Center for Veterinary Medicine

Bovine Spongiform Encephalopathy Feed Ban

Title 21, Code of Federal Regulations, Part 589, Section 2000
21 CFR 589.2000
Animal Proteins Prohibited in Ruminant Feed

This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). The use of protein derived from mammalian tissues, as defined by 21 CFR 589.2000(a)(1), as an animal feed ingredient or in animal feeds must comply with the requirements of 21 CFR 589.2000. Products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed (prohibited material) must be labeled with the cautionary statement, "Do not feed to cattle or other ruminants."...

FDA maintains a Web Page devoted entirely to the topic of BSE. To view the Web Page go to: http://www.fda.gov/oc/opacom/hottopics/bse.html.

National Recall of *Four* Animal Feed Products Containing Prohibited Ingredients

On June 16, 2006, H.J. Baker & Brothers, located in Albertville, Alabama, announced that in cooperation with FDA they began efforts to retrieve the following products: PRO-PAK WITH PORCINE MEAT AND BONE, PRO-LAK, AND PRO-AMINO II. These products were produced at the firm's Albertville, Alabama facility. These products are used as an ingredient in the manufacturing of livestock feed, including feed for dairy animals. The New Orleans District Office initiated inspections of the feed mill, Alabama Farmers Cooperative, and H.J. Baker, both located in Alabama, as a traceback pursuant to feed samples collected by the Florida Department of Agriculture and Consumer

Services, testing positive for prohibited ruminant materials.

Samples of the feed's protein component also tested positive for prohibited ruminant materials. Because none of these feeds or protein concentrates were labeled with the BSE cautionary statement, this recall was initiated to address potential risk of unintentional contamination with ruminant derived protein that may have occurred at this facility from August 2005 to June 2006. Certain mammalian protein is prohibited for use in ruminant feed. These products were distributed in bulk or bags to feed manufacturers and dairy farms in Georgia, Kentucky, Michigan, Florida, Alabama, Tennessee, Mississippi, California, and Louisiana. There have been 34 additional recalls of products manufactured from these protein sources.

The firm advised that if anyone received any of these products, to discontinue their use immediately and quarantine the product so that it cannot be inadvertently used in the manufacture of feeds. The firm also advised companies to contact the manufacturer at 501-664-4870 for further instructions

"All production and shipment of these products from the Albertville mill have ceased and all of our customers are being notified of the potential contamination. With the advice and support of FDA, we were able to respond rapidly to address this matter," said the President and CEO.

The full text of this Press Release is available online at: http://www.fda.gov/oc/po/firmrecalls/hjbaker06_06.html.

Warning Letter Issued for Animal Proteins Prohibited in Ruminant Feed

On May 17, 2006, FDA's New Orleans District Office issued a Warning Letter to the owner of Louisiana Proteins d/b/a Riegel By-Products, Dallas Texas. An FDA investigation of the rendering plant owned by the company in Shreveport, Louisiana, revealed deviations from the requirements of 21 CFR 589.2000, Animal Proteins Prohibited in Ruminant Feed. The inspection revealed that the company caused feed products being manufactured and distributed to be misbranded.

FDA's investigation disclosed that the company failed to provide measures, including sufficient written procedures, to prevent commingling or cross-contamination and to maintain sufficient written procedures to prevent carryover of protein derived from mammalian tissues into feeds which may be used for ruminants.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5883d.pdf.

Drug Residues in Edible Animal Tissue

Consent Decree of Permanent Injunction - Williams Cattle Co.

On February 7, 2006, U.S. District Judge

Karen Caldwell entered a Consent Decree of Permanent Injunction against Williams Cattle Co., Inc., and its officers and directors: Elmer Lee Williams, Michael Lee Williams, Mark A. Williams, Pamela W. Collette, and Jewell Williams (collectively "defendants"). The injunction follows a Complaint filed on January 31, 2006, charging defendants with delivering for introduction into interstate commerce adulterated food -- cattle whose edible tissues contained residues of antibiotic drugs including excessive levels of gentamicin, penicillin, tilmicosin, and sulfadimethazine.

Specifically, the defendants violated the Federal Food, Drug, and Cosmetic Act (the Act), by introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, articles of food, namely the edible tissues of animals, that are adulterated in that they contained unsafe new animal drugs, and that they had been held under insanitary conditions whereby they may have been rendered injurious to health.

Under the terms of the Decree, the defendants must develop and implement, among other things, a plan to avoid illegal drug residues in the cattle they transport to slaughter. Furthermore, if FDA notifies defendants that they are not in compliance with the terms of the Decree or the Act, FDA may require defendants to cease operations until they are in compliance. The Decree also provides for defendants to pay liquidated damages for each day they fail to comply with the Decree and for each animal that defendants sell or deliver for sale in violation of the Decree.

FDA's Press Release is available online at: http://www.fda.gov/cvm/CVM_Updates/williamsup.htm.

Consent Decree of Permanent Injunction - Jay Parker and Sons, LLC, et al.

Permanent Injunction was Based on 23 Illegal Residues in the Edible Tissue of 10 Bovine Animals

On June 16, 2006, Judge Allen Sharp, U.S. District Court District Judge for the Northern District of Indiana, South Bend Division, signed a Consent Decree of Permanent Injunction enjoining defendants, Jay Parker and Sons, LLC, a limited liability company, and Chris J. Parker, and Ted R. Parker, individuals, Silver Lake, Indiana.

The Decree enjoins the firm from distributing animals in interstate commerce and administering any new animal drug received in interstate commerce. This injunction is in force until the firm has established and implemented a system that ensures that all animals they handle are individually identifiable and traceable. The Decree also requires the firm to establish and implement a written record-keeping system that prevents the distribution of any animal with illegal new animal drug residues.

The system must include complete animal medication treatment records and documentation that the drugs are used under the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. The Decree requires the firm to submit an affidavit

within 20 calendar days describing their compliance. The Complaint for Injunction was filed after FDA's investigation disclosed that the firm offered adulterated culled dairy cows for human consumption despite repeated warnings from USDA/FSIS and FDA.
The firm has had a history of at least ten tissue residue violations dating back to 1999. The district's follow-up inspection in January/ February of 2006, found minimal corrective actions by the firm and verified an additional drug residue violation.

FDA's Press Release is available online at: http://www.fda.gov/cvm/bseparkerup.htm.

Warning Letters for Illegal Drug Residues

Flunixin Meglumine and Sulfadimethoxine

On May 23, 2006, FDA's Denver District Office issued a Warning Letter to the owner of Desertland Dairy, Mesquite, New Mexico. An FDA investigation of this dairy operation conducted in April 2006, confirmed that the firm offered two animals for sale for slaughter as food that were adulterated under the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that the firm caused the new animal drugs, Sulfadimethoxine and Flunixin Meglumine, to become adulterated and unsafe.

FDA's investigation disclosed that the firm sold a dairy cow on November 17, 2005, for slaughter as food. This animal was slaughtered on November 18, 2005. The U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) conducted an analysis of tissue samples collected from that animal and identified the presence of 8.329 parts per million (ppm) Flunixin in the liver tissue. A tolerance of 0.125 ppm has been established for residues of Flunixin in cattle liver tissue. The presence of this drug in the edible tissue of animals in amounts exceeding the tolerance set out in FDA regulations causes the food to be adulterated.

Furthermore, on January 26, 2006, the firm sold a dairy cow for slaughter as food. USDA/FSIS analysis of tissue samples collected from that animal identified the presence of 1.87 ppm Sulfadimethoxine in the liver tissue, and 1.30 pp in Sulfadimethoxine in the muscle tissue.

FDA regulations establish a tolerance of 0.1 ppm for residues of Sulfadimethoxine in the edible tissues of cattle. The presence of this drug in the edible tissues of this animal in amounts exceeding the tolerance causes the food to be adulterated.

FDA's 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. For example, the firm failed to maintain and review complete treatment records for their cattle. Thus, the firm lacked an adequate system to ensure that animals that were medicated were withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

In addition, the firm adulterated Flunixin Meglumine and Sulfadimethoxine when they failed to use the drugs in conformance with their approved labeling. The "extra-label" use of approved veterinary or human drugs must comply with the Act. "Extra-label use," i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, 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. FDA's investigation found that the firm's extra-label use of Sulfadimethoxine and Flunixin Meglumine failed to comply with these requirements.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5859d.pdf.

Oxytetracycline and Sulfadimethoxine

On June 2, 2006, FDA's Chicago District Office issued a Warning Letter to the President of J.B. Timmermann Farms Limited, Breese, Illinois. An FDA investigation of this dairy operation located in Breese, Illinois, was conducted on December 13 and 22, 2005. FDA inspection confirmed that Timmermann Farms offered a dairy cow for sale for slaughter as food that was adulterated under the Act. The inspection revealed that the dairy farm caused the new animal drugs Terra-Vet 100 (Oxytetracyline hydrochloride Injection) and Sulfadimethoxine Injection 40% to become adulterated and unsafe.

On or about November 14, 2005, Timmermann Farms consigned a dairy cow and delivered the dairy cow for slaughter as food. USDA/FSIS's analysis of tissue samples collected from that animal identified the presence of 0.59 parts per million (ppm) sulfadimethoxine in the liver tissue and 0.43 ppm sulfadimethoxine in the muscle tissue. FDA regulations have established a tolerance of 0.1 ppm for negligible residues of sulfadimethoxine in the uncooked edible tissues of cattle. The presence of this drug in excess of this amount in edible tissues from this animal causes the food to be adulterated.

In addition, the firm failed to use Oxytetracyline hydrochloride Injection) and Sulfadimethoxine Injection 40% in conformance with their approved labeling thereby adulterating these drugs in violation of the Act. "Extra label use," i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, 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.

The extra-label use of approved veterinary or human drugs must comply with the Act and FDA regulations. FDA's investigation found that Timmermann Farms extra-label use of Terra-Vet 100 and Sulfadimethoxine Injection 40% failed to comply with these requirements.

The full text of this Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5872d.pdf.

Penicillin G Procaine

Analysis Finds 3.15ppm of Penicillin In Kidney Tissue of Dairy Cow - FDA Regulations Provide a Tolerance of 0.05 ppm for Residues of Penicillin in Edible Tissues of Cattle

On May 25, 2006, FDA's Seattle District Office issued a Warning Letter to the Owners of Theo and Cheryl Van Berkum Dairy, Everson, Washington. An FDA investigation of this dairy farm, located in Everson, Washington, was conducted on March 13 and 16, 2006. This FDA inspection confirmed that this dairy farm offered animals for sale for slaughter as food that were adulterated under the Act. The inspection also revealed that the firm caused the new animal drug Penicillin G Procaine to become adulterated and unsafe.

On or about November 4, 2005, the dairy farm sold a dairy cow for slaughter as food. The USDA/FSIS's analysis of tissue samples collected from that animal identified the presence of Penicillin in the kidney tissue at 3.15 parts per million (ppm). FDA regulations have established a tolerance of 0.05 ppm for residues of Penicillin in the edible tissues of cattle. The presence of this drug in uncooked edible tissue above the established tolerance from this animal causes the food to be adulterated.

FDA's inspection also found that the dairy farm holds animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. The Warning Letter noted that the dairy farm lacked an adequate system to ensure that animals medicated at the farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

In addition, the dairy farm caused the drug, Penicillin G Procaine, to be adulterated when the firm failed to use the drug in conformance with its approved labeling. "Extralabel use," i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, 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. The extralabel use of approved veterinary or human drugs must comply with the Act and FDA regulations. FDA's investigation found that the firm's extralabel use of Penicillin G Procaine failed to comply with these requirements.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5877d.pdf

Sulfadimethoxine and Penicillin

On February 21, 2006, FDA's Minneapolis District Office issued a Warning Letter to the President of Norm-E-Lane, Inc., Chili, Wisconsin. An FDA investigation of this dairy operation located in Chili, Wisconsin, was conducted on December 23, 2005, and January 3, 2006. This inspection confirmed that this firm offered an animal for sale for slaughter as food that was adulterated under the Act. The inspection also revealed that the firm caused the new animal drugs

sulfadimethoxine and penicillin G procaine to become adulterated and unsafe.

Specifically on or about November 10, 2005, the firm consigned a dairy cow for slaughter as food. On or about November 11, 2005, this animal was slaughtered. USDA/FSIS analysis of tissue samples collected from that animal identified the presence of 2.06 ppm sulfadimethoxine in liver tissue, and 0.61 ppm penicillin in kidney tissue.

USDA analysis of the residues of sulfadimethoxine and penicillin of the presence of these drugs in the edible tissues of cattle were found to be in excess of the tolerances set forth in FDA laws and regulations. These excesses in this animal caused the food to be adulterated under the Act.

FDA's investigation also found that this 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 firm lacked an adequate system to ensure that animals medicated by the firm had been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. In addition, the firm lacked an adequate monitoring system to ensure that medications are administered to the designated animal. Food from animals held under such conditions is adulterated. The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5732d.pdf.

Warning Letter Issued to Owner of Veterinary Service

On March 6, 2006, FDA's Kansas City District Office issued a Warning Letter to Chris P. Hytrek, DVM, the owner of Willow Creek Veterinary Service, Cortland, Nebraska. FDA issued the Warning Letter based on an investigation conducted on October 21, 2005, of this veterinary practice.

The inspection revealed that Dr. Hytrek caused animal drugs used in his practice to be unsafe and adulterated because they were used in a manner that did not conform with their approved use or the regulations for Extralabel Drug Use in Animals, 21 CFR Part 530.

The investigation revealed that Dr. Hytrek prescribed the drugs kanamycin and amikacin to Wil Mar Sen Dairy. A U.S. Department of Agriculture analysis of tissue samples identified the presence of these two drugs in the kidney tissue of a cow offered for sale for slaughter as food from Wil Mar Sen Dairy. Neither kanamycin nor amikacin is approved for use in cattle. No tolerance levels have been established for these drugs in edible tissues from cattle.

The detectable presence of kanamycin and amikacin in the edible tissues of the animal caused the food to be adulterated. The extra-label use of approved veterinary or human drugs is permitted only if it complies with the Act and 21 CFR Part 530. Dr. Hytrek failed to comply in for the following reasons:

- Failure to establish substantially

extended withdrawal periods supported by appropriate scientific information for the extralabel use of these two drugs in food producing animals;

- Failure to institute procedures to assure that the identity of treated animals was carefully maintained; and
- Failure to take appropriate measures to ensure that there were no illegal residues in the dairy cows for which he
- prescribed the extralabel use of kanamycin and amikacin.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5750d.pdf.

Medicated Feeds

Consent Decree of Permanent Injunction – Cooperative Agricultural Services

On August 16, 2006, a Consent Decree of Permanent Injunction was filed in the U.S. District Court for the District of Kansas against Cooperative agricultural Services, Inc. (CO-AG) and CO-AG's Feed Department Manager (the defendants) of Grinnell, Kansas. The firm produces medicated and non-medicated feed for consignees in Kansas, Oklahoma and Colorado.

The injunction was based on multiple consecutive inspections where significant violations of FDA's Good Manufacturing Practice (GMP) requirements for feed manufacturers, Title 21 Code of Federal Regulations, Part 225, were documented. The impetus for these investigations was the death of livestock where suspect CO-AG feed was fed to the animals.

Under the terms of the Consent Decree, the defendants agreed to stop manufacturing and distributing medicated animal feeds until they provide assurance, to FDA's satisfaction, that their medicated feeds are made in compliance with current GMP requirements, in accordance with label specifications, and in a manner ensuring that all uses of new animal drugs conform to each drug's approved application. Under the Decree, the defendants are required to retain an expert consultant to conduct inspections of their manufacturing facility

and certify to FDA that corrections have been made.

The Decree also requires the defendants to have a qualified laboratory conduct analyses on their medicated feeds and to take corrective action for all medicated feeds that the laboratory determines are outside the assay (potency) limits set by FDA regulation. Further, the Decree provides for FDA to require a recall or shutdown in the event of future violations.

A CVM Update is available online at: http://www.fda.gov/cvm/co-aginj.htm.

Recall of Horse Feed Possibly Cominated with Rumensin

On June 22, 2006, Western Stockmen's,

Caldwell, Idaho, a business unit of J.R. Simplot Company, announced a recall of all Pride Mature Horse feed, Lot number 7701-050306, because it may have contained monensin sodium (Rumensin), a drug compound approved for use in some livestock species but which can be fatal if fed to horses.

Pride Mature Horse feed was distributed by the Western Stockmen's (WSI) store to customers in Caldwell, ID, and to Cowpoke Ranch Supply in Corvallis, Montana, and 3 Rivers in Lostine, Oregon.

Consumers can identify the product by the WSI Pride Feed bag label on 50-pound bags, which have a feed tag on the top left of the bag labeled Pride Mature Horse, with the lot number 7701-050306 at the bottom.

FDA and Western Stockmen's conducted an investigation to determine how Rumensin appeared in some of the feed. At least two horse deaths were related to the consumption of this feed. Consumers who had any of the affected lot number, were advised to cease use immediately and contact Leeon Martineau, General Manager or Julie Johnston, Quality Assurance Supervisor at Western Stockmen's.

Feed Mill Receives Warning for CGMP Deviations

On March 17, 2006, FDA's San Francisco District Office issued a Warning Letter to Jensen & Pilegard, Fresno, California. FDA issued the Warning Letter because an investigation of the licensed medicated feed mill found significant deviations from the CGMP regulations for medicated feeds. Such deviations cause feeds manufactured at this facility to be adulterated under of the Act. In addition, the investigation revealed deviations from labeling requirements that cause the medicated feeds manufactured at this facility to be misbranded.

The deviations from the label requirements also cause the medicated feed to be unsafe and, therefore adulterated. FDA inspection found following deviations from the CGMP requirements:

- Failure to have adequate cleanout procedures for all equipment used in the manufacture and distribution of medicated feeds to avoid unsafe contamination of feed with drugs;

- Failure to maintain a Master Record File, which includes the correct name of each drug ingredient to be used in the manufacture of the medicated feed. In addition, the Master Record File had not been prepared, checked, dated, and signed or initialed by a qualified person;

    - Failure to maintain a Master Record File, which includes a copy or description of the label or labeling that will accompany the medicated feed;

    - Failure to accurately test all scales used in the manufacture of medicated feeds at least once per year or more frequently as may be

necessary to insure their accuracy; and

- Failure to have suitable construction to minimize access by rodents, birds, insects, and other pests, to maintain the building in a reasonably clean and orderly manner, and to maintain the building grounds so that they are reasonably free from waste and refuse.

The medicated feeds were misbranded due to the mill's practice of using a page from the *Feed Additive Compendium* as labeling. This practice does not provide sufficient information to allow the purchaser of the medicated feed to use the feed in a safe manner. In addition, there were serious concerns over the mill's drug inventory and reconciliation practices. Specifically, the mill has a practice of rounding drug usage amounts up or down to simplify calculations and had failed to take corrective action to reconcile drug discrepancies and accurately weigh drug ingredients.

FDA's regulations require that drug inventory be maintained by means of a daily comparison of the actual amount of drug used with the theoretical drug usage and to investigate any significant discrepancy and take corrective action.
The full text of the Warning Letter is available at:
http://www.fda.gov/foi/warning_letters/g5763d.pdf.

FDA Inspection Discloses Significant Problems

On October 19, 2005, FDA's Kansas City District Office issued a Warning Letter to the Chairman and Chief Executive of Archer Daniels Midland Company (ADM) located in Decatur, Illinois. An FDA investigation of this medicated feed mill, located Higginsville, Missouri, conducted in May/June 2005, found significant deviations from the CGMP regulations for Medicated Feeds. Such deviations cause feeds being manufactured at this facility to be adulterated.

FDA investigation disclosed the following deviations from CGMPs:

- Failure to perform assays on representative samples of medicated feeds requiring a medicated feed mill license;
- Failure of the drug inventory records to accurately reflect the firm's current inventory; and
- Failure to properly identify, store, handle and control the drugs stored in the mixing area in order to maintain their integrity and identity.

In addition, FDA investigator noted the following:

- At the time of the inspection, the medicated feed mill had not performed any assays on medicated feeds during the past calendar year; and,
- There were instances of whiteout used on official records, poor sanitation practices and labeling issues.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5572d.pdf.

Warning Letter Issued to Medicated Feed Mill and Drug Manufacturing Site

On February 7, 2006, FDA's Kansas District Office issued to a Warning Letter to the President of International Nutrition, Inc., Omaha, Nebraska. FDA investigation conducted between July 26, 2005 and August 10, 2005 of this medicated feed mill and drug manufacturing site found a significant deviation from the CGMP regulations for medicated feeds. Such a deviation causes the feed being manufactured at this facility to be adulterated. The investigation found that the firm failed to implement adequate safeguards to prevent unsafe contamination in the production of feeds.

In addition, several labeling deviations were observed that cause certain feed products manufactured by the firm to be adulterated. Product labels for ZINPRO Corporation products containing the statement "Manufactured By ZINPRO Corporation" when the products were actually manufactured by International Nutrition Inc. for ZINPRO Corporation. Also, the distribution of Type A medicated articles to consignees from whom the firm did not obtain an unrevoked written statement caused the new animal drug to be deemed unsafe and, thus, adulterated.

Further, the investigation found that labels for feeds containing procaine penicillin and decoquinate, for use in poultry laying hens and sheep, respectively, were not in conformance with the approved new animal drug applications. The approval for procaine penicillin provides that feed be labeled with a warning against use in poultry laying eggs for human consumption.

The approval for decoquinate provides that feed be labeled with a warning against use in sheep producing milk for food. Labeling these products without the required warning statements causes these feeds to be unsafe and, thus, adulterated. It was also determined that the firm had not maintained in its possession the New Animal Drug Application approved labels as required by 21 CFR 510.305.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5727d.htm.

Deviations from CGMPs Results in Warning Letter

On November 10, 2005, FDA's Kansas District Office issued a Warning Letter to the President of Custom Feed Services Corporation, Norfolk, Nebraska. An FDA investigation of this medicated feed mill, located in Norfolk, Nebraska, conducted in June 2005, found significant deviations from the CGMP regulations for Medicated Feeds.

Violations included, but were not limited to the following:

- Master Record Files and production records were deficient in some of the

following areas:

- Lack of complete manufacturing instructions for medicated feeds;
- Lack of a copy or description of the label or labeling that would accompany the medicated feed;
- Lack of control instructions for the sampling procedures regarding the manner and frequency of sample collections;
- Master Record Files were not signed or initialed by a qualified person.

- Failure to maintain a proper receipt record for each lot of drug received; and
- Failure to maintain the facility in a reasonably clean and orderly manner.

In addition, during FDA investigation, the investigator found feeds manufactured and distributed by the firm that contained Carbon black. There is no color additive regulation currently allowing for the use of carbon black in food, including animal feeds.

The investigator also determined that labels for feeds containing monensin intended for use in dairy cattle were not in conformance with the approved application. This labeling caused these feeds to be unsafe and thus adulterated.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5614d.pdf.

Pet Foods

Recall of Contaminated Pet Food by Diamond Pet Foods

At Least 76 Dog Deaths Were Associated with Pet Foods Contaminated With Aflatoxin

Diamond Pet Foods, Meta, Missouri, discovered aflatoxin in a product manufactured at their facility in Gaston, South Carolina. Aflatoxin levels found ranged from 9-1000 parts per billion (ppb). The official action level for aflatoxin in pet foods is 20 ppb.

Thirty-one multiple brand pet food products, totaling more than 700,000 packages, were included in this recall. These products were distributed in twenty-four states and thirty foreign countries. At least seventy-six dogs deaths were associated with these contaminated products and an undetermined number of animal illnesses.

Warning Letter Issued for Alfaltoxin in Cat and Dog Pet Food

On April 12, 2006, FDA's Atlanta District Office issued a Warning Letter to the president of Schell and Kampeter, Inc., Meta, Missouri. FDA issued the Warning Letter following an inspection of the company's pet food manufacturing facility located in

Gaston, South Carolina, The inspection was conducted from December 21, 2005 through January 19, 2006. The investigation determined that the facility manufactures various dog and cat food products under several labels including Diamond, Country Value, and Professional. The inspection revealed significant deviations from the Act.

FDA's investigator documented that the facility manufactured a number of lots of dog food between September 1 and November 30, 2005, which were released for distribution in interstate commerce that were adulterated because they contained a poisonous or deleterious substance (aflatoxin), which may render them injurious to health. In addition, these lots of pet food were adulterated pursuant to 21 U.S.C. § 342(a)(4)].

The inspection also revealed that the facility failed to implement appropriate controls to prevent the adulteration of the pet food, and that the plant personnel failed to follow established procedures. The inspection also revealed that the waste or salvaged materials from pet food production (scrapes) were being sold to a local hog farmer in bulk. Some of the pet food manufactured at the plant contained protein derived from mammalian tissues. The scrape product, which may contain prohibited material, was not labeled with the statement "Do not feed to cattle or other ruminants" as required by 21 CFR 589.2000. This regulation is intended to help prevent the establishment and amplification of Bovine Spongiform Encephalopathy. This labeling deviation causes the distributed pet food scrapes to be misbranded.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5811d.pdf.

Turtles

Warning Letter Issued for Distribution of Undersized Turtles

On January 17, 2006, FDA's Florida District Office issued a Warning Letter to the President of Filo Corporation, d/b/a Turtle Mania, Hallandale Beach, Florida. On October 6, 2005, FDA investigators inspected Turtle Mania's retail Kiosk located within the Fort Lauderdale Swap Shop, Fort Lauderdale, Florida.

FDA investigators observed the business offering live turtles with a carapace length of less than four inches to retail customers as pets. The Warning Letter advised that this is a serious violation of the Public Health Service Act.

In addition, the practice of selling undersized turtles is in violation of FDA regulations. These 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 type of commercial or public distribution. Turtles of this size may carry Salmonella bacteria and transmit these bacteria to humans, causing Salmonellosis.

Previously, FDA had received a complaint which involved a young child requiring

medical care for signs and symptoms of Salmonellosis after playing with undersized turtles purchased from Turtle Mania. A laboratory sample taken by the pediatrician's office confirmed Salmonella bacteria. The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5811d.pdf.

Veterinary Drugs

Poor CGMPs and Poor Recordkeeping Result in Warning Letter

On June 23, 2006, FDA's Center for Veterinary Medicine issued a Warning Letter to the General Manager of Guilin Pharmaceutical Corporation, Limited, Guangxi, China. An FDA inspection in March of 2006 found significant deviations from CGMP regulation for Finished Pharmaceuticals. Such deviations caused the animal drug product Levamisole Phosphate to be adulterated.

Although the firm has made some changes and corrections in response to inspectional findings, the firm failed to institute sufficient corrections in Quality Management, and Documentation and Records Systems to achieve CGMP compliance for an API facility

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5898d.pdf.

Unapproved New Animal Drugs Result in Warning Letter

On June 14, 2006, FDA's Baltimore District Office issued a Warning Letter to the president of Boesl Packing Company, Inc., Baltimore, Maryland. FDA issued the Warning Letter following an inspection of the company's pet food manufacturing facility located in Baltimore, Maryland. The inspection revealed that the company was offering a product for sale that it is considered a new animal drug without an approval and also the facility was not properly registered.

In the March 10, 2006 inspection of the company established that "K-9 Kraving Dog Food" was a drug because it is intended for use in the cure, mitigation, treatment, or prevention of a disease. Also it was determined that the facility was subject to the registration requirement in section 415 of the Act.

The full text of the Warning Letter is available online at:

http://www.fda.gov/foi/warning_letters/g5891d.pdf

Promotion and Advertising Concerns Result in Warning Letter

Adverse Events Indicated that Heartguard and Heartguard Plus Were Not 100% Effective as Promoted

On August 14, 2006, FDA's Center for Veterinary Medicine issued a Warning Letter

to the Director of Regulatory Affairs of Merial Limited, Duluth, Georgia. A review of promotional materials on the company's website revealed that false and misleading claims were being made about an approved antihelmenthic product for dogs and cats.

Heartguard and Heartguard Plus were promoted as being 100% effective in heartworm prevention. Post-approval adverse drug events received by the Center indicate this claim cannot be true. The Center requested that the company immediately cease the dissemination of violative promotional materials for Heartgard and Heartgard Plus.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5983d.pdf

Poor CGMPs in Manufacture of Teat Dip Result in Warning Letter

On March 16, 2006, FDA's Kansas City District Office issued a Warning Letter to the president of FRM Chemical, Inc., Washington, Missouri. An FDA inspection in January and April 2005, found significant deviations from CGMP regulation for Finished Pharmaceuticals.

Such deviations caused the animal drug products (such as FRM Dine 1 Teat Dip Concentrate with Lanolin and Lanisyn 10 Teat Dip with 10% Glycerin & Lanolin products) to be adulterated. The investigation found the following deviations:

- Failure to establish and follow a written program for calibration of instruments, apparatus, gauges, and recording devices used to assure that drug products conform to appropriate standards of identity, strength, quality, and purity;
- Failure to perform at least one specific identity test on each drug component received, in lieu of testing each component for conformity with all appropriate written specifications for purity, strength, and quality;
- Failure to conduct CGMP training on a continuing basis;
- Failure to establish written procedures describing the in-process controls and tests, or examinations to be conducted on appropriate samples of in-process controls and tests, or examinations to be conducted with appropriate samples of in-process materials of each batch;
- Failure to establish written procedures designed to prevent -objectionable microorganisms in drug products;
- Failure to establish written control procedures for the issuance of labeling;
- Failure to establish written procedures for evaluation, at least annually, of the quality standards of each drug product.

The full text of the Warning Letter is available online at: http://www.fda.gov/foi/warning_letters/g5761d.pdf.