Import Alert, FDA can refuse admission of these products unless third party analysis or other evidence demonstrates they are not contaminated with melamine or its analogues. To read the full text of this Import Alert, go to: http://www.fda.gov/ora/fiars/ora_import_ia9929.html.

During the investigations that traced the distribution of contaminated pet food, it was discovered that byproducts (or scraps) from the manufacture of this pet food were distributed to farms in a limited number of states and added to the feed consumed by swine and poultry. A panel of scientists from five Federal agencies determined that consuming food from the animals that ate the tainted feed was unlikely to pose a significant risk to human health, due to the small amounts of contaminant present and the small amounts that would be consumed.

The full text of the safety assessment of melamine in foods is available online at: <http://www.cfsan.fda.gov/~dms/melamra.html>.

Castleberry's Dog Food Recall

Castleberry's Food Products - Including Canned Dog Food - Found Contaminated with *Clostridium botulinum*

On July 19, 2007, Castleberry's Food Company ("Castleberry's"), Augusta, Georgia, owned by Bumble Bee Foods, LLC,



recalled multiple food products – including canned dog food – due to possible contamination with the bacteria *Clostridium botulinum*, known to cause botulism.

Subsequently, on July 21, 2007, “Castleberry’s” voluntarily expanded its July 19th recall of canned meat products due to possible contamination with *Clostridium botulinum* after information gathered by FDA and U.S. Department of Agriculture (USDA)/Food Safety Inspection Service (FSIS) indicated that processing malfunctions at the establishment existed longer than initially estimated.

For that reason, “Castleberry’s” agreed to expand its recall of all products that still might be in commerce, regardless of the “best buy” date stamped on the bottom of the can. A complete list of all products subject to recall can be found on the USDA’s website at:

http://www.fsis.usda.gov/News_&_Events/Recall_033_2007_expanded/index.asp. Products include both products for human consumption such as beef stew, chili, hot dog chili sauce, etc., and pet food products.

Dog foods subject to recall included the following products:

- Irish Stew Natural Balance Eatables for Dogs;
- Chinese Take Out with Sauce with Vegetables & Chicken Natural Balance Eatables for Dogs;
- Southern Style Dumplings with Gravy with Chicken & Vegetables Natural Balance Eatables for Dogs; and,
- Hobo Chili with Chicken Pasta Natural Balance Eatables for Dogs.

Consumers who had any of these products or any foods made with these products were advised to throw them away immediately. Consumers were instructed to double bag the cans in plastic bags that are tightly closed, then to place them in a trash receptacle for non-recyclable trash outside of the home.

Additional instructions for safe disposal can be found at:

www.cdc.gov/botulism/botulism_faq.htm.

Salmonella in Dry Dog Food Recall

CDC Reported 64 Cases of Human Illnesses Traced to Contaminated Dog Food

On August 25, 2007, FDA alerted consumers that Mars Petcare US, Inc., was recalling two dry dog food products because of the potential that the product was contaminated with *Salmonella* Schwarzengrund.

Mars Petcare US, based in Franklin, Tennessee, voluntarily recalled five-pound bags of Krasdale Gravy dry dog food sold in Connecticut, Massachusetts, New Jersey, New York, and Pennsylvania, and 50-pound bags of Red Flannel Large Breed Adult Formula dry food sold in Pennsylvania.

Salmonella can potentially be transferred to people handling pet food, especially if they have not thoroughly washed their hands after having contact with the product or any surfaces exposed to the product. As of August 25th, there had been 64 cases of illness in humans related to *Salmonella* Schwarzengrund reported to the U.S. Centers for Disease Control and Prevention (CDC). However, none of the reported cases were directly linked to the recalled product that was tested. FDA worked with local and state officials, and with officials at the CDC in the investigation.

To view the full text of FDA's Press Release related to this recall, go to: <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01689.html>.

Warning - Cat Food With Salmonella



On February 13, 2007, FDA issued a warning to consumers not to purchase, or use, Wild Kitty Cat Food due to the presence of *Salmonella*, a pathogen. During routine monitoring activities, FDA collected and analyzed a sample of frozen raw Wild Kitty Cat Food and detected *Salmonella* in the product. Cats and other pets consuming this food may become infected with *Salmonella*. People can also become infected with *Salmonella* if they handle or ingest this cat food, touch pets that consumed the food, or touch any surfaces that came into contact with the food or pets.

The specific products covered by this warning were Wild Kitty Raw All Natural, Frozen Cat Food - Chicken with Clam Recipe, Net Wt. 3.5 ounce (100g) and 1 pound in plastic containers; Raw Duck with Clam Recipe, Net Wt. 3.5 ounce (100g) and Net Wt. 16 ounce (453.6g); and Raw Tuna with Conch Recipe 3.5 ounce (100g) all lot codes.

The Wild Kitty Cat Food was sold nationwide to retail stores and through distributors and internet sales, nationwide. The manufacturer declined to recall this product despite several requests by FDA that it do so.

FDA advised that consumers who purchased this product should not feed it to their pets, but should instead dispose of it in a safe manner (e.g., in a securely covered trash receptacle). Anyone who experienced the symptoms of *Salmonella*

infection after having handled the product were advised to seek medical attention, and report use of the product and illness to FDA's Office of Emergency Operations. In addition, people with concerns that they may have contracted *Salmonella* were instructed to contact their medical doctors and the local health departments. People who were concerned that their pet may have been infected with *Salmonella* were advised to contact their veterinarian.

To view the full text of the Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01562.html>.

To read the full text of the Import Alert go to:

http://www.fda.gov/ora/fiars/ora_import_ia9929.html

Testimony: <http://www.fda.gov/ola/2007/melamine050907.html>

The Warning Letters presented in this chapter were chosen to provide examples of the types of Warning Letters issued for violations of FDA laws and regulations. A list of Warning Letters issued by FDA is available at:
<http://www.fda.gov/foi/warning.htm>.

Warning Letter Issued for Salmonella in Dog Chews

FDA Inspection Finds *Salmonella muenster* In Dog Chews

On June 11, 2007, FDA's Seattle District Office issued a Warning Letter to TW Enterprises, Ferndale, Washington. An inspection



was conducted by a representative of FDA on January 18 and 23, 2007. A sample of "AMERICAN BULLIE A .B . DOG CHEW, 6" MEDIUM," manufactured by this facility was collected and analyzed. FDA analysis of this dog chew revealed the product to be contaminated with *Salmonella muenster*. *Salmonella*, including *Salmonella muenster*, is a micro-organism that is known to be pathogenic to animals and humans. Dog chews bearing or containing *Salmonella* pose a danger to human and animal health and are adulterated

The FDA inspection of this firm in January 2007, revealed the practice of allowing pizzles to thaw overnight, then to submerge them in gallons of water containing bleach. Household bleach is not approved for use in animal feeds. The

Warning Letter advised that the firm should have either contacted the FDA before use of the bleach or filed a food additive petition to establish the safety and utility of bleach for its intended use.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/s6402c.htm.

Nationwide Recall - *Salmonella* in Jerky Treats

On March 30, 2007, Eight In One, Inc. of Hauppauge, New York, a division of United Pet Group, Inc., announced that the firm was recalling nationally all lots of Dingo® Chick'n Jerky treats due to company concerns that the jerky treats have the potential to be contaminated with *Salmonella*, which can cause serious infections in dogs and cats, and, if there is cross contamination, in people, especially children, the aged, and people with compromised immune systems. The Eight In One products affected were sold at Target, PetSmart and other retailers. The products subject to this voluntary recall are Dingo Chicken Jerky 3.5 ounce. and 8 ounce for dogs and Dingo Kitty Chicken Jerky 1.5 ounce for cats and Dingo Ferret Chicken Jerky 1.5 oz for ferrets.

Pets with *Salmonella* infections may be lethargic and have diarrhea or bloody diarrhea, fever, and vomiting. Some pets will have only decreased appetite, fever and abdominal pain. Apparently well animals can be carriers and infect other animals or humans.

Recall of Feed Ingredients

FDA Asks Feed Manufacturers to Avoid Adding Ingredients Containing Melamine

On May 30, 2007, FDA issued a Press Release alerting livestock and fish/shrimp feed

manufacturers about a voluntary recall of products used in feed production because several were found to contain melamine and related compounds. The feed ingredients were made by Tembec BTL SR Inc., of Toledo, Ohio, and Uniscope, Inc., Johnstown, Colorado.

Tembec, a contract manufacturer for Uniscope, makes AquaBond and Aqua-Tec II, which it distributes for Uniscope. Uniscope makes Xtra-Bond using

ingredients supplied by Tembec. All of the products are binding agents that are used to make pelleted feed for cattle, sheep, and goats, or fish and shrimp.

The companies confirmed that Tembec added melamine as part of the formulation of the products to improve the binding properties of pelleted feed. Melamine is not approved as an additive for animal or fish/shrimp feed. The companies stopped adding melamine to the feed products.

Based on the levels of melamine and related compounds in the initial ingredients, FDA estimated the probable level of melamine and related compounds in livestock feed was less than 50 parts per million (ppm) based on the recommended mix rate of two to four pounds of binding agent per ton of livestock feed. The estimated levels in fish and shrimp feed were less than 233 ppm and 465 ppm, respectively, of melamine and related compounds. The estimated levels of melamine and related compounds varied in the livestock feed and the fish and shrimp feed because of differing levels of melamine in the binding agents used for each type of feed.

In the most extreme scenario considered in the assessment, scientists assumed that all the solid food a person consumes in an entire day was contaminated with melamine at the levels observed in animals fed contaminated feed. In this scenario, the potential exposure to humans was about 2,500 times lower than the level considered safe. In other words, it was well below any level of public health concern.

To view the full text of FDA's assessment of melamine, go to:
<http://www.fda.gov/consumer/updates/melamine051407.html>

Animal Drugs

Injunctions

Consent Decree of Permanent Injunction Nova-Tech, Inc., and Gloria J. Thesenvitz

On September 25, 2007, U.S. District Judge Richard G. Kopf entered a Consent Decree of Permanent Injunction against Nova-Tech, Inc. and the firm's president, chief executive officer, and owner, Gloria J. Thesenvitz, (collectively the "defendants") after the defendants introduced into interstate commerce animal drugs that were manufactured, processed, packed, labeled, and held in violation

of CGMPs, causing them to be adulterated under the Federal Food, Drug, and Cosmetic Act (the Act).

Under the terms of the Consent Decree, the defendants are permanently restrained and enjoined from introducing or causing to be introduced into interstate commerce any article of drug that is adulterated, and permanently restrained and enjoined from causing any article of drug to become adulterated after shipment of one or more of its components in interstate commerce.

Pursuant to the Consent Decree, the defendants are required to retain an auditor to conduct inspections of their facilities not less than once every six months for a period of five years and provide reports to FDA analyzing the defendants' compliance with CGMPs. Further, the Consent Decree provides for FDA to order a recall or shutdown in the event of future violations. Lastly, the Consent Decree requires defendants to reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses.

Consent Decree of Permanent Injunction Sparhawk Labs., Inc.

On August 9, 2007, U. S. District Judge Carlos Murguia entered a Consent Decree of Permanent Injunction against Sparhawk Laboratories, Inc. and its co-owners, Everett Bert Hughes and John U. Bascom. Pursuant to the terms of the Decree, Sparhawk is enjoined from manufacturing and distributing animal drugs until the firm remedies its numerous violations of CGMPs for drugs.

The terms of the Consent Decree require the defendants to, among other things: hire an expert to perform a comprehensive inspection of the defendants' facilities to ensure that the firm is complying with CGMPs; the expert must certify in writing that the defendants are in compliance with CGMPs; and the defendants must report to FDA the changes made to comply with CGMPs.

In addition, the defendants shall hire an auditor (the auditor may be the same person or persons retained as an expert) to conduct inspections every six months and prepare a written report analyzing whether defendants are in compliance with CGMPs. If an audit report indicates that defendants are not in compliance with CGMPs, defendants shall correct the problems within 30 calendar days of receipt of the audit report. The Decree also requires the defendants to reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses.

The Decree authorizes FDA to order Sparhawk to immediately cease operations and recall any affected drugs if the agency determines that the firm has violated the terms of the Decree or the Act.

Warning Letter Issued for Unapproved New Animal Drugs



On March 15, 2007, FDA's Cincinnati District Office issued a Warning Letter to the president of Nich Marketers, Inc., Columbus, Ohio, for marketing adulterated new animal drugs. FDA conducted an investigation of the firm's own-label distribution facility located in Columbus, Ohio, on January 23, 2007. This inspection confirmed that the firm was marketing the following animal products; Sorb-A-Tox Suspension, BIS-CO-SORB Suspension, Aspir-SLO, Colloidal Silver, B-Mune™ Capsules (Beta-1,3-D glucan), Nich UAAGel® (Universal Animal Antidote Gel), and "Tongue to Tail."

The FDA investigator collected copies of product labels, labeling, and other promotional material with respect to animal products the firm was distributing. Additionally, on February 8, 2007, FDA reviewed this firm's website which disclosed that several of the firm's aforementioned products were being promoted for various animal uses.

The Warning Letter advised the president of Nich Marketers that some of the products were misbranded because they are not generally recognized as safe and effective by scientific experts for their labeled intended uses. New animal drugs that are not covered by approved New Animal Drug Applications (NADAs), cannot be legally marketed in the United States. Because the new animal drugs listed above were not covered by approved NADAs, they are adulterated pursuant to section 501(a)(5) of the Act.

The Warning Letter also noted that the drugs Colloidal Silver, B-Mune™ Capsules (Beta-1, 3-D glucan), and "Tongue to Tail" are misbranded because the labeling fails to bear adequate directions for the intended uses. Colloidal Silver and B-Mune™ did not include instructions for use and "Tongue to Tail" did not include the species for which it is intended for use. Additionally, the drug Sorb-A-Tox Suspension was misbranded because its labeling was false or misleading in that it contained a false National Drug Code (NDC) number.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/archive/b6295d.htm.

Warning Letter Issued to Manufacturer of Dairy Wipes

On June 1, 2007, FDA's New England District Office issued a Warning Letter to the President and CEO of ImmuCell Corporation, Portland, Maine. FDA conducted an inspection of this pharmaceutical manufacturing facility located in Portland, Maine, on October 10 - 23, 2006. This inspection confirmed that ImmuCell manufactures and markets Wipe Out® Dairy Wipes.

Because ImmuCell markets this product as being intended for use in the prevention of mastitis, including being proven effective at killing mastitis causing organisms, Wipe Out® Dairy Wipes, is a drug under section 201(g) of the Act. The Warning Letter advised the firm that Wipe Out® Dairy Wipes are unapproved new drugs because there is no approved NDA for this product.

In addition, FDA's inspection revealed serious deviations of CGMP regulations for the manufacture of finished pharmaceuticals:

- Drug products did not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use;
- Laboratory controls did not include the establishment of scientifically sound and appropriate standards or specifications designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality, and purity; and
- Sampling and testing plans for drug products were not described in written procedures which include the method of sampling.

To read the full text of the Warning Letter go to:
http://www.fda.gov/foi/warning_letters/s6400c.htm.

Warning Letter Issued to Animal Drug Manufacturer

On July 9, 2007, FDA's Chicago District Office issued a Warning Letter to the president of First Priority, Inc., an animal drug manufacturer located in Elgin, Illinois. The Warning Letter was issued following an inspection from October 24 through November 9, 2006. This inspection disclosed numerous violations of

CGMP regulations.

The inspection also revealed that the firm was manufacturing and marketing a product called "Purple Lotion Wound Dressing," which was described on the firm's website and in the product's immediate label as "a germicidal, fungicidal, antiseptic, and protective wound dressing for use in the treatment of minor cuts, scratches and superficial abrasions".

The warning letter stated that "Purple Lotion Wound Dressing" product is adulterated because it is a new animal drug which is unsafe. A new animal drug is considered to be unsafe unless there is an approved new animal drug application (NADA) for the product. "Purple Lotion Wound Dressing" product is not covered by an approved NADA.

To view the full text of the Warning Letter, go to:
http://www.fda.gov/foi/warning_letters/s6415c.htm.

BSE Enforcement Activities

Holmes By-Products Co., Inc. Consent Decree of Permanent Injunction



On February 26, 2007, U.S. District Judge James S. Gwin entered a Consent Decree of Permanent Injunction against Holmes By-Products Co., Inc. ("Holmes"), its president Abe L. Miller, and vice president and general manager, Dennis K. Koshmider, because of violations of the Federal Food, Drug, and Cosmetic Act (the Act) and FDA's Ruminant Feed Ban. FDA's Ruminant Feed Ban was promulgated to prevent the transmission of Bovine Spongiform Encephalopathy. The defendants operated a rendering company that produces both mammalian meat and bone meal, which contained prohibited material as defined by the Ruminant Feed Ban, as well as poultry by-product meal. Defendants had been using common equipment to process all products without sufficiently cleaning between uses.

Pursuant to the Consent Decree, defendants are permanently enjoined from manufacturing, processing, labeling, holding for sale, and distributing poultry by-product meal unless and until their practices are brought into compliance with the Act and its implementing regulations through one or more of the following measures: 1) labeling their poultry by-product meal with the cautionary statement "Do Not Feed to Cattle or Other Ruminants";

2) maintaining separate lines of equipment for producing separate types of products; or 3) sufficiently cleaning existing equipment between uses. The Consent Decree also requires defendants, under certain circumstances, to retain an independent laboratory to analyze their poultry by-product meal and to retain an expert to inspect their equipment and manufacturing processes. The Consent Decree gives FDA shutdown and recall authority in the event of future violations and requires defendants to reimburse FDA for its costs.

Illegal Drug Residues

Court Decree of Permanent Injunction Ysselstein Dairy Inc., and Sjerp W. Ysselstein

On August 10, 2007, a Consent Decree of Permanent Injunction was signed by the court the U.S. District Court for the Northern District of Iowa, Western Division, against Ysselstein Dairy Inc., Rock Valley, Iowa, and its owner and president, Sjerp W. Ysselstein, after illegal drug residues were found in the dairy's cows. The action occurred after FDA's Kansas City District Office conducted investigations of the dairy and its practices.

Ysselstein Dairy produced milk for human consumption and sells dairy cows for slaughter for human consumption. The injunction was based on nine illegal residues in the edible tissue of seven dairy cows sampled by the USDA's FSIS between July 21, 1992, and March 10, 2006. The drug residues found by FSIS included antibiotics such as tetracycline, sulfadimethoxine, flunixin, oxytetracycline, and penicillin at levels not permitted by the FDA.

Under the terms of the Consent Decree, the dairy and Ysselstein must implement systems for identifying animals, keeping records, drug control, drug accountability, and drug residue withdrawal control. If the FDA informs the defendants of their non-compliance with the terms of the Consent Decree or the Federal Food, Drug, and Cosmetic Act, the FDA may require them to cease operations until they are in compliance. The Consent Decree also provides for the dairy and Ysselstein to pay a fine for each day they fail to comply with the Consent Decree and for each animal that they sell or deliver for sale in violation of the Consent Decree.

**Order of Permanent Injunction
J.M. Dairy and Las Martas, Inc.,
and Juan Manuel Barreto Ginorio**



On August 8, 2007, the U.S. District Court for the District of Puerto Rico issued an Order of Permanent Injunction against J.M. Dairy Inc. and Las Martas Inc., and Juan Manuel Barreto Ginorio, the owner of the dairies, after illegal drug residues were found in cows.

The court order follows a civil complaint filed against the defendants on September 19, 2006, based upon FDA's investigations into the dairies and their practices. The dairies produce milk for human consumption and sell dairy cows for slaughter for human consumption.

The injunction is based, in part, on five illegal residues found in the edible tissue of three dairy cows sampled by the USDA's FSIS between August 2003, and September 2005. The drug residues found by FSIS included antibiotics such as sulfamethazine, sulfathiazole, sulfadimethoxine, and penicillin at levels not permitted by FDA. More recent FDA inspections confirmed that the dairies continued to use animal drugs in a manner contrary to the label directions, without the benefit of a veterinarian's oversight, and the firms failed to maintain record-keeping systems to ensure that they did not sell milk or animals for slaughter for human food with illegal drug residues.

Under the terms of the August 8, 2007, Order, the defendants were required to implement record-keeping systems to ensure that their use of drugs conforms to FDA regulations and that no milk or animals for slaughter for human food enter into interstate commerce with illegal drug residues.

The defendants may only resume selling or delivering food – milk or animals for slaughter for human food – in interstate commerce after they are notified by FDA that they are in compliance with the terms of the Order.

Warning Letters Issued for Illegal Drug Residues

Ampicillin, Oxytetracycline, and Sulfadimethoxine

- On February 28, 2007, FDA's Minneapolis District Office issued a Warning Letter to Roger and Julie Lanners, Royalton, Minnesota, for adulterating animals sold for food, and for causing animal drugs to be unsafe and

adulterated. USDA analyses of tissue samples of three dairy cows sold by the farm for slaughter revealed drug residues of oxytetracycline, ampicillin, and sulfadimethoxine above tolerance limits.

On October 26, 2006, an investigation of this dairy operation located in Royalton, Minnesota, was conducted by investigators from the Minnesota Department of Agriculture, acting on behalf of FDA. This investigation revealed failure to maintain adequate treatment records, extralabel use of oxytetracycline, penicillin G procaine, amoxicillin, and isoflupredone acetate without veterinary supervision, and extralabel use of sulfadimethoxine in an animal class for which the drug is prohibited from extralabel use.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/archive/b6274d.htm.

Gentamicin

- On March 26, 2007, FDA's New England District Office issued a Warning Letter to Rockland Farm, Bolton, Connecticut, for offering an animal for sale for slaughter for food that was adulterated. An inspection of this dairy farm operation located in Bolton, Connecticut, conducted by representatives of the FDA on January 9, 11, 18, and 31, 2007, confirmed that an animal was offered for sale for slaughter as food that was adulterated. USDA/FSIS analysis of tissue samples collected from that animal identified the presence of gentamicin in the kidney tissue of this adult dairy cow. No tolerance has been established for residue of gentamicin in the uncooked edible tissues of cattle.

The presence of this drug in the uncooked edible tissues from this animal causes the food to be adulterated. The investigation also disclosed that the farm held animals under conditions that were so inadequate that medicated animals bearing potentially harmful drug residues were likely to enter the food supply. For example, the farm lacked an adequate record keeping system for determining the medication status of animals offered for slaughter.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/b6310d.htm.

Flunixin Meglumine

- On March 5, 2007, FDA's San Francisco District issued a Warning Letter to J & D Wilson & Sons Dairy, located in Riverdale, California. An inspection of this dairy was initiated in response to violative levels of flunixin meglumine in a dairy cow and penicillin in another dairy cow. Following FDA's inspection, the firm had an additional violative residue of flunixin meglumine reported in a dairy cow. The Warning Letter also advised the firm of the fact that the firm was not following its veterinarian's label directions for flunixin meglumine and penicillin-dihydrostreptomycin. In addition, the firm did not maintain complete medication records, and failed to maintain a drug inventory and accountability system.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/archive/b6279d.htm.

- On March 19, 2007, FDA's New England District Office issued a Warning Letter to the Co-Owner of Fairmont Dairy, LLC, Craftsbury, Vermont. An investigation of Fairmont Dairy conducted by a representative of FDA on December 5, 2006, confirmed that the firm offered two animals for sale for slaughter as food that were adulterated. Illegal drug residues (penicillin G procaine and flunixin meglumine) were found in the edible tissues of these two cows (repeat violator) that originated from the farm. The farm was also cited in the Warning Letter for failure to use the animal drugs in conformance with their approved labeling (extra-label use) and without the supervision of a licensed veterinarian. Additionally, the farm was cited for using lasalocid to feed bob veal calves being processed for slaughter and for not reviewing and maintaining complete, permanent animal treatment records.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/b6307d.htm.

- FDA's San Francisco District Office issued a Warning Letter on March 22, 2007, to Madera Calf Ranch located in Madera, California (owned by Michael Copeland). The inspection of this calf-raising operation was initiated by a report of a violative gentamicin residue in an animal previously raised by the calf ranch. The inspection of the calf ranch operation followed an inspection of the dairy owning the violative animal, which confirmed that the dairy had neither used nor purchased subject drug. The calf ranch was using gentamicin to treat calves under its care.

FDA's inspection found the calf ranch was adulterating the drugs gentamicin, penicillin G procaine, tylosin, and ceftiofur hydrochloride by either not following the drug label directions and/or their veterinarian's prescription directions for those drugs. Also, the calf ranch was not maintaining treatment records for calves in which medication was administered it was not maintaining a drug inventory. The calf ranch sent a generic letter to its customers indicating their animal "may" have been treated with drugs while at the ranch at the time of an illness, but no details were provided as to which animals and what drugs were administered or when they were administered. The calf ranch was also feeding medicated hospital milk from dairy cows without knowing what drug residues and amounts were in the milk.

Penicillin

- On June 19, 2007, the Cincinnati District Office issued a Warning Letter to S&W Farms, Cave City, Kentucky. During an investigation on March 26 – 27, 2007, it was determined that this dairy farm sold two cows to be slaughtered for human consumption that contained illegal drug residue levels. USDA determined that the one cow's liver and kidney tissues contained illegal levels of penicillin; and a second cow's kidney tissue contained illegal levels of penicillin. The investigation also determined that the farm lacked an adequate system for assuring that the medicated animals had been withheld from slaughter for appropriate periods of time; failed to keep treatment records for cows; lacked an adequate drug inventory system for determining the quantity of drugs used to medicate their animals; and was not adequately identifying and segregating treated animals.
- On March 9, 2007, FDA's New England District issued a Warning Letter to the Co-Owner of Fairmont Farm, Inc., East Montpelier, Vermont. USDA/FSIS analysis of tissue samples collected from that animal on September 26, 2006, identified the presence of 0.14 parts per million (ppm) of penicillin in the kidney tissue of the cow. A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle. In the Warning Letter the firm was also cited for failure to use the drug in conformance with its approved labeling (extra-label use) and without the supervision of a licensed veterinarian. In addition, the firm was cited twice in 1993 for tissue residue violations and twice in 2006 for beta-lactam residues in milk.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/archive/b6283d.htm.

- On February 26, 2007, FDA's Seattle District Office issued a Warning Letter to the three Co-Owners of De Vries Dairy, Mt. Vernon, Washington. FDA issued the Warning Letter to the Co-Owners for offering animals for sale for slaughter as food in violation of the Act by failing to use a drug in conformance with its approved labeling. On September 26, 2006, De Vries Dairy sold a dairy cow destined for slaughter as human food that contained 0.58 parts per million (ppm) of penicillin in the kidney tissue and 0.16 ppm of penicillin in the liver tissue. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle. The firm also failed to maintain complete medication records and administered a new animal drug without following the dosage level of treatment, duration of treatment, or the methods for injecting the drug as set forth in the approved labeling and also without the supervision of a licensed veterinarian as required by FDA regulations.

To view the full text of the Warning Letter, go to:

http://www.fda.gov/foi/warning_letters/archive/b6288d.htm.

FDA Re-Emphasizes Warnings to Consumers on Risks of Pet Turtles



On April 6, 2007, FDA issued an urgent warning to the public that contact with baby turtles can pose a serious health risk to infants, small children, and adults with impaired immune systems as they can be natural hosts to *Salmonella*, a group of bacteria that can cause severe illness and death. Recently, a four-week old infant in Florida died of infection traced to *Salmonella* Pomona, a bacteria that was also found in a pet turtle in the home.

Salmonella is the genus name of a number of bacteria commonly associated with food poisoning from contaminated or undercooked foods, and salmonellosis is the disease the bacteria can cause. *Salmonella* can be found on the outer skin and shell surfaces of the turtles causing salmonellosis for those handling turtles without properly washing their hands after handling the animals.

FDA's warning reminded parents and others who care for children of the following:

- The sale of turtles with a shell less than four inches long is illegal. Exceptions to FDA's regulation include sales of these turtles intended for export only or for bona fide scientific, educational, or exhibitional purposes;
- *Salmonella* infection can be caused by contact with turtles in petting zoos, parks, child day care facilities and other locations; and
- It is important to wash hands thoroughly with soap and water after handling or touching turtles and their housing.

In the early 1970's, it was determined that pet turtles, particularly red-eared sliders, were responsible for an estimated 280,000 cases of salmonellosis each year in the United States. In 1975, FDA banned the sale of turtles with a shell less than four inches long as a necessary public health measure. FDA has repeatedly emphasized the risks of turtle-associated salmonellosis because of a resurgence in the sales of such turtles in the last four years. The public health impact of turtle-associated salmonellosis in humans is an estimated 74,000 cases in the United States per year.

To view the full text of the Press Release, go to:

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01604.html>.

For more information on FDA's regulation of turtles, please see the following:

<http://www.fda.gov/cvm/turtlereg.htm>.

References

1. Testimony By Stephen F. Sundlof, D.V.M., Ph.D., Director, FDA Center for Veterinary Medicine, Department of Health and Human Services before The Senate Agriculture, Rural Development, and Related Agencies Appropriations Subcommittee, April 12, 2007. [Available online at: <http://www.fda.gov/ola/2007/petfood041207.html>].
2. Statement of Murray M. Lumpkin, M.D., Deputy Commissioner for International and Special Programs, U.S. Food and Drug Administration: "Safety of Chinese Imports: Oversight and Analysis of the Federal Response," Hearing before the Committee on Commerce, Science, and Transportation, United States Senate, July 18, 2007. [Available online at: <http://www.fda.gov/ola/2007/chineseimport071807.html>.]
3. Statement of David Acheson, M.D., F.R.C.P. Assistant Commissioner for Food Protection, Food and Drug Administration before Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, September 25, 2007. [Available online at: <http://www.fda.gov/ola/2007/foodsafety092507.html>.]
4. Import Alert #99-29, "Detention Without Physical Examination of All Vegetable Protein Products From China for Animal or Human Food Use Due to the Presence of Melamine and/or Melamine Analogs" [Available online at: http://www.fda.gov/ora/fiars/ora_import_ia9929.html.]
5. Statement of Steven M. Solomon, D.V.M., M.P.H. Deputy Director of the Office of Regional Operations, Office of Regulatory Affairs, Food and Drug Administration, before, Committee on Ways and Means Subcommittee on Trade, October 4, 2007. [Available online at: <http://www.fda.gov/ola/2007/importsafety100407.html>.]