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## Chapter 5 – Center for Veterinary Medicine

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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. The hyperlinks provided may change and to locate the archived Warning Letters go to:<http://www.fda.gov/foi/warning.htm>.

## Animal Feed

### Several Indicted for Importing Contaminated Ingredients Used in Pet Food

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Efforts of FDA's criminal investigations result in successful indictment of feed importer



On February 6, 2008, the Food and Drug Administration (FDA), Office of Criminal Investigations (OCI), announced that two Chinese nationals and the businesses they operated, along with a U.S. company, its president and chief executive officer (CEO) were indicted by a Federal grand jury in separate but related cases. The indictments were related to a scheme to import products purported to be wheat gluten that were contaminated with melamine into the United States (U.S.). These products were domestically used to make pet food.

Xuzhou Anying Biologic Technology Development Co., LTD. (XAC), a Chinese firm that processed and exported plant proteins to the U.S.; Mao Linzhun, a Chinese national who was the owner and manager of XAC; Suzhou Textiles, Silk, Light Industrial Products, Arts and Crafts I/E Co. LTD. (SSC), a Chinese export broker that exported products from China to the U.S.; and Chen Zhen Hao, president of SSC and a Chinese national, were all charged in a 26-count indictment returned by a federal grand jury in Kansas City, Missouri.

Also indicted were ChemNutra, Inc., a Las Vegas, Nevada corporation that bought food and food components from China to sell to U.S. companies in the food industry, along with ChemNutra owners Sally Qing Miller and her husband, Stephen S. Miller, who were charged in a separate, but related, 27-count indictment. Sally Qing Miller, a Chinese national, was the controlling owner and president of ChemNutra; Stephen Miller was an owner and CEO of

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ChemNutra. The indictments charged all seven defendants with delivering adulterated food that contained melamine, a substance which may render the food injurious to health, into interstate commerce; introduction of a misbranded food into interstate commerce; and other charges.

On March 15, 2007, a pet food manufacturer alerted FDA to the deaths of 14 cats and dogs, several reported by consumers and several that died during routine taste trials conducted by the company. The animals were reported to have developed kidney failure after eating pet food that had been manufactured with the purported wheat gluten.

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

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01792.html>

### **Animal Food Products Seized at Petco**

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Under FDA direction, U.S. Marshals seized various animal food products at the PETCO Animal Supplies Distribution Center located in Joliet, Illinois, on June 19, 2008. All FDA-regulated animal food susceptible to rodent and pest contamination located at the facility was seized because these products were being held under insanitary conditions.

During an FDA inspection of the PETCO distribution center in April 2008, widespread and active rodent and bird infestation of the premises was observed. The FDA reinspected the facility in May 2008 and found continuing and widespread infestation, which was determined to be a direct result of the company's continuing failure to adequately control and prevent pests at the facility.

The Federal Food, Drug, and Cosmetic Act (the Act) prohibits animal feed from being stored in filthy and insanitary conditions, just as it does for human food. The distribution center provided pet food products and supplies to PETCO retail stores in 16 states including Alabama, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Missouri, Nebraska, Ohio, Oklahoma, Tennessee, Texas, and Wisconsin.

The FDA has had no reports of pet illness or death associated with consumption of animal food distributed by PETCO. However, the seized products were in permeable packages and held under insanitary conditions that could affect the food's integrity and quality.

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

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01854.html>

### **Pet Food Maker Obtained Emergency Operating Permit**

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On April 24, 2008, the FDA issued an order requiring that Evanger's Dog & Cat Food Company, Inc., in Wheeling, Illinois, obtain an emergency permit from the FDA. This requires the firm to submit a request to FDA before canned pet food manufactured at the facility is entered into interstate commerce.



A recent inspection revealed significant deviations from prescribed documentation of processes, equipment, and recordkeeping in the production of the company's thermally processed low acid canned food (LACF) products. These problems could result in under-processed pet foods, which can allow the survival and growth of *Clostridium botulinum* (*C. botulinum*), a bacterium that causes botulism in some animals as well as in humans.

The FDA determined that the company failed to meet regulatory requirements to process a product that does not present a health risk and issued the Order of Need for Emergency Permit. Evanger's must document that corrective actions and processing procedures have been implemented to ensure that the finished product will not present a health hazard in order to resume business.

While FDA's Center for Veterinary Medicine (CVM) has authority over animal feed and foods the Center for Food Safety and Applied Nutrition (CFSAN) is responsible for regulating all human and animal LACF processing. The two centers are collaborating on this enforcement action.

To view the full text of FDA's Press Release related to this recall, go to:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01825.html>

### **CGMP Violations Cited for Medical Feed Mill**

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On January 8, 2008, the FDA issued a Warning Letter to John Thacker, President and CEO of Wilbur-Ellis Company, after an inspection of the licensed medicated feed mill located in Ellensburg, Washington, revealed significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds.

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The investigator observed the following deviations:

- Failure to perform assays on at least three representative samples of medicated feed containing each drug or drug combination during calendar year 2006; and
- Failure to implement an investigation and corrective action, or maintain a record on the premises of corrective action when results of laboratory assays of drug components indicated that a medicated feed was not in accord with permissible limits.

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

[http://www.fda.gov/foi/warning\\_letters/s6649c.htm](http://www.fda.gov/foi/warning_letters/s6649c.htm)

### **Pet Food Recalls involving *Salmonella***

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On September 12, 2008, Mars Petcare US announced a voluntary recall of products manufactured at its Everson, Pennsylvania, facility. The pet food was voluntarily recalled because of potential contamination with *Salmonella* serotype Schwarzengrund. Pet food products from the same plant were previously recalled on August 25, 2007. Subsequent investigations by both the FDA and the firm revealed continued contamination with the same *Salmonella* organism. An epidemiological investigation had previously associated pet food manufactured at this facility with human illnesses in households in which the product was fed to pets. Shortly after the second recall, Mars Petcare US announced its intention to permanently close the facility.

To view the full text of FDA's Press Release related to this recall, go to:

[http://www.fda.gov/oc/po/firmrecalls/marspetcare09\\_08.html](http://www.fda.gov/oc/po/firmrecalls/marspetcare09_08.html)

## **Animal Drugs**

### **Return of Heartworm Drug to U.S. Market**

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On June 5, 2008, the FDA announced a limited return of a reformulated heartworm prevention drug for dogs. The drug manufactured by Fort Dodge Animal Health, of Overland Park, Kansas, was withdrawn because of serious, life-threatening adverse reactions, including loss of appetite, lethargy, vomiting,

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seizures, difficulty walking, jaundice (a yellowish appearance), bleeding disorders, allergies, and convulsions, followed in some cases by death. ProHeart® 6 (moxidectin), a sustained release injectable, is an approved heartworm prevention product for dogs. FDA is concurring with its limited return to the veterinary market under a risk minimization and restricted distribution program designed to provide for safe, appropriate use of the product and minimizing risk to dogs.

The risk minimization and restricted distribution program is intended to educate veterinarians and pet owners regarding the possible risks associated with the use of ProHeart® 6. Therefore, Fort Dodge Animal Health requires veterinarians who wish to purchase ProHeart® 6 to register with the company and participate in a Web-based training program prior to obtaining the product.

The return of ProHeart® 6 to the market was based on results of additional toxicological and pharmacologic studies by Fort Dodge Animal Health coupled with the low adverse reaction frequency in international markets.

ProHeart® 6 is the first animal drug to be marketed under a risk minimization and restricted distribution program. Numerous drugs for use in people have been successfully marketed under similar programs. While the Agency concurs with the limited return of ProHeart® 6 to the U.S. market, FDA strongly encourages veterinarians and pet owners to report any possible adverse reactions.

To view the full text of FDA's Press Release related to this recall, go to:  
<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01844.html>

### **Animal Food Contains Drugs**

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On May 13, 2008, the FDA issued a Warning Letter to Central Connecticut Cooperative Farmers Association after an inspection on January 25 and February 8, 2008, at a licensed medicated feed mill, located in Manchester, Connecticut. Samples obtained during the investigation revealed significant violations of the Act in that samples of the equine feed, 12% Equinator Integrity Horse Pellets, BH617, were found to contain the new animal drugs lasalocid sodium and salinomycin. Lasalocid sodium and salinomycin are not approved for use in equine feed and may cause toxicosis and potentially death in horses consuming feeds containing toxic amount of these products.

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FDA acknowledged receipt of a letter dated February 21, 2008, that responds to the FDA Form 483, Inspectional Observations. FDA found the response inadequate because it lacked specific information about how the firm intended to prevent similar situations from occurring in the future.

Failure to promptly correct these violations may result in regulatory or administrative sanctions. Sanctions could include, but are not limited to, seizure or injunction.

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

[http://www.fda.gov/foi/warning\\_letters/s6841c.htm](http://www.fda.gov/foi/warning_letters/s6841c.htm).

### **Unapproved New Drugs on Internet**

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On September 5, 2008, FDA's Minneapolis District Office issued a Warning Letter to Dr. Race Foster and Dr. Martin Smith of Drs. Foster and Smith, Inc., of Rhinelander, Wisconsin, regarding statements made on the Internet about Joint Care Primary 1, Joint Care Primary Plus 1, Joint Care~Advanced 2 with MSM, Joint Care Premium 3, Joint Guard Treats, and Premium Plus Omega-3 Gel Caps.

Some of the statements on the Website indicated the products were intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in dogs and cats. The statements were supplemented by keywords used to direct consumers to the Website through Internet searches. The products are not the subject of approved New Animal Drug Applications and were unapproved new animal drugs.



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

[http://www.fda.gov/foi/warning\\_letters/s6915c.htm](http://www.fda.gov/foi/warning_letters/s6915c.htm)

### **Adulterated Drugs - Extralabel Use**

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On May 13, 2008, the San Juan District of the FDA issued a Warning Letter to Eduardo Rivera, owner of Vaquenia Paso Real, Manati, Puerto Rico, after an inspection of the firm revealed that new animal drugs were not used in conformance with the approved labeling.



A drug was administered without following the withdrawal period set forth in the approved labeling and without the supervision of a licensed veterinarian.

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Furthermore, the extralabel use of the drug resulted in an illegal drug residue in human food. In addition, the drug was administered to lactating dairy cows when the directions in the approved labeling states intravenous (in the vein) use only, and the extralabel use states it is prohibited for use in lactating dairy cows.

Extralabel use, includes the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, and is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/ client/ patient relationship, and complies with 21 Code of Federal Regulations (CFR) Part 530.

The firm was requested to take prompt action to correct the violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure or injunction. The Act and associated regulations governing new animal drugs are on the Website at [www.fda.gov](http://www.fda.gov).

To view the full text of the Warning Letter, go to:  
[http://www.fda.gov/foi/warning\\_letters/s6959.html](http://www.fda.gov/foi/warning_letters/s6959.html)

## **BSE Enforcement Activities**



### **Certain Cattle Materials Barred from Pet Food**

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On April 23, 2008, the FDA issued a final regulation barring certain cattle materials from all animal feed, including pet food. The final rule further protects animals and consumers against bovine spongiform encephalopathy (BSE), also known as "mad cow disease," from an already low risk of BSE. The new measure builds on FDA's 1997 feed regulation, which prohibited the use of certain mammalian proteins in ruminant feed.

The materials that can no longer be used in animal feed are the tissues that have the highest risk for carrying the agent thought to cause BSE. These high risk cattle materials are the brains and spinal cords from cattle 30 months of age and older. The entire carcass of cattle not inspected and passed for human consumption was also prohibited, unless the cattle were less than 30 months of age, or the brains and spinal cords had been removed. The risk of BSE in cattle less than 30 months of age is considered to be exceedingly low.

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Scientific studies have linked BSE to cases of variant Creutzfeldt Jakob Disease (vCJD) in humans, an invariably fatal disease that most likely results from human consumption of infectious material from cattle with BSE. Rules issued in 2004 prohibited specified risk materials from use in the human food supply. There have been no vCJD cases definitively linked to consumption of U.S. beef and the risk of BSE among U.S. cattle is low.

For more information about the FDA's work on BSE, go to:  
[www.fda.gov/oc/opacom/hottopics/bse.html](http://www.fda.gov/oc/opacom/hottopics/bse.html).

To view the full text of the Press Release go to:  
<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01823.html>

## **Illegal Drug Residues**

During FY08, FDA issued over 30 Warning Letters to dairies and farms that offered for sale animals as food that contained approved and unapproved drug residues in residual tissues in excess of FDA tolerance levels. FDA found that the animals were held under conditions that were inadequate so that medicated animals bearing potentially harmful drug residues were likely to enter the food supply. Many of the drugs were not used in conformance with the approved labeling.

FDA has established tolerance levels for the following drugs when present in the tissues of slaughtered animals for food: ampicillin, oxytetracycline, gentamicin, tilmicosin, neomycin, flunixin meglumine, and penicillin.

FDA has not established a tolerance level for residues of gentamicin in the edible tissues of cattle nor is there established tolerance for residues of sulfamethazine in lactating dairy cows.

All the dairies and farms that sold the animals as a source of food were requested to address the violations in writing by stating the steps taken to bring the operations into compliance with the law. Further actions were taken when the responses of operations were found to be inadequate.

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## **Livestock Owner Sentenced in Criminal and Civil Contempt Case**

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On September 11, 2008, the FDA announced that a West Virginia cattle dealer had been sentenced to six months probation for refusing to obey court orders in 2006 and 2008 that prohibited the introduction of animals into the food supply until the FDA had approved a record-keeping system for the operation. The FDA initiated the case after illegal levels of drug residue were found repeatedly in calves that Shirley A. Rhodes of Sandyville sold for use as human food.

On July 30, 2008, U.S. District Court Judge Joseph R. Goodwin sentenced Rhodes, finding her guilty of criminal and civil contempt for introducing adulterated food into the marketplace and for failing to maintain proper medication records for calves as part of her business, Rhodes Livestock. The violations involved 23 positive tests for drugs such as neomycin, penicillin, gentamicin, and other antibiotics.

Under terms of the probation, Rhodes was barred for six months from purchasing, selling, obtaining, or transferring any animals that may be used as human food. After that date, Rhodes was prohibited from these activities until the FDA approves Rhodes' written record-keeping system.

There are numerous drugs approved for use in animals ultimately intended for food. The FDA establishes drug tolerance levels to assure that there will be no harmful effects to consumers eating these food products. The U.S. Department of Agriculture (USDA) routinely tests tissue samples from animals intended for food in order to monitor for violations of drug tolerance levels.

## **Warning Letters Issued for Illegal Drug Residues**

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On December 13, 2007, the Seattle District Office of FDA issued a Warning Letter to Donald Moisan, owner, of Moisan Dairy, in Salem, Oregon, after an inspection on August 22 to 23, 2007, confirmed that Moisan Dairy offered an animal for sale for slaughter as food that contained potentially harmful drug residues.

The Food Safety and Inspection Service (FSIS) of the USDA analyzed tissue samples collected from an animal and identified the presence of sulfadimethoxine in both the liver at 7.27 parts per million (ppm) and the muscle at 1.60 ppm of the cow. Analyses of tissue samples collected from that animal also identified the presence of penicillin in the kidney at 2.22 ppm. A tolerance of 0.1 ppm has been established for residues of



sulfadimethoxine in the uncooked edible tissues of cattle and a tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle.

The investigation also found that the firm held animals under conditions that were so inadequate that medicated animals bearing potentially harmful drug residues were likely to enter the food supply. The dairy lacked an adequate system to ensure that medicated animals were withheld from slaughter for appropriate periods of time, allowing depletion of potentially hazardous residues of drugs from edible tissues.

Furthermore, on March 8, 2007, Moisan Dairy certified to the buyer that none of the animals being sold contained illegal levels of drug residues.

FDA reminded Moisan Dairy that the extralabel use of sulfonamide drugs in lactating dairy cattle is prohibited. At least two dairy cows attributed to the operation have been found to have violative levels of sulfadimethoxine.

Moisan Dairy was requested to take prompt action to correct the violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

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

[http://www.fda.gov/foi/warning\\_letters/s6612c.htm](http://www.fda.gov/foi/warning_letters/s6612c.htm)

## **Turtles**

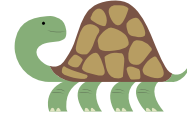
The FDA regulations specify that viable turtle eggs and live turtles with a carapace length of less than four inches shall not be sold, held for sale, or offered for any other type of commercial or public distribution. Turtles of this size may carry *Salmonella* bacteria and transmit these bacteria to humans, causing salmonellosis. Salmonellosis is characterized by severe gastrointestinal symptoms (abdominal pain, nausea, fever, and diarrhea) and occasionally results in death.

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## FDA Issued Warning Letter on Risks of Pet Turtles

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On January 30, 2008, the FDA issued a Warning Letter to Animal Magnetism, Inc., of Naples, Florida, after an investigation confirmed that the firm offered live turtles with a carapace length of less than four inches for sale to retail customers as pets.



The investigation followed up on a complaint involving a young child exhibiting clinical symptoms of salmonellosis after playing with a turtle having a carapace of less than four inches that had been purchased from Animal Magnetism. The child required urgent medical care and hospitalization. Laboratory samples taken by the hospital confirmed the presence of *Salmonella* bacteria.

FDA requested the immediate cessation of the selling or further distribution of turtles with a carapace length of less than four inches at any retail location. Selling, holding for sale, and/or offering for any other type of commercial or public distribution of turtles with a carapace length of less than four inches in violation of the Public Health Service Act and 21 CFR 1240.62 and may result in the initiation of further regulatory action against the firm without notice.

To view the full text of the Warning Letter, go to:  
[http://www.fda.gov/foi/warning\\_letters/s6729.html](http://www.fda.gov/foi/warning_letters/s6729.html).

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## Distributor of Pet Turtles Convicted

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On July 14, 2008, the U.S. District Court in Fort Lauderdale, Florida, convicted and sentenced Strictly Reptiles, Inc., for its role in illegally selling, and offering for sale, live undersized turtles. The Office of Criminal Investigations (OCI) and the U.S. Fish and Wildlife Service investigated the case leading to the conviction, with help from the FDA's Center for Veterinary Medicine (CVM).

The owner of Strictly Reptiles admitted to OCI agents that he intentionally did not ask customers their purpose for purchasing the turtles in order not to lose sales. At sentencing, the court ordered a criminal fine of \$5,000, the forfeiture of more than 6,300 turtles, and two years probation that allows federal agents to inspect sales records of all Strictly Reptiles live turtles. The court further ordered Strictly Reptiles to obtain a signed document from every buyer of undersized turtles that indicates the buyer is aware of the legal restrictions placed on the sale, or holding for sale, of these turtles.

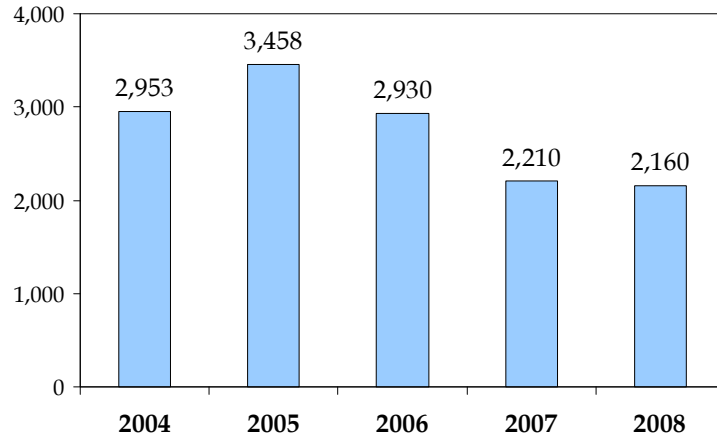
To view the full text of the Warning Letter, go to:

<http://www.fda.gov/consumer/updates/turtles112808.html#conviction>

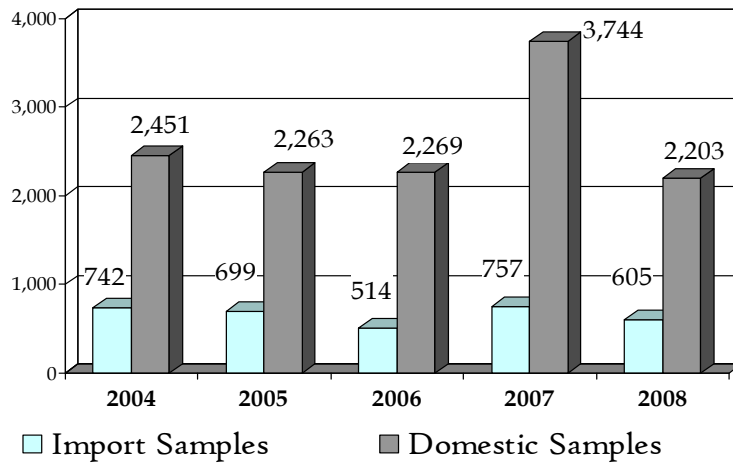
### Enforcement Statistics



Center for Veterinary Medicine  
FDA Foreign and Domestic Inspections  
Fiscal Years 2004 - 2008

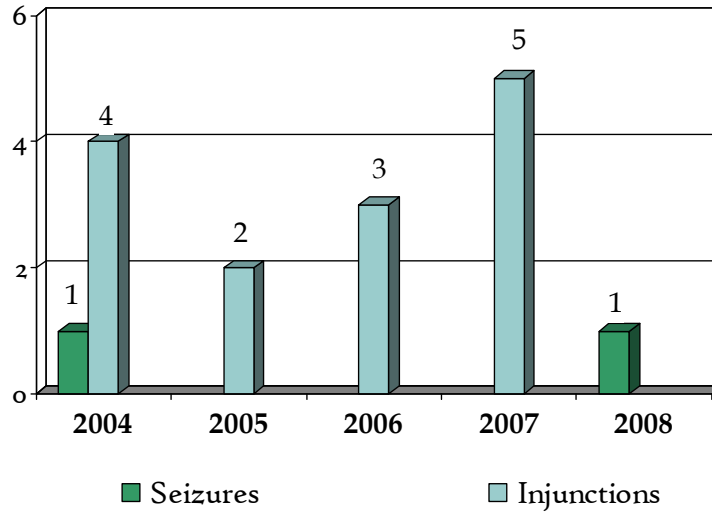


Center for Veterinary Medicine  
Surveillance: Import and Domestic Samples  
Fiscal Years 2004 - 2008





Center for Veterinary Medicine  
Enforcement Statistics  
Fiscal Years 2004 - 2008



NB: These data are not comparable to those reported in FY07 as partial seizures have been assigned to one Center. A single seizure may involve more than one Center's products.



Center for Veterinary Medicine  
Five-Year Total Product Recall Statistics  
Fiscal Years 2004 - 2008

