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Recently Enacted FDA Amendments Act Has Major Food Safety Components

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

The FDA Amendments Act of 2007 (FDAAA) was signed into law by the President on September 27, 2007 (Public Law 110-085). Among its many provisions, the law reauthorizes and expands user fees for prescription human drugs and for medical devices. These programs are designed to ensure that FDA staff has the additional resources needed to conduct the complex and comprehensive reviews necessary to make new drugs and devices available to consumers. The new law also reauthorizes the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, both of which are designed to encourage more research into, and more development of, treatments for children.

Focus on food safety

Title X of the FDAAA imposes several requirements in the food safety arena. Many of these apply to human and pet food and generally deal with processing and ingredient standards, improved communication during an ongoing recall, and a mechanism for reporting food determined to be threatening to human or animal health.

According to the new law, the impetus behind enactment of the FDAAA was to increase the public's confidence in the safety of the food supply.

Of major concern has been the increased amount of imported food, which now accounts for 13 percent of the average American diet, including 9.5 percent of red meat, and 78.6 percent of fish and shellfish. Also cited in the legislation is the decrease since 2003 in the number of full-time FDA inspectors.

In order to further enhance the safety of pet food, the new law directs that within 2 years the Secretary of Health and Human Services (HHS) is to promulgate new regulations to establish ingredient standards and definitions, processing standards, and updated standards for labeling to include nutritional and ingredient information.

Early warning system and effective communications

The new law also requires that, within 1 year, an early warning and surveillance system be established in order to identify any adulteration incidents affecting the pet food supply and also to alert the public about any outbreaks of illness associated with pet food. To do this, the law instructs the Secretary of HHS to consider the use of surveillance and monitoring mechanisms already in place to monitor human or animal health (e.g., FoodNet, PulseNet, and FDA's Food Emergency Response Network).

FDA has already taken several steps to improve communication about a pet food recall, including posting information about the recall on FDA's Internet Web site in a single location.

Reportable Food Registry

By September 27, 2008, FDA is also directed to establish a "Reportable Food Registry" to which instances of "reportable food" would be submitted by the Agency via an electronic portal, based on reports submitted by food facilities (i.e., manufacturers, processors, packers) that have registered pursuant to Section 415(a) of the Federal Food, Drug, and Cosmetic Act. For purposes of this requirement, "reportable food" means an article of food (other than infant formula) for which there is a reasonable probability that use of it will cause serious adverse health consequences or death to humans or animals.

Generally, any reports about such foods are to be submitted to the registry no later than 24 hours after a firm has determined that the food item poses possible serious adverse health effects. However, the law says that no report would be required if the party with which the adulteration originated detected the adulteration prior to any transfer of it to another person and either corrected the adulteration or destroyed the adulterated product.

(Continued, next page)

IN THIS ISSUE

Consent Decrees of Permanent Injunction Signed to Correct Illegal Drug Residues 2
CVM's New Deputy Director Brings Diverse, Far-Reaching Experience to Job 6
Video on Cleaning Trucks, Transports to Prevent BSE Wins Awards 13

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

Consent Decrees of Permanent Injunction Signed to Correct Illegal Drug Residues

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

The presence of illegal drug residues in the tissues of dairy cows offered for slaughter as food is the basis for two recent court actions taken by the Department of Justice and the Food and Drug Administration.

Case in Iowa

In the first case, an Order of Consent Decree of Permanent Injunction was signed by a U.S. District Court Judge in the Northern District of Iowa, Western Division, against Ysselstein Dairy, Inc., Rock Valley, IA, and its owner and president, Sjerp W. Ysselstein. Ysselstein Dairy produces milk for human consumption and dairy cows for slaughter as human food.

The permanent injunction is based on nine illegal residues in the edible tissues of seven dairy cows sampled by the U.S. Department of Agriculture's Food Safety Inspection Service (FSIS) between July 1992 and March 2006. The drug residues found by FSIS included antibiotics, such as tetracycline, sulfadimethoxine, flunixin, oxytetracycline, and penicillin at levels exceeding the tolerances set by FDA; no residue of tetracycline is permitted in the edible tissues of dairy cattle. The presence of the high levels of drugs in the tissues of the cows sold for slaughter as food rendered them adulterated under the Federal Food, Drug, and Cosmetic Act (FFDCA).

In the seven different animals offered for sale by the Ysselstein Dairy from 1992 to 2006, the concentrations of antibiotic drugs demonstrated that the dairy and its owner did not administer the drugs consistent with the dosage, withdrawal period, species limitations, or other use requirements set forth in the drugs' labeling. The violations continued over an extensive period, despite the issuance by FDA of several "findings of inspections" (Form 483s) and several Warning Letters. Pursuant to the Court's order, the dairy and Mr. Ysselstein must implement systems for identifying animals, keeping records, drug control, drug accountability, and drug residue withdrawal control. In addition, if FDA informs them about not being in compliance with the terms of the Consent Decree or the FFDCA, the agency may require them to cease operations until they are in compliance. The Decree also provides for the dairy and Mr. Ysselstein to pay a fine for each day they fail to comply with the Decree and for each animal that they sell or deliver for sale in violation of the Decree.

(Continued, next page)

Recently Enacted FDA Amendments Act... *(Continued)*

Also, the new legislation authorizes persons submitting these reports to include a statement to the effect that the submitter "denies" that the report or notification constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness.

The new law delineates several follow-up actions after a report is submitted to the registry, and all responsible parties are instructed to maintain records related to each report for 2 years. In addition, this law gives FDA 9 months to develop regulations and a guidance to industry to implement the food registry. The guidance is to include specific information on how to submit the reports to the registry via the electronic portal and how to provide the required notification to other persons in the supply chain about a suspect feed product that poses a "reasonable probability" of causing serious adverse health consequences.

Aquaculture and seafood inspection; genetically engineered seafood

The new law also authorizes the Secretary of HHS to enhance FDA's inspection program for aquaculture and seafood, consistent with obligations of the United States under international agreements and U.S. law. In addition, upon the request of any State, the Secretary may enter into partnership agreements to implement inspection programs to Federal standards regarding the importation of aquaculture and seafood products.

Lastly, the Commissioner of Food and Drugs is directed by the new law to consult with the Assistant Administrator of the National Marine Fisheries Service to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

FDA VETERINARIAN

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CVM Staff Member Honored Among FDA's Other Late Duty Officers

by Jon F. Scheid, Editor

The Commissioner of Food and Drugs, Dr. Andrew von Eschenbach, in August recognized the contribution of volunteers for the Food and Drug Administration's Late Duty Officer Response Team, a program that draws volunteers from across the Agency to be on-call outside normal business hours to respond to emergency phone calls involving FDA-regulated products.

FDA has approximately 50 Late Duty Officer Response Team volunteers, who, for a week at a time, make themselves accessible at night and on weekends to deal with emergencies that consumers, health care professionals, veterinarians, and others report via FDA's emergency phone system.

Dr. von Eschenbach sent each volunteer a "Commissioner's Special Citation" plaque acknowledging his or her participation in the program.

One of the plaques went to Fredda Shere-Valenti, a consumer safety officer in the Center for Veterinary Medicine's Office of Surveillance and Compliance. She has volunteered for the Late Duty Officer program since it began 4 years ago, and volunteered for similar programs before it.

In August, the Center for Veterinary Medicine's Fredda Shere-Valenti received a Special Citation plaque from the Commissioner of Food and Drugs for her participation in the Food and Drug Administration's Late Duty Officer Response Team program. Approximately 50 volunteers from across FDA received plaques. As a member of the Late Duty Officer Response Team, Mrs. Valenti volunteers her time for a week or more per year to respond to after-hour and weekend calls made to FDA's emergency phone system. During regular hours, she is a member of the Bioresearch Monitoring and Administrative Actions team in CVM's Office of Surveillance and Compliance. In that capacity, she issues assignments to FDA's field organizations to inspect the work of clinical investigators, sponsors, monitors, and non-clinical laboratories to determine compliance with the regulations. She reviews the data the inspectors gather. She also helps train CVM's animal drug reviewers and members of FDA's field organizations.

The Late Duty Officer Response Team program is operated by FDA's Office of Emergency Operations (OEO), which is part of the Office of the Commissioner. OEO is staffed by FDA employees during regular working hours, 8:00 a.m. to 4:30 p.m. (Eastern), Monday through Friday (except holidays). During those hours, an emergency call goes to one of the regular OEO staff members. After hours, the Late Duty Officer program takes over.

Any after-hours call placed to the emergency number goes first to an answering service, which contacts the Late Duty Officer with the information necessary for returning the call. All domestic calls are returned.

In a recent interview, Mrs. Valenti said no one can predict the

(Continued, next page)

Consent Decrees of Permanent Injunction Signed… *(Cont.)*

Case in Puerto Rico

In the second case, the U.S. District Court for the District of Puerto Rico issued an Order of Permanent Injunction on August 8, 2007, against J.M. Dairy, Inc., Las Martas, Inc., and Juan Manuel Ginorio, the owner of both dairies, after illegal drug residues were found in cows offered for slaughter as food. The court order follows a civil complaint filed against all of the parties in September 2006, based on FDA's investigations into the dairies and their practices.

The injunction is based, in part, on five illegal residues in the edible tissue of three dairy cows sampled by FSIS between August 2003 and September 2005. These residues included antibiotics, such as sulfamethazine, sulfathiazole, sulfadimethoxine, and penicillin at levels not permitted by FDA. Inspections conducted more recently by FDA confirmed that the two dairies continued to use animal drugs in a manner contrary to the label directions, without the benefit of a veterinarian's oversight. In addition, the dairies failed to maintain record-keeping systems to ensure that they did not sell milk or animals for slaughter for human food with illegal new drug residues. The court order requires that these conditions be rectified. The order also stipulated that the defendants may resume selling or delivering food (milk or animals for slaughter for human food) in interstate commerce only after they are notified by FDA that they are in compliance with the terms of the court order.

...Honored Among FDA's Other Late Duty Officers *(Cont.)*

number or type of calls that will come in. Not all of the calls require further action, she added. Some can be handled on the spot. Others can wait until business hours the next day. Each morning, the Late Duty Officer reports to OEO all activities, including calls that need further attention during business hours.

However, when a caller needs an immediate response, Mrs. Valenti explained, the Late Duty Officer has access to an OEO backup staff member, as well as contact information for key staff members in all parts of FDA.

Not all calls involved products for humans. Pet food or animal feed contamination cases are sometimes reported on FDA's emergency phone system.

OEO Director Dorothy Miller explained that volunteers for Late Duty Officers do not need any specialized training or backgrounds. They are given general instruction and a manual that sets out guidelines for responses.

Beyond that, Mrs. Valenti said, the Late Duty Officer relies on experience and knowledge of the Agency to make sure all calls are properly handled.

Late Duty Officers work one-week shifts during which they are on call whenever the OEO office is closed, starting Monday afternoon at the close of business and ending the following Monday morning at the start of the business day.

When a Late Duty Officer begins a week-long shift, OEO provides a "kit" that includes a beeper, a cell phone, and a book with contact information for all key FDA staff.

Emergency Office

Before the OEO was established, Mrs. Miller said, the after hours duty was assigned to personnel from FDA's Office of Regulatory Affairs. After the "9/11" tragedy, when officials across the Federal Government wanted to elevate the emergency response functions within their organizations, FDA moved its emergency response to the Commissioner's Office. OEO officially became part of the Commissioner's Office in 2003.

Within the Commissioner's Office, OEO is assigned to the Office of Crisis Management, which has responsibility for coordinating FDA counterterrorism and emergency exercises; planning, developing, and directing physical and personnel security programs; coordinating Agency evaluation of emergencies to determine appropriate responses; and coordinating intra-agency and interagency emergency preparedness.

The Office of Crisis Management also is responsible for activating FDA's Emergency Operations Center, a physical facility that is staffed during emergencies to coordinate FDA's response. The center was activated for several weeks during the recall of melamine-contaminated pet food and animal feed.

Volunteers

Mrs. Miller said that using volunteers to staff the Late Duty Officer Response Team program has several advantages over assigning the after-hours duty to FDA staff.

One advantage that the volunteer process offers is far less employee stress. Emergency response work is demanding. Calls must receive a prompt and accurate response, even when they come in the middle of the night, Mrs. Miller said. Individuals required to do that sort of work regularly for any length of time can burn out, she added. With a group of volunteers, the work is spread out. A typical volunteer does a Late Duty shift only once during the year, and normally the volunteer gets to choose which week to work.

A second advantage, perhaps more important, is that the cadre of Late Duty Officer volunteers gives FDA a large pool of emergency workers from which to draw. Through the Late Duty Officer program, the volunteers gain experience in emergency operations, which makes them a valuable resource to be called on when an emergency threatens to overwhelm FDA's regular response resources. Mrs. Miller called the reserve of trained individuals FDA's "surge capacity."

Mrs. Miller cited the need for this surge capacity when Hurricane Katrina hit Louisiana, and the Federal response lasted for weeks. A more recent example was the melamine-contaminated pet food recall. Mrs. Miller explained that, during the recall, FDA received more than 19,000 calls about pet food in the course of just a few months. Normally, FDA receives only about 5,000 calls a year for all the products it regulates.

In addition, she added, the National Response Plan, developed by the U.S. Department of Homeland Security as a blueprint for a U.S. response to terrorist attacks, calls for the use of volunteers.

Mrs. Valenti started volunteering to be the after-hours contact in 1985. She has continued doing it because the program gives her a "great opportunity to touch somebody's life, to make a difference," she said.

Comings and Goings

New Hires

OFFICE OF NEW ANIMAL DRUG EVALUATION

- Stacey R. Gore, Staff Fellow

OFFICE OF SURVEILLANCE AND COMPLIANCE

- Xin Li, Staff Fellow
- Maureen Majors, Management Officer

Departures

OFFICE OF THE DIRECTOR

- Melanie Fleming, Office Automation Assistant

OFFICE OF SURVEILLANCE AND COMPLIANCE

- George Graber, Deputy Director (Retirement)

FDA Emergency Numbers

The Food and Drug Administration maintains a system of emergency phone numbers for complaints or concerns about any product FDA regulates.

The main number, which can be used to contact FDA headquarters, is 301-443-1240. Calls to that number go to FDA's Office of Emergency Operations (OEO) during regular business hours, or to a Late Duty Officer volunteer at other times. All calls are returned.

Callers, in many cases, should consider contacting their local Complaint Coordinator (see below). The District of Columbia, Puerto Rico, the Virgin Islands, and each State has one (and California has two).

Dorothy Miller, OEO Director, said that the emergency numbers should be used only for FDA-regulated products, and not for medical emergencies. For medical emergencies, call 911.

Main FDA number ..... (301) 443-1240

Here are the numbers of Complaint Coordinators:

Alabama	(866) 289-3399
Alaska	(425) 483-4949
Arizona	(949) 608-3530
Arkansas	(214) 253-5200, ext. 5233
California (Northern)	(510) 337-6741
California (Southern)	(949) 608-3530
Colorado	(303) 236-3044
Connecticut	(781) 596-7700
Delaware	(215) 597-9064
District of Columbia	(410) 779-5713
Florida	(866) 337-6272
Georgia	(404) 253-1161
Hawaii	(510) 337-6741
Idaho	(425) 483-4949
Illinois	(312) 353-7840
Indiana	(313) 393-8100
Iowa	(913) 752-2440
Kansas	(913) 752-2440
Kentucky	(513) 679-2700, ext. 124
Louisiana	866-289-3399
Maine	(781) 596-7700
Maryland	(410) 779-5713
Massachusetts	(781) 596-7700
Michigan	(313) 393-8100
Minnesota	(612) 758-7221
Mississippi	866-289-3399
Missouri	(913) 752-2440
Montana	(425) 483-4949
Nebraska	(913) 752-2440
Nevada	(510) 337-6741
New Hampshire	(781) 596-7700
New Jersey	(973) 331-4917
New Mexico	(303) 236-3044
New York	(718) 340-7000, ext 5588
North Carolina	(404) 253-1161
North Dakota	(612) 758-7221
Ohio	(513) 679-2700, ext. 124
Oklahoma	(214) 253-5200, ext. 5233
Oregon	(425) 483-4949
Pennsylvania	(215) 597-9064
Rhode Island	(781) 596-7700
South Carolina	(404) 253-1161
South Dakota	(612) 758-7221
Tennessee	866-289-3399
Texas	(214) 253-5200, ext. 5233
Utah	(303) 236-3044
Vermont	(781) 596-7700
Virginia	(410) 779-5713
Washington	(425) 483-4949
West Virginia	(410) 779-5713
Wisconsin	(612) 758-7221
Wyoming	(303) 236-3044
Puerto Rico and U.S. Virgin Islands	(800) 332-0127

Need for Veterinarians in Biomedical Research

The Food and Drug Administration's "Critical Path" Initiative is reinvigorating the field of biomedical research, making it more productive and efficient, and creating opportunities for veterinarians to become involved in scientific research in academia, the private sector, or government, according to Dr. Stephen F. Sundlof, Director of FDA's Center for Veterinary Medicine.

In a speech he presented to the Association of American Veterinary Medical Colleges (AAVMC) in August, Dr. Sundlof said that veterinarians are ideally suited to take advantage of those research opportunities, because, as veterinarians, they acquire a

(Continued, page 11)

CVM's New Deputy Director Brings Diverse, Far-Reaching Experience to Job

by Vashti Klein, Management Analyst, Communications Staff

Dr. Bernadette Dunham, appointed as Deputy Director of the Food and Drug Administration's Center for Veterinary Medicine earlier this year, brings to the post a perspective gained from wide experience in veterinary and human medicine.

Dr. Dunham received her Doctor of Veterinary Medicine degree from the Ontario Veterinary College, University of Guelph, Ontario, Canada. Her career began in Ontario, where she was in private practice, treating primarily companion animals, including some equine.

She later acquired a Ph.D. in cardiovascular physiology from Boston University and worked as a biomedical researcher at both Boston University and Harvard Medical School studying the microvascular vasoactivity and vasotoxicity of arachidonic acid products that underlie inflammation as well as intervention by various non-steroidal anti-inflammatory drugs.

Later, at the State University of New York Health Science Center at Syracuse, NY, she served as an Adjunct Professor in the Department of Pharmacology, concurrent with being Director of Laboratory Animal Medicine. There the research focus was on the molecular regulation of cardiac gap junction proteins and intercellular communication.

In 1995, she joined the American Veterinary Medical Association's (AVMA's) Governmental Relations Division in Washington, DC, where she had the opportunity to work with members of Congress and their staff regarding legislation impacting human and animal health.

She came to CVM in 2002 as Deputy Director of CVM's Office of New Animal Drug Evaluation (ONADE). In 2006, Dr. Dunham was appointed Director of CVM's Office of Minor Use and Minor Species (OMUMS) Animal Drug Development. In February 2007, she was appointed CVM Deputy Director.

Based on her years of experience inside and outside of government, Dr. Dunham is able to say that CVM is a great place for veterinarians and other scientists to work. "It is like being in a mini-university, because of the extensive diversity that we have in scientific expertise, i.e., veterinary medicine, microbiology, toxicology, animal science, pharmacology, pathology, law, chemistry, molecular biology, physiology, aquaculture, mathematical statistics, policy and regulation, public health, business, and education—all within CVM," she said.

Dr. Bernadette Dunham, who earlier this year was appointed Deputy Director, CVM, brings to that post a background in veterinary and human medicine.

Tying into CVM's mission

At each step of her career, Dr. Dunham's goal has been to improve and enhance animal and human health. Her vast experience in veterinary and human medicine serves as the foundation for her work as Deputy Director of CVM.

"My background in human and animal medicine ties into CVM's mission, which is to protect public and animal health," Dr. Dunham said in a recent interview. She pointed out the link between human and animal research that she found was evident when she was involved in human biomedical research. "The information gleaned from laboratory animal studies leads to advances not only in human medicine, but it is frequently added to the body of medical knowledge about animal health. Many times the medicines are the same for both animals and humans," she added.

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CVM's New Deputy Director *(Continued)*

Because of the combined human and animal benefit she saw in the research she was doing, Dr. Dunham strongly endorses the concept behind the "One Health" initiative. Under that initiative, the American Medical Association (AMA) and AVMA are forging a partnership between the worlds of human and animal medicine. "I deeply subscribe to the sentiments of the One Health initiative," Dr. Dunham said. (See the following article, "Dr. Dunham Supports AVMA/AMA 'One Health' Initiative.")

What you know, who you know

Her varied background has helped her in other ways, Dr. Dunham said. "The vast network and friendships that I have built up over the years have helped me at CVM. My contacts with people from various associations, members of Congress and their staff, and my university colleagues have assisted with a number of issues being addressed at CVM."

Knowing more than just the scientific issues has helped Dr. Dunham in other ways, too. "Even though CVM is a science-based and science-led organization that has a tremendous caliber of scientific expertise," she said, "other issues come into play. Science alone does not always decide the regulatory policy under which we operate, because there is always a degree of inherent uncertainty that can be challenged."

"My experiences with the AVMA's Governmental Relations Division, where I was involved with numerous coalition groups that helped develop and influence various pieces of legislation that Congress addressed, helped me appreciate the importance of society's role in developing policy," she said.

Key skills beyond those of a scientific nature for Dr. Dunham are people skills, and she acquired many of them as a practicing veterinarian. "In veterinary medicine, you learn the science of medicine, but you cannot treat a single pet in your hospital without the owner's consent. Developing good people skills helps in the communication outreach. Clients will better understand the need for a specific medical treatment or procedure for their pets and will make an informed decision. I have always been a strong advocate of encouraging clients to ask questions to ensure they understand the specific disease their pet may be afflicted with or side effects of a medication to watch for, and the need to stay in touch with their veterinarian," Dr. Dunham said.

Mentoring

Though Dr. Dunham's efforts in ONADE were focused on assisting and supporting ONADE Director Dr. Steven Vaughn in planning, managing, organizing, and directing all of the regulatory review operations, program segments, functions, and activities of the Office, she also served as a mentor to the staff in the organization.

Mentoring is an important aspect of CVM's management philosophy—"High Performance Organization," or HPO. An organization such as CVM uses HPO as a lens through which to see what is happening within it and what needs to happen to improve its performance.

Dr. Dunham describes a good mentor as someone who has the ability to listen to people and understand them. "Mentors must be interested in learning about their employees, understanding their skills and interests, and then must take the time to help the employees identify gaps. A mentor also includes their mentee in networking opportunities, which is very important," she added.

"Some mentors use individual development plans (IDPs), which they create alongside their employees. There are different models of IDPs from which to choose, and they can be structured according to an individual's or organization's needs. For example, it can be something as simple as taking the time to look at someone's educational background and their career goals and making recommendations for further study to improve their skills. A mentor can also help the mentee become more visible in an organization," she said.

In ONADE, Dr. Dunham was known for devoting the time it takes to recognize people's skills and talents, and she took time to provide the staff with opportunities to grow. She is known for having provided the ONADE staff with encouragement, support, and appreciation for the work done. She also has the ability to listen to opposing points of view and to incorporate the best ideas into a solution.

Dr. Dunham attributes her mentoring and many of her people skills to the fact that during her career she was able to work with individuals that she considered to be remarkable mentors and role models. She was able to take the skills and lessons learned from those experiences and share them with others at CVM, she said.

"My parents were fabulous mentors, and I had wonderful mentors in my high school teachers and my university professors. It is through my mentors' encouragement that doors have opened for me. The mentors were also role models, as I learned how their careers evolved and what they did to achieve their career goals." Dr. Dunham said.

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CVM's New Deputy Director *(Continued)*

When she left ONADE to become Director of the OMUMS, the ONADE staff recognized Dr. Dunham for her mentoring skills. They provided her with a special award that reads, "In deep appreciation for your superior service through unrivaled kindness, compassion, and personal friendship for each member of ONADE."

OMUMS

While taking on the duties as Deputy Director of the Center, Dr. Dunham continues as Director of OMUMS, a job she willingly kept because of the importance she sees in increasing the supply of safe and approved drugs for minor uses and minor species. (Minor species are all animal species other than cattle, swine, chickens, turkeys, horses, cats, and dogs, which are considered the major species. Minor use is the use of a drug in a major species to treat a rare disease.)

"There will never be enough FDA approved drugs for all of the animal species and their specific diseases or ailments, due to the economics of drug development. This situation is especially true for minor species, where the numbers of animals are often small and the return on investment is low. We are hopeful that some of the incentives afforded through the MUMS Animal Health Act (passed in 2004) will encourage pharmaceutical companies to develop some of the needed medications for minor species or for minor uses in major species." Dr. Dunham said.

OMUMS was established in November of 2004. "Its development involved a lot of hard work by a coalition of stakeholders, CVM, and Congress," she said.

Under the careful direction of Dr. Andrew Beaulieu, the former OMUMS Director, and Dr. Margaret Oeller, a Veterinary Medical Officer who conducts most of the OMUMS day-to-day activities, many provisions of the MUMS Act have been implemented. "Dr. Beaulieu and Dr. Oeller have been the backbone of the OMUMS and now we are all looking forward to building the office up over the next few years," Dr. Dunham said.

Dr. Dunham said there was a need for the MUMS Act to change the Federal Food, Drug, and Cosmetic Act (FFDCA), thus creating a pathway that would help make drugs for either a minor use or minor species economically viable.

"It is very frustrating for you as a veterinarian not to have a safe and effective product in your armamentarium of therapies to reach for to treat the vast array of minor species that come to your clinic, or that you travel to treat on farms. And there are exotic species of animals that are in zoos and aquariums that require treatment. Even though the Animal Medicinal Drug Use Clarification Act of 1994 enables legal extralabel drug use by veterinarians, it is preferable to have an approved drug for a specific species, for a specific indication, and with a known dosage range that is safe and effective. MUMS makes that possible," Dr. Dunham said.

As Director of OMUMS, Dr. Dunham is responsible for developing regulations to implement the MUMS Act, according to the schedule described in the law, and publishing MUMS drug designations on the MUMS Web page.

The MUMS Act modifies provisions of the FFDCA in three ways: designation, indexing, and conditional approval. The implementing regulation for drug designation was the first to be developed by the new Office, with a proposed regulation issued on September 27, 2005, and a final regulation issued on July 26, 2007. The proposed regulation for the indexing provisions of the law was issued on August 22, 2006, and will become effective upon publication of final implementing regulation. The proposed regulation for conditional approval is under development.

Dr. Dunham is a strong advocate of MUMS. She was involved at the beginning and now is involved during implementation. She was working for AVMA's Governmental Relations Division when the Minor Use and Minor Species (MUMS) Coalition was formed in 1999. The MUMS Coalition worked closely with CVM and members of Congress to develop the MUMS Act. When Dr. Dunham joined CVM in 2002, she was involved in the final public outreach to help educate stakeholders about the MUMS legislation.

Goals at CVM

When asked during the interview what she would like to accomplish during her tenure at CVM, Dr. Dunham replied, succinctly:

- "Successful implementation of all of the regulations developed under the MUMS Act; completion of the guidances for each of the regulations; a fully funded and staffed OMUMS, complete with an operational grants program; and many new approved products on the market for minor uses and minor species."
- "Heightened awareness of CVM as a terrific place to pursue a career, as evidenced by our ability to attract and keep highly talented individuals."
- "Enhanced communication and collaboration among the CVM offices."

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Dr. Dunham Supports AVMA/AMA "One Health" Initiative

Dr. Bernadette Dunham, Deputy Director of the Center for Veterinary Medicine, is a strong proponent of the initiative called "One Health," aimed at developing more collaboration and communication between human and veterinary medicine.

The concept behind the One Health initiative is not new (it was first articulated in the 19th Century), but it gained increased attention as the American Medical Association's House of Delegates voted in June to approve a resolution to support it, and the American Veterinary Medical Association (AVMA) in July at its annual convention named members to a One Health Initiative Task Force. AVMA had endorsed the concept earlier.

Dr. Roger Mahr, Immediate Past President of the AVMA, made the One Health initiative his top priority during his presidency (2006-2007). It was his recommendation to establish the task force.

According to an AVMA press release, the task force was given the job of "articulating a vision of One Health that will enhance the integration of animal, human, and environmental health for the mutual benefit of all."

The One Health initiative addresses the significance of zoonotic diseases. The most obvious zoonotic diseases are variant Creutzfeldt-Jakob disease, West Nile virus, avian influenza, rabies, and salmonellosis. But many other diseases can move between humans and animals. Approximately 60 percent of all infectious agents of humans are zoonotic, according to experts. In addition, 75 percent of emerging human diseases seen in the past 25 years have been zoonotic, AVMA's Dr. Mahr stated during the group's annual conference in July.

The leading advocates of the initiative are Dr. Laura H. Kahn, a physician on the research staff of the Woodrow Wilson School of Public and International Affairs, Princeton University; Dr. Bruce Kaplan, a veterinarian in Sarasota, FL, and previously with the U.S. Department of Agriculture's Food Safety and Inspection Service; and Dr. Thomas P. Monath, a physician previously with the Centers for Disease Control and Prevention (Fort Collins, CO) and the U.S. Army Medical Research Institute of Infectious Diseases (Fort Detrick, MD), and currently with the investment firm Kleiner Perkins Caufield & Byers, Menlo Park, CA.

They have drafted this One Health mission statement:

"Recognizing that human and animal health are inextricably linked, One Health seeks to promote, improve, and defend the health and well-being of all species by enhancing cooperation and collaboration between physicians and veterinarians, and by promoting strengths in leadership and management to achieve these goals."

The initiative seeks increased educational opportunities between human and veterinary medical schools, more communications, and more cross-species disease surveillance, as well as other coordination.

Dr. Kaplan is collecting statements of support for the One Health initiative. Dr. Dunham, who has had veterinary clinical experience as well as human and veterinary research experience, sent him this statement of support:

"Sir William Osler, M.D. (1849-1919) promoted the philosophy of 'one medicine.' How exciting to witness, in 2007, the official adoption of the 'One Health' initiative by both the AMA and the AVMA!! Through mutual collaborations—clinical and research experiences—veterinarians and physicians can accomplish so much more together to advance the health of humans and animals. Today, we truly live in a global village where people, animals, and microbes all travel. So, it is even more imperative that we all embrace the One Health initiative. I look forward to joining my colleagues in a multidisciplinary approach as we address the global health needs of humans, animals, and their environment."

Others who have sent testimonials supporting the One Health Initiative include Major General Gale S. Pollock, Acting, Surgeon General, U.S. Army; and former U.S. Senator Bill Frist, MD. Dr. Kaplan is continuing to collect testimonials.

CVM's New Deputy Director *(Continued)*

- "A communication and outreach program with our stakeholders and the general public; and improved awareness, understanding and support of CVM by the general public." (See next page: "Dr. Dunham Stresses Importance of Communications for CVM")
- "Expanded involvement for CVM in new technologies, for example, cloning; genetically engineered animals; pharmacogenomics, microarrays, nanotechnology."
- "Finally, to know that, as Deputy Director, I am able to assist Dr. Sundlof with his vision for CVM and to make his job easier wherever possible."

Dr. Dunham Stresses Importance of Communications for CVM

Dr. Bernadette Dunham, who was appointed Deputy Director of the Food and Drug Administration's Center for Veterinary Medicine earlier this year, and who became Director of CVM's Office of Minor Use Minor Species in 2006, brings to those posts strong ideas about the importance of communications to government, regulated industry, associations, and the public in general. Recently, FDA Veterinarian *interviewed Dr. Dunham to find out more about her communications goals.*

by Vashti Klein, Management Analyst, Communications Staff

What are your communications goals for CVM?

CVM's mission of protecting public and animal health through the approval of safe and effective drugs is critical, and the more stakeholders understand our mission, the better we can work together. Educating stakeholders about the complexities of FDA/CVM's regulatory process is vitally important to good communications. This includes explaining complex processes like the intricacies of the pre-market review process, the importance of post-market surveillance, and the role that research plays. These processes require working closely together to protect the public health.

You have had significant experience outside and inside CVM. From that experience, can you identify the aspects of what CVM does that most stakeholders may not realize or fully understand?

Pharmaceutical companies know a great deal about us, but there is still a lot that they do not know. Something the regulated industry may not be aware of is the exciting research that is conducted at our facilities in Laurel. (CVM's Office of Research is in Laurel, MD.)

Stakeholders do not always realize how well people at CVM stay abreast of cutting-edge technologies and advances in the biomedical sciences through seminars and lectures, as well as through the courses offered by the CVM Staff College, which now includes a program to obtain a Master's degree in Public Health.

I want our stakeholders to know that we value their perspectives and that we strive to resolve issues of concern in an efficient manner. Three years ago, FDA launched the Critical Path Initiative: FDA's effort to stimulate and facilitate a national effort to modernize the sciences through which FDA-regulated products are developed, evaluated, and manufactured. Since the initial report in March 2004, the Critical Path Initiative has been broadened to include veterinary medicine, generic drugs, and foods. (See the article, "Need for Veterinarians in Biomedical Research," which discusses more about the Critical Path Initiative, elsewhere in this edition.)

The more we all understand the challenges facing animal drug development or can set up collaborations to identify areas ready for improvement (as part of the Critical Path Initiative), the easier it will be to coordinate, develop, and/or disseminate solutions to scientific hurdles that are impairing the efficiency of developing and evaluating FDA-regulated products. We need to foster strong and sustained scientific advances that will enhance the health of animals and protect public health.

What are your views on internal communications at CVM?

Communication is quintessential no matter where one works. At CVM, the more people are aware of the issues confronting various offices, understand what is expected of them, freely exchange ideas and solutions, and sustain transparency, then the more cohesive the entire CVM team becomes and the easier it is to embrace change and meet the challenges of the future. People take pride in their organization and feel a genuine part of the organization the more they understand the issues, the applicable regulations, our customers, and our overall goals.

Feeling left out or feeling unappreciated often results when communications break down. Communicating often, honestly, and respectfully can resolve most workplace tensions. Encouraging tolerance of people who are different from us and taking time to get to know others can diffuse daily tensions. Resolving differences quickly and moving on—these are small steps that have large results.

When various offices in CVM understand what other offices are doing and there is a free exchange of ideas and solutions, the more cohesive the entire CVM team becomes in the performance of our jobs.

Keeping morale high is an important part of an organization's work culture. In doing so, it is very important to show people that they are appreciated and to acknowledge the strengths and attributes that each person brings to the table. Moreover, people will seek a positive work environment where everyone treats one another with respect, honesty, and integrity.

(Continued, next page)

Importance of Communications for CVM . . . *(Cont.)*

How can we communicate better with the public?

CVM's external communications can be enhanced. One needs to be proactive and to quickly put out messages of importance using various multimedia resources: Internet, pod casts, radio, television, newspapers, national and trade magazines. And creative ways must be found to reach out to today's generation so that they will tune in, listen, and engage in discussions with us.

It is easy for people to misunderstand the complex scientific issues of the day, especially if those issues are reduced to short sound-bites. We have to improve how we explain complex scientific problems to a public that may not have a science background. Moreover, public perception is often not based on scientific fact, and emotions often come into play, further complicating the communication between groups. Collaboration and outreach with various professional groups, academia, associations, and industry is an important way to help convey the facts surrounding a specific issue to the public, and to enhance the public's understanding.

What else should CVM do?

It can be as easy as speaking with your next door neighbor and letting him or her know what CVM is all about…many people do not know that drugs for animals go through an FDA approval process similar to that for human drugs. Taking a moment to explain this can help improve the public's understanding of how CVM is supporting and protecting them. Embracing opportunities to address students in public schools and universities helps highlight the multitude of careers within CVM while simultaneously explaining what we do to protect public health and animal health.

What problems will better communications address?

Through clear communication and transparency, CVM can, for example, help industry meet the regulatory requirements for animal drug approvals. Pre-submission conferences have greatly enhanced the understanding of what is expected when a sponsor is embarking on the drug approval pathway and helps avoid misinterpretations. This, in turn, impacts the quality of submission and hopefully leads to a one cycle review (meaning that a drug sponsor will fully understand the data requirements of an application before it is submitted, so the sponsor will not need to submit it multiple times), which is a goal we all embrace.

The more the public understands and is continually educated about the overall mission of CVM, the more we can be successful in protecting the public health.

And the better we communicate internally, the better able we are to accomplish this.

Communications on anything can always be improved!

Need for Veterinarians in Biomedical Research . . . (

broad range of biomedical disciplines that go from working at the molecular level to encompassing entire ecosystems.

Critical Path

FDA launched its Critical Path Initiative in 2004 to address the problem of medical product development bottlenecks. In its report published that year, FDA said the problem was that "the applied sciences needed for medical product development have not kept pace with the tremendous advances in the basic sciences." In other words, many medical innovations developed by companies or in academia were not reaching patients as new, effective, affordable, and safe medical products.

FDA began the Critical Path Initiative to create a new "product development toolkit" that would include better ways to assess a product's safety, medical utility, and potential for manufacturing, Dr. Sundlof said.

The 2004 report said, "Not enough applied scientific work has been done to create new tools to get fundamentally better answers about how the safety and effectiveness (the measure of medical product performance) of new products can be demonstrated in faster timeframes with more certainty and at lower costs." The report added that product sponsors in some cases have had to use last century's tools to assess potential new products. With older tools, companies may not be able to detect failures early. The sooner a sponsor can detect products likely to fail, the fewer resources will be wasted on those products.

Using resources to develop products that ultimately do not work means fewer resources for products that do work, a situation that could potentially delay or even prevent products from getting to patients.

And, without better tools to determine safety and effectiveness early, some products can get to market before the problems are uncovered, Dr. Sundlof said.

FDA is the only organization that could be expected to implement a program such as Critical Path, because it has a unique position in biomedical research, Dr. Sundlof said. FDA oversees

(Continued, next page)

Need for Veterinarians in Biomedical Research . . . *(Cont.)*

the evaluation of all U.S. medical products. Therefore, FDA is in a position to identify key product development hurdles that commonly delay companies trying to bring products to market.

Also, FDA is the only organization that can set the scientific standards for product development, so it is the only organization that can ensure that new Critical Path tools become the standards for proving efficacy, assessing safety, and ensuring the safety of medical products, Dr. Sundlof said.

Although FDA is implementing Critical Path, the initiative was never designed to apply only to FDA. The Critical Path Initiative uses applied science and is meant to work in partnership with the discovery science carried out by industry, academia, and other health-related organizations, he said.

"The expected outcome of Critical Path, in fact the outcome we have already seen, is an increase in the movement of new products down the pipeline from discovery to patients," Dr. Sundlof said. FDA issued a report, "Critical Path Opportunities Initiated During 2006," that listed more than 40 initiatives begun by industry and academia, so the program has had a strong beginning.

The report pointed out that not all of the projects identified in the Opportunities List are for human medicine. Several are in veterinary medicine, Dr. Sundlof said.

For example, he said, scientific advances under Critical Path can improve the tools FDA uses to evaluate safety and effectiveness of veterinary and human products. The advances can help FDA determine the safety of food ingredients, through new rapid tests for biological and chemical contamination of animal-derived foods. Improved analysis technologies can be used for assessing safety and nutritive value of foods, food ingredients, and feeds. Sophisticated cross-disciplinary scientific review is necessary to appropriately assess the issues of genetic engineering and animal cloning.

In animal production, FDA sees a need for new technologies to reduce various pathogens and will need to be ready to evaluate them as they are developed. An example is the therapeutic intervention for the reduction of *E. coli* O157:H7 in cattle immediately prior to slaughter, which could lower human exposure to the pathogen through food.

Role of veterinarians in Critical Path projects

"We believe that, whether working for a government agency, for industry, or in academia, veterinarians can offer a great deal of scientific know-how to advance Critical Path goals," Dr. Sundlof told the AAVMC audience.

"We believe that veterinarians are uniquely trained to succeed in research. They have a broad range of biomedical training, and they often are involved in one of a large number of specialties," he added.

Veterinary specialties include:

- Toxicology
- Laboratory animal medicine
- Theriogenology
- Anesthesiology
- Behaviors
- Clinical pharmacology
- Dermatology
- Internal medicine
- Microbiology
- Animal nutrition
- Ophthalmology
- Pathology
- Preventive medicine
- Radiology
- Surgery
- Dentistry

And, while veterinarians often have in depth knowledge in one area, they also have an awareness of the bigger picture through their training, a fact acknowledged in a report, the *Pew Health Professions Commission in Health America: Practitioners for 2005*, Dr. Sundlof said. In its report, Pew said: "Veterinarians are more knowledgeable about the impact of animals and diseases on human health and the role and use of animals in the improvement of health and well-being than any other health professional in most communities. Thus veterinarians should be more directly available to human health providers for consultation on these subjects."

In addition to all that, "Veterinarians must become resourceful and creative in problem solving, simply due to the nature of their work," Dr. Sundlof said.

FDA employs more than 100 veterinarians. They have scientific skills that allow them to do many jobs, Dr. Sundlof said. They direct science-based programs, are involved in epidemiology, drug review, risk assessment, food safety, biosecurity, and international trade.

CVM employs approximately 90 of the FDA veterinarians. At CVM, the veterinarians are involved in scientific research in areas such as:

- Animal drug safety and efficacy;
- Microbiology, including DNA fingerprinting, determining antimicrobial resistance mechanisms, and gathering data from the National Antimicrobial Resistance Monitoring Program;
- Toxicology (for instance, veterinarians helped significantly in resolving the incident concerning melamine and cyanuric acid contamination of pet food);
- Immunopharmacology;
- Metabolism, pharmacokinetics, and residue depletion;
- Residue chemistry, detecting drug residues in animal products;
- Method trials and validation;
- Aquaculture research, such as developing model species and infections for testing drug efficacy, providing data for non-sponsored drugs, developing pharmacokinetic/marker residue data in different species; and
- Developing techniques, such as state-of-the-art polymerase chain reaction techniques and immunochemical-based methods to detect

(Continued, page 14)

Video on Cleaning Trucks, Transports to Prevent BSE Wins Awards

An important way to help prevent the spread of bovine spongiform encephalopathy (BSE, also known as mad cow disease) is to make sure trucks and other equipment used to haul feed and feed ingredients are clean. To highlight that point, the Center for Veterinary Medicine, in cooperation with trade associations representing feed and feed ingredient suppliers, produced an award winning video that explains the concern.

The video, titled "Preventing the Spread of BSE," provides a short, to the point presentation that can be viewed by truck drivers waiting for their trucks to be unloaded at a feed mill. The video describes the situation and explains why truck operators need to properly clean out their trucks when hauling feed material.

The BSE feed regulations require that truckers and other transporters implement clean-out procedures to avoid cross-contamination if their conveyances are used to haul mammalian-origin material prohibited from being fed to cattle or other ruminants, as well as feed or feed ingredients that may be fed to ruminant animals.

CVM developed the video with the cooperation of the American Feed Industry Association, the National Grain and Feed Association, and the National Renderers Association. The trade associations represent nearly all feed manufacturers and animal protein ingredient manufacturers in the United States.

Actual production of the video was done by the Food and Drug Administration's Center for Devices and Radiological Health, in the video studio of its Division of Communication Media.

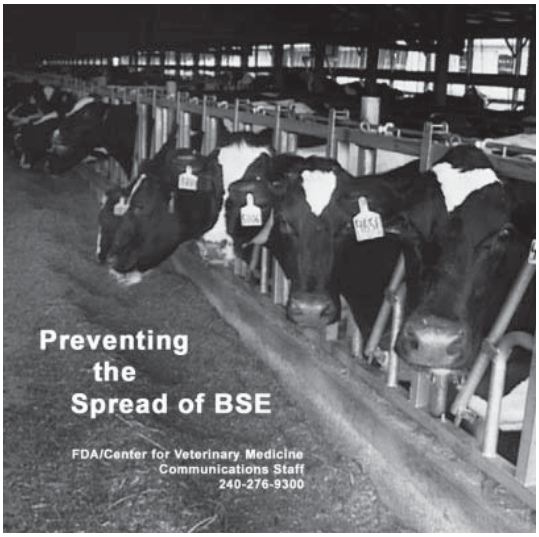
The video has won the following awards:

- U.S. International Film and Video Festival, Silver Screen Award.
- Hermes Creative Awards, Gold Winner, 2007.
- Telly Award, honoring outstanding local, regional, and cable TV commercials and programs and the finest video and film productions, 2007 Bronze Winner.
- The Communicator, an international competition honoring A/V programs, Award of Distinction.
- Mercury 06 Excellence Awards, honoring outstanding achievement in public relations and corporate communications, Bronze Winner.

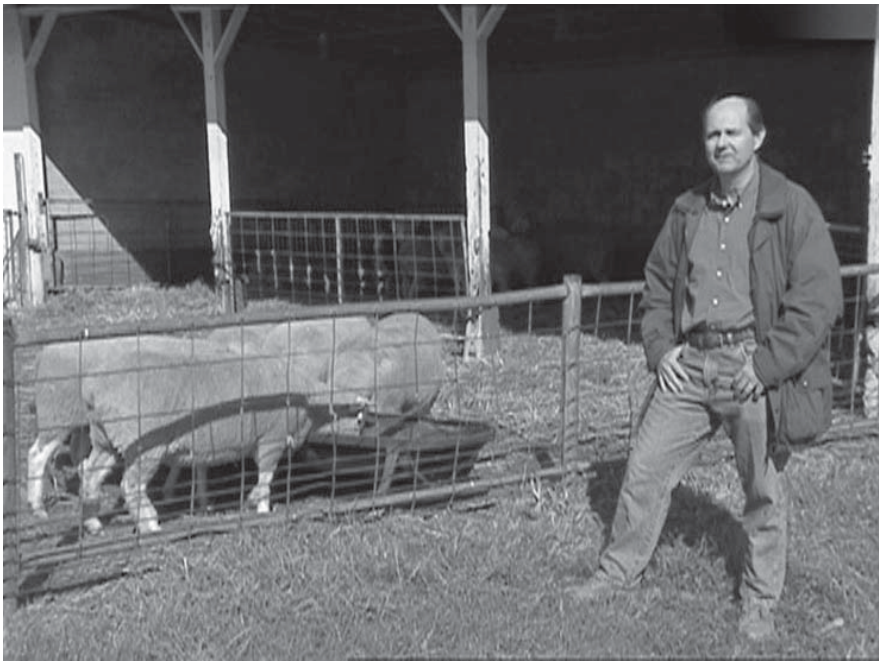
The cooperating trade associations have made copies of the video available to their members. In addition, CVM has made copies available through FDA's Office of Regulatory Affairs for distribution to FDA District Offices, FDA field investigators, and State feed regulatory officials.

Additional copies are available. To see about obtaining a copy, please send your request through the CVM Homepage.

The video is also available through CVM's Web site at *http://www.fda.gov/cvm/bseOtherInfo.htm*

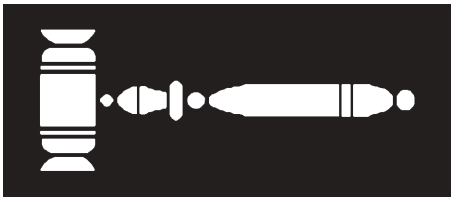


CVM created the video, "Preventing the Spread of BSE," in association with the American Feed Industry Association, the National Feed and Grain Association, and the National Renderers Association, to explain to truck drivers and others the need to properly clean equipment when hauling feed ingredients to avoid the spread of BSE through cross contamination of feed.



The narrator in the video, "Preventing the Spread of BSE," describes the need for properly cleaning equipment used to carry feed ingredients to prevent the spread of BSE.

August-September Regulatory Activities



Warning Letters

Significant deviations from the Food and Drug Administration's Current Good Manufacturing Practice (cGMP) Regulations for Medicated Feeds has led to the issuance of a WARNING LETTER to John A. Rickman, president of Farmers Market of Bolivar, Missouri, in Bolivar, MO. Such deviations caused medicated feeds being manufactured at this facility to be adulterated within the meaning of section 501(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Specifically, FDA's inspection of the facility revealed the following: (1) A failure to document the investigations and any corrective actions taken as a result of out-of-specification assay results. For example, in 2006, medicated feeds pyrantel tartrate/carbadox, nicarbazin, amprolium were not within permissible assay limits and no investigation and correction actions, including discontinuing distribution of the out of specification medicated feeds, were taken. (2) A failure to have a Master Record File for the manufacturing of all products. For example, either no Master Record File existed or the file was created after the medicated feed was manufactured. (3) A failure to maintain complete production record(s). For example, the production records often failed to identify that the feed was a medicated feed.

FDA issued a WARNING LETTER to William P. Rogers, owner of the Rogers Farm in Warren, MA, for offering a cow for slaughter as food that was adulterated within the meaning of section 402(a) of the FFDCA. Tissue samples collected by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) revealed the presence of gentamicin in the kidney tissue. No tolerance has been established for residues of gentamicin in the uncooked edible tissues of cattle. FDA's investigations also revealed 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. Mr. Rogers also lacked an adequate system to ensure that medicated animals had been

(Continued, next page)

Need for Veterinarians in Biomedical Research . . . *(Cont.)*

prohibited materials in feed, to allow FDA to enforce the BSE rule.

Pre-market evaluation of medical products must change from the current passive, empirical (trial-and-error) system that uses patient-exposure as a basis for assessing adverse events to become a predictive evaluation, based on a "robust body of prior knowledge about the molecular or the physical mechanisms of a product," FDA said in its "Critical Path Opportunities Report" released in March 2006.

Moving in that direction of predictive evaluation will require developing expertise in the new sciences, particularly:

- Genomics and proteomics, and related disciplines;
- Metabolomics;
- Bioinformatics; and
- Even "*in silico* testing," which is computer simulation, rather than laboratory or animal testing.

Stepping stone

A significant benefit to the individual veterinarian involved in biomedical research is that the experience can serve as a stepping stone to more significant, more influential positions, such as overseeing public health programs or protecting food safety, Dr. Sundlof said. Those types of positions can be filled only by someone who has broad experience beyond just the practice of veterinary medicine, he said, adding that research positions will provide that necessary experience.

Conclusion

Critical Path is making it possible for companies to more efficiently, effectively move products from biomedical innovation stage to the products that help to keep humans and animals healthy.

As the Critical Path Initiative picks up momentum, the opportunities for those interested in biomedical research are increasing, Dr. Sundlof added.

Veterinarians, because of their in-depth knowledge of certain biomedical specialties, combined with their broad understand of biomedical science, are uniquely suited to do biomedical research. In return, meeting the challenges of biomedical research prepares veterinarians for leadership roles in government or industry in research, public health, program management, and many other areas. And many of those roles are open because of FDA's Critical Path Initiative.

The time has never been better for a veterinarian to seek a position in research, and the experience can help them in their careers. Dr. Sundlof said. At the same time, a veterinarian might find that time spent doing research could be very rewarding personally, because it is an effort that ultimately will benefit a large number of humans and animals, he added.

Regulatory Activities . . . *(Continued)*

withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. In addition, Mr. Rogers adulterated gentamicin sulfate within the meaning of section 501(a) of the FFDCA when he failed to use the drug in conformance with its approved labeling. Other violations included providing a false guaranty in violation of section 301(h) of the FFDCA.

A WARNING LETTER has been issued to Ross A. Tappan, general manager of the Arizona Dairy Company, LLP, Mesa, AZ, for violations of the adulteration provisions in sections 402(a) and 501(a) of the FFDCA. Specifically, this dairy operation sold a culled dairy cow for slaughter as human food to a broker/hauler. An analysis of tissues samples by FSIS revealed the presence of penicillin at 0.64 parts per million (ppm) in the kidney, 0.08 ppm in the liver, and 1.08 ppm in the muscle tissue. FDA has set a tolerance of 0.05 ppm for residues of penicillin in the edible tissues of cattle (21 CFR 556.510). In addition, the FSIS analysis revealed the presence of flunixin in the liver tissue at 3.70 ppm. FDA has set a tolerance for this drug of 0.125 ppm in the liver tissue of cattle (21 CFR 556.286). A second animal was sold for slaughter, and the FSIS analysis of tissue samples collected from that animal identified the presence of flunixin at 0.235 ppm in the liver. A tolerance of 0.125 ppm has been established for residues of flunixin in the liver tissue of cattle as codified in 21 CFR 556.286. A third animal was also sold to a broker/hauler, and this animal contained sulfadimethoxine at 0.17 ppm in the liver and 0.14 ppm in the muscle tissue. A tolerance 0.1 ppm has been established by FDA for residues of this drug in the edible tissues of cattle (21 CFR 556.640). Flunixin was also found at 0.14 ppm in the liver and at 0.083 ppm in the muscle tissue. A tolerance of 0.125 ppm and 0.025 ppm has been established for residues of flunixin in the liver and muscle tissue of cattle, respectively, as codified in 21 CFR 556.286. These excessive amounts of the drugs caused all three animals to be adulterated under section 402(a) of the FFDCA. In addition, the firm's extralabel use of penicillin G procaine and flunixin meglumine was not in compliance with 21 CFR Part 530, rendering them adulterated under section 501(a) of the FFDCA.

Recalls

A Class I firm-initiated recall is ongoing by Mars Petcare USA of Brentwood, TN, for 1,176 bags of its 55-lb. Ol' Roy Complete Nutrition Dry Dog Food. The reason for the recall is that the product may be contaminated with *Salmonella*. The recalled products were distributed in Virginia, Maryland, North Carolina, Pennsylvania, West Virginia, and Ohio.

Petraport, Inc., of North Bergen, NJ, is in the process of conducting a Class I recall of 132,640 bags of Beefeaters Brand and Berkley & Jensen bulk units of pig ear dog treats that may be contaminated with *Salmonella*. Distribution of the products, which were manufactured by Graneles de Chile S.A., of Rancagua, Chile, took place nationwide.

Alltech, Inc., of Nicholasville, KY, is carrying out a Class III recall of various types of its feed premix packaged in 25-lb. bags. The recall was begun because Bioplex Copper 10%, a feed premix, and premixes containing Bioplex Copper, were made using copper sulfate pentahydrate that was contaminated with dioxin-like polychlorinated biphenyls. Distribution of the 147,785 kg of products took place nationwide and internationally.

Approvals for August and September 2007

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

PROFENDER (emodepside and praziquantel) Topical Solution (NADA 141-275), filed by Bayer HealthCare LLC. The NADA provides for the use of PROFENDER (emodepside and praziquantel) Topical Solution for the treatment and control of infections caused by several internal parasites in cats. Notice of approval was published August 2, 2007.

(Continued, next page)

Approvals for August and September 2007 *(Continued)*

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

AMPICILLIN SODIUM POWDER (ANADA 200-335), filed by G.C. Hanford Manufacturing Co. The ANADA provides for the use of ampicillin sodium as a constituted solution by injection in horses for the treatment of various bacterial infections, including respiratory, skin, and soft tissue infections. The product was approved as a generic copy of Pfizer's AMP-EQUINE, approved under NADA 55-084. Notice of the ANADA approval was published August 13, 2007.

FORMACIDE-B (formalin) (ANADA 200-414), filed by B.L. Mitchell, Inc. The ANADA provides for the use of FORMACIDE-B (formalin) in a water bath for the control of certain external parasites on finfish and shrimp and for the control of certain fungi on finfish eggs. The product is approved as a generic copy of Parasite-S, sponsored by Western Chemical, Inc., under NADA 140-989. Notice of approval was published August 13, 2007.

OXYTET 10 (oxytetracycline hydrochloride) Injection (ANADA 200-452), filed by Norbrook Laboratories, Ltd. The ANADA provides for the use of OXYTET 10 (oxytetracycline hydrochloride) Injection in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for the treatment of various bacterial diseases. Norbrook Laboratories' OXYTET 10 Injection is approved as a generic copy of Boehringer Ingelheim Vetmedica's MEDAMYCIN Injectable, approved under NADA 108-963. Notice of approval was published August 2, 2007.

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