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President Bush Signs Bill Reauthorizing ADUFA, Authorizing AGDUFA

by Shannon Cameron, Assistant Editor, and Jon F. Scheid, Editor

On August 14, 2008, President Bush signed a bill reauthorizing the Animal Drug User Fee Act (ADUFA) and authorizing the Animal Generic Drug User Fee Act (AGDUFA), which will provide the Food and Drug Administration with more funding for timely animal drug reviews. The reauthorized ADUFA also begins a new "end-review amendment process" that gives FDA additional flexibility in dealing with new animal drug applications. The plan to implement the reauthorized ADUFA also is designed to improve communication with industry.

Congress initially approved ADUFA legislation in 2003. Under that law, FDA collected $43 million in user fees over the 5 years of the first ADUFA program. Under the reauthorized program, FDA expects to collect approximately $98 million over the 5-year life of the program.

The AGDUFA program calls for user fees to generate a total of $27 million for generic animal drug review over the 5-year life of the measure, beginning in FY 2009. AGDUFA is FDA's first user fee program to cover generic animal drugs. Currently, the generic animal drug review process is entirely funded through appropriations. Under both ADUFA and AGDUFA, FDA will collect funds through application fees, product fees, and sponsor fees. The fees will supplement appropriated resources for drug review.

Under a plan developed by CVM and the animal drug industry for implementing the reauthorized ADUFA, CVM and sponsors will be able to use a new end-review amendment process for a drug application. The process gives the Center the option of allowing a sponsor more time to submit additional, non-substantial data or information that CVM needs to finish reviewing an animal drug submission. Previously, when data were missing, CVM typically had to issue an "incomplete" letter to the sponsor, which meant the entire review process had to start again, once the sponsor submitted the missing information.

Among the new provisions in the ADUFA reauthorization are plans to improve the timeliness and predictability of foreign pre-approval inspections and conduct 10 public workshops during the program's 5-year life. The workshop topics will be mutually agreed upon by FDA and the regulated industry. CVM also plans to develop an electronic submission tool for industry submissions which will have online review capability. In addition, CVM and sponsors will discuss the applicable use of pharmacokinetic/pharmacodynamic data.

FDA has promised to meet specific performance goals for generic animal drug review as it begins to collect generic animal drug user fees. For example, FDA has agreed to review 90 percent of non-administrative Abbreviated New Animal Drug Applications in fiscal year 2009, the first year of generic animal drug user fees, within 700 days. The review timeframe is reduced over the life of the program to 270 days by fiscal year 2013.

Antimicrobial drug distribution reports

Under the ADUFA reauthorization, drug sponsors must report annually the amount of an antimicrobial active ingredient sold or distributed for use in food-producing animals the previous calendar year. The new law requires the reports to specify the amount by "container size, strength, and dosage form" of the antimicrobial active ingredient. Domestic as well as export sales must be reported.

The measure requires drug sponsors to submit the information to the Secretary of Health and Human Services. The Secretary is directed to make summaries of the information available publicly. The public summaries will present the information by class of antimicrobial, but only if three or more sponsors produce that class of antimicrobial.

The reports will be due March 31 each year, with the first report due in 2010.

In This Issue

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

Reptile Dealer Convicted, Sentenced for Illegally Selling Turtles

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

After entering a guilty plea in a Federal district court on July 14, 2008, a reptile firm was convicted of violating a public health law that prohibits the sale of turtles with shells less than 4 in. long.

Strictly Reptile, Inc., Hollywood, FL, forfeited approximately 7,000 turtles and tortoises seized by government agents on May 2, 2008, in the course of executing a Federal search warrant. The company was ordered to pay a criminal fine of $5,000 and was placed on 2 years' probation. The court also ordered the company to implement a business practice requiring it to secure a signed notice document from every buyer of undersized turtles that they are aware of the legal restrictions placed on the sale or holding for sale of these reptiles, and to file semi-annual reports to the court during the 2-year probation period, as well as to the Food and Drug Administration and the Fish and Wildlife Service.

Strictly Reptile, Inc., sold approximately 1,000 undersized turtles in March 2008 from its Hollywood location to a tourist souvenir business in Panama City, FL. The principal of the firm had admitted to investigators that he intentionally did not ask customers the purpose of their purchases so as not to lose sales.

The limitation on turtle sales was put into effect in 1975, pursuant to the Public Health Service Act, because of the public health impact of turtle-associated salmonellosis. FDA enforces the regulation in cooperation with State and local health jurisdictions. Exceptions to the regulation are made for sales of turtles less than 4 in. long for bona fide scientific, educational, or exhibition purposes, other than the use as pets.

Public health investigators had identified undersized turtles as a major source of *Salmonella* and other infections, especially in small children who are prone to handling turtles without washing their hands afterwards, and to putting the turtles in their mouths.

Team Revises AFSS Framework Document

by Jon F. Scheid, Editor

The Animal Feed Safety System (AFSS) Team has revised the AFSS Framework Document by adding a new component about reporting unsafe feed and by identifying additional gaps in the existing feed safety system.

The Center for Veterinary Medicine released the revised Framework Document (the 3rd version) in April 2008 and posted it on its Web site at *http://www.fda.gov/cvm/AFSS3rdDraftFramework.html*.

The changes to the Framework Document came about because of the requirements placed on the Food and Drug Administration by provisions of the FDA Amendments Act (FDAAA) of 2007. Besides continuing FDA's user fee programs for human drugs and devices, FDAAA requires FDA to take steps designed to improve the safety of pet food and ingredients.

Title 10 of FDAAA requires FDA to establish, "by regulation," ingredient standards and definitions, processing standards, and labeling standards—including nutritional and ingredient information—for pet food. It also requires FDA to establish an Early Warning Surveillance and Notification System to identify adulteration of the pet food supply and illness outbreaks and to notify veterinarians and other stakeholders of pet food recalls.

In addition, the legislation requires FDA to establish a searchable database of recalled human and pet foods to ensure efficient and effective communications during a recall. And it requires a "Reportable Food Registry" for animal as well as human food. Reportable food is any food that carries a reasonable probability that its use or exposure to it will cause serious adverse health consequences or death to humans or animals.

Revised AFSS Framework Document

The six components of the AFSS presented in the revised Framework Document now are:

A. Ingredients and the approval process *(includes a new gap)*

B. Limits for animal feed contaminants

C. Process control for the production of feed ingredients and mixed feed

(Continued, next page)

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Team Revises AFSS Framework Document *(Continued)*

CVM Director Dr. Bernadette Dunham addresses the Animal Feed Safety System public meeting on May 14, 2008

D. Reporting of unsafe feed (new component, added for the 3rd draft of the Framework Document, and includes a new gap)

E. Regulatory oversight

F. Education and outreach *(includes a new gap)*

The focus of the new component, D (what used to be Component D is now Component E, and what was E is now F), is gathering information about feed problems. To help protect the health of animals and prevent food safety problems, FDA should know about the feed problems before they become widespread. Also, other feed users and the public should know about the incidents so that they can protect themselves.

The new Component D addresses the FDAAA provisions requiring FDA to establish a Reportable Food Registry. The component includes the lack of information about pet food, feed, and ingredient contaminants as a gap, and the requirements of the FDAAA as the fix for that gap.

Another gap noted in Component D of the revised Framework Document is that FDA needs to know quickly about unsafe pet food and feed incidents. Knowing about such incidents before they cause widespread injury or death would greatly assist FDA. Further, the public needs to be advised about those incidents to protect themselves and their pets.

In response to this gap, as required by FDAAA, FDA will implement an early warning and surveillance system to identify adulteration incidents affecting pet food supplies. It would also alert the public about any outbreaks of illness connected to pet food.

Component A was also changed in the revised Framework Document. An earlier version of the document noted that the AFSS Team had begun developing a Compliance Policy Guide to explain the relationship between the Association of American Feed Control Officials (AAFCO) and FDA and to establish a policy by which FDA could recognize the ingredient definitions presented in AAFCO's *Official Publication*. FDA has no complete list of all acceptable animal feed ingredients. AAFCO's *Official Publication* contains the most complete list available, and it includes comprehensive ingredient definitions. FDA relies heavily on the *Official Publication*, even though it is a non-Federal document and lacks the force and effect of law.

The revised Framework Document says that the AFSS Team has put on hold its plans to write the Compliance Policy Guide under Component A, while FDA works to implement FDAAA's requirement to write regulations for feed ingredient standards for pet food.

The new gap listed under Component F concerns updating labeling standards for pet food, as required by FDAAA. Through that Act, Congress has required a regulation that includes standards for nutritional and ingredient information on the label.

AFSS, Food Protection Plan fit together

The AFSS initiative fits well into FDA's overarching Food Protection Plan, which is designed to integrate all Federal, State, and local food safety and food defense (counterterrorism) programs in the United States. The Food Protection Plan was developed last year and announced in November 2007. It has specific action items that involve FDA's Federal and State counterparts.

At an AFSS public meeting held in May 2008, Dr. George Graber, consultant to CVM's AFSS Team, pointed out that the AFSS Initiative and the Food Protection Plan have many "cross-cutting" principles.

(Continued, next page)

Stakeholders listen to presentations at the 5th public meeting of the Animal Feed Safety System, held May 14 in Gaithersburg, MD.

NRC Publishes Report on Horse, Cat, Dog Dietary Supplement Safety

by Jon. F. Scheid, Editor

The National Research Council (NRC) has published a report examining considerations for the safe use of dietary supplements in companion animals, highlighting needs for consistent data, a good system of adverse event reporting, and clarification of the regulations covering the supplements.

The Center for Veterinary Medicine commissioned the report, "Safety of Dietary Supplements for Horses, Dogs, and Cats," to help the Food and Drug Administration address the public's desire to use dietary supplements for companion animals.

The Dietary Supplement Health and Education Act (DSHEA), passed in 1994, created a less restricted pathway for dietary supplements for humans to get to market. Since then, CVM has maintained that the less restrictive pathway should not apply to products for animals. However, according to the report's summary, FDA and other regulatory bodies are "under pressure" to resolve the gulf between the public's desire to use the products and the different regulatory requirements. The committee was charged with developing considerations about the safety of the products, but not about product utility or efficacy.

A key finding listed in the report's summary was that data on safety for dietary supplements fell short of what would typically be required for reviewing the safety of animal drugs or animal food additives.

According to the summary, "The report was intended to help form the basis of a more general framework for evaluating animal dietary supplement safety." The committee used public data to conduct safety assessments of three dietary supplements – lutein, evening primrose oil, and garlic. "The knowledge gained from conducting these assessments allowed the committee to review and begin to define factors that should be considered when evaluating the safety of animal dietary supplements in general," the summary said.

A key finding listed in the report's summary was that data on safety for dietary supplements fell short of what would typically be required for reviewing the safety of animal drugs or animal food additives. In addition, it said, "There is a clear need for a comprehensive adverse event reporting system." Existing systems have limitations for supplements, it said.

The report also recommended that FDA review the regulation of animal dietary supplements. The regulations need to differentiate between an animal dietary supplement, a food additive, and an animal drug, "as well as factors that differentiate regulation of human and animal dietary supplements."

To develop the report, the NRC assembled a committee of experts, including animal nutritionists, veterinarians, clinical pharmacologists, and toxicologists. Dr. William Price, special assistant to the Director of CVM's Division of Animal Feeds and project officer for the report, described the panel members as "highly qualified scientists" in the areas of animal health and nutrition.

On the panel were:

- Dr. Jim E. Riviere, (Chair), D.V.M., Ph.D., North Carolina State University
- Dr. Dawn M. Boothe, D.V.M., Ph.D., Auburn University
- Dr. Gail L. Czarnecki-Maulden, Ph.D., Nestle Purina PetCare PT
- Dr. David A. Dzanis, D.V.M., Ph.D., Dzanis Consulting and Collaborations
- Dr. Patricia A. Harris, M.R.C.V.S., Ph.D., Waltham Centre for Pet Nutrition
- Dr. Wouter H. Hendricks, Ph.D., Wageningen Agricultural University
- Dr. Claudia A. Kirk, D.V.M., Ph.D., The University of Tennessee
- Dr. Lori K. Warren, Ph.D., University of Florida

Copies of the report are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242, or (in the Washington, DC, area) (202) 334-3313; *http://nap.edu*.

Team Revises AFSS Framework Document *(Cont.)*

- For example, FDA's definition of food includes food for animals as well as humans. Therefore, food safety must mean feed safety, too.
- Both the AFSS and the Food Protection Plan focus on risks over a food product's life cycle—from production to consumption.
- Both initiatives use a risk-based approach, targeting resources in a way that will permit the greatest reduction of risk.
- Both address accidental as well as deliberate contamination of food.
- And both rely on science and modern technology, including enhanced "IT" systems, to be most effective.

CVM Begins "Animal Health Literacy Campaign" Initiative

by Shannon Cameron, Assistant Editor

As part of the Food and Drug Administration's goal to improve public health, the Center for Veterinary Medicine has initiated the Animal Health Literacy Campaign to provide timely information to consumers, industry, trade, and Federal/State organizations about pressing animal and human health issues.

The Animal Health Literacy Campaign began as a grassroots outreach program through which the Communications staff would partner with veterinarians and others in various CVM program offices to create and produce informational materials for various stakeholders, with an emphasis on educating consumers.

Through a proactive approach to animal health literacy and with the help of Michelle Sharkey, D.V.M., from the Office of New Animal Drug Evaluation, CVM's Communication Staff is working in conjunction with subject matter experts throughout the Center to produce informative materials on animal health literacy and participate in outreach activities.

In 2007, CVM produced a brochure about non-steroidal anti-inflammatory drugs entitled *Treating Pain in Your Dog: Keeping Your Best Friend Active, Safe and Pain Free* (available for free through the Federal Citizen Information Center in Pueblo, CO, at *http://www.pueblo.gsa.gov/rc/vetnsaids.html*) and the success of that publication led the way for the current campaign. More than 50,000 brochures have been ordered in bulk by veterinary practitioners and another 10,000 by individuals.

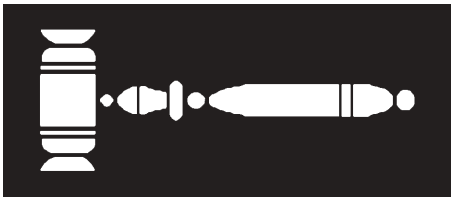
CVM is currently working on new informational materials such as posters, brochures, handouts, and children's school book covers to offer safety information about subjects as varied as aquaculture drugs, turtles and salmonella, CVM clerkships, opportunities for statisticians, and the ombudsman services.

As a second phase of the Animal Health Literacy Campaign, CVM is planning to increase its outreach program to key stakeholders.

Strategic communication is vital to CVM's relationship with the public and with the industries it regulates. Through our strategic communication efforts, CVM can communicate more effectively about policy and regulatory responsibilities. By exchanging ideas with outside groups and institutions we can better advise policymakers and educate the public.

If you have ideas for possible outreach opportunities or suggestions for topics for our next brochure/fact-sheet, please call Shannon Cameron at 240-276-9300, or email us at CVM_Homepage@fda.gov.

Regulatory Activities – July & August 2008



Warning Letters

The Food and Drug Administration has sent a WARNING LETTER to Wayne R. Mathis, managing partner of Mathis Ranch, d/b/a Texas Legend Ranch, Kendalia, TX, for violations of the adulteration provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). Specifically, the ranch sold a goat for slaughter as food that was found to contain 0.0577 parts per million (ppm) moxidectin in the liver tissue and 0.0161 ppm moxidectin in the muscle tissue. Because no tolerance for residues of this drug in the edible tissues of goats has been established by FDA, the animal was found to be adulterated within the meaning of Section 402(a) of the FFDCA. The firm was also found to have adulterated moxidectin (Cydectin) within the meaning of Section 501(a) of the FFDCA for failing to use it in conformance with its approved labeling. Also, FDA's extralabel use requirements set forth in 21 Code of Federal Regulations (CFR) 530 with respect to moxidectin were violated, and use of the drug was found to be unsafe within the meaning of Section 512(a) of the FFDCA.

Todd Simmons, president and chief executive officer of Simmons Pet Food, Inc., Siloam Springs, AR, has received a WARNING LETTER for serious deviations from the Low-Acid Canned Food Regulations described in CFR Parts 108 (Emergency Permit Control) and 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers). Specific violations included the following: the firm has not established a product traffic control system to prevent unretorted product from bypassing the retort process (21 CFR 113.87(b)); the firm's container cooling water was not chlorinated or otherwise sanitized as necessary for

(Continued, page 14)

NRSP-7 Minor Use Research Program Holds Semi-Annual Meeting to Reach Out to Stakeholders

by Dr. Meg Oeller, Director, Office of Minor Use and Minor Species Animal Drug Development, and Dr. John Babish, NRSP-7 National Coordinator

The U.S. Department of Agriculture's National Research Support Project #7 (NRSP-7) held its Spring Meeting for 2008 in April at the Food and Drug Administration's Center for Veterinary Medicine in Rockville, MD. The committee that runs the NRSP-7 program used the opportunity to invite stakeholders (see related article, "Importance of Minor Species to Regional, U.S. Economy") and legislative affairs professionals to come to the table to discuss the importance of minor species to the U.S. economy and the importance of the NRSP-7 program to the various minor species groups that benefit from its work.

The purpose of the NRSP-7 Minor Use Animal Drug Program is to address the shortage of minor species animal drugs by providing funding and overseeing effectiveness, target animal safety, and human food safety research and the environmental assessment required for the approval of a New Animal Drug Application. Pharmaceutical companies then are able to use these data at no cost in conjunction with their own manufacturing and labeling information to support an application for approval of a new animal drug for an intended use in the minor species.

Minor species and minor uses represent small markets when compared to the value of markets for major food-producing animals such as poultry, cattle, and swine or for companion animals such as dogs, cats, and horses.

The major species are horses, cattle, swine, dogs, cats, chickens, and turkeys. All other species, except humans, are minor species. The scope of the program includes minor species of agricultural importance and generally excludes companion animals.

Why is NRSP-7 needed?

Minor species and minor uses represent small markets when compared to the value of markets for major food-producing animals such as poultry, cattle, and swine or for companion animals such as dogs, cats, and horses. The costs of studies to support drug approval cannot be easily recovered from such small markets. The work done by NRSP-7 and other public research entities makes it possible for pharmaceutical sponsors to get their products approved at a much reduced cost.

Despite incentives for companies to increase drug availability for these minor species, there are few to no drugs approved for their use. Much work remains to be done for the benefit of the numerous fish species in U.S. aquaculture, for sheep and goats, gamebirds, deer, rabbits, honey bees and other even less common species.

What is the mission of the NRSP-7 program?

The committee that runs the NRSP-7 program (see "The NRSP-7 Committee") meets twice yearly to assess the status of ongoing projects and to select new ones.

At the April 2008 meeting, Dr. John Babish and Dr. Garry Adams provided the attendees with a complete history of the NRSP-7 program and described its ongoing problems with inadequate funding, increasing costs, and more rigorous regulatory requirements that have evolved over the program's 25-year existence.

They described the mission of NRSP-7 as fourfold: 1) ***identify*** animal drug needs for minor species and minor uses in major species, 2) ***generate*** and 3) ***disseminate*** data for safe and effective therapeutic applications, and 4) ***facilitate*** FDA/CVM approvals for drugs identified as a priority for a minor species or minor use.

To accomplish these goals, NRSP-7 functions through coordinated efforts among animal producers, pharmaceutical manufacturers, CVM, USDA/Cooperative State Research, Education, and Extension Service (CSREES), universities, State Agricultural Experiment Stations, and veterinary medical colleges throughout the country.

(Continued, next page)

Semi-Annual Meeting *(Continued)*

Dr. Gary Sherman described the funding methods of the program and the complexities of the budget process. He also described the activities of USDA/CSREES. Its mission is to advance knowledge for agriculture, the environment, human health and wellbeing, and communities.

Dr. Meg Oeller, FDA liaison to NRSP-7, provided additional information about the mission and organization of NRSP-7 and the relationship between NRSP-7 and CVM.

The meeting was also attended by CVM Director Dr. Bernadette Dunham. In a presentation, she described new and ongoing programs within CVM that are intended to facilitate the drug approval process for minor uses and minor species. She stressed the importance of the partnership between all interested parties as the best way to achieve success.

In addition, other members of CVM also participated in the meeting to help increase understanding between the scientific reviewers on the regulatory side and the scientists and producers responsible for the studies intended to support approval of these needed products.

In a presentation, Dr. Bernadette Dunham described new and ongoing programs within CVM that are intended to facilitate the drug approval process for minor uses and minor species.

What are the plans for regaining funding?

For many years, the program has operated on the same limited funding of approximately $500,000 a year. This is a very small budget, given the large number of needed projects and the high cost of studies to support new animal drug approvals. For the past few years, the funding has been severely cut, and the future of the program is in peril.

Several legislative affairs professionals attended the meeting to discuss their efforts to support the NRSP-7.

Mr. John Hamilton, (ANR Federal Relations Liaison of UC Davis), Ms. Dianne Miller (Director of the Federal Government Relations for Cornell University), and Mr. Dustin Bryant (Meyers and Associates, for Texas A&M University) gave updates on the lobbying efforts of the institutions participating in NRSP-7 as well as the status of the 2008 Farm Bill. Dr. Mark T. Lutschaunig (Director, Governmental Relations Division of the American Veterinary Medical Association) emphasized the importance of NRSP-7 and the support that the American Veterinary Medical Association has for the program.

The attendees discussed possible future lobbying efforts and stakeholder participation. Action items included further contacts with stakeholder lobbyists to emphasize the need to support funding for NRSP-7 in the USDA budget and to support inclusion of the program in the 2008 Farm Bill. (The lobbying efforts were not successful, and the NRSP-7 program was not include in the 2008 Farm Bill.)

Progress of the program

Each of the Regional Coordinators described the accomplishments and ongoing work of NRSP-7 in their region.

- **NORTHEAST REGION:** An outline of aquaculture "species grouping" research conducted in the Northeastern Region was provided by Dr. Paul Bowser. His work has focused on human food safety (tissue residue elimination studies) in tilapia, walleye, hybrid striped bass, and summer flounder. Results to date indicate species grouping is a viable method for the reduction of animals used in research.

  In addition to modeling species grouping, these studies will be used to extend the label indications for oxytetracycline, sulfadimethoxine/ormetoprim, and florfenicol.

- **NORTH CENTRAL REGION:** Dr. Ronald Griffith described the North Central Region's active projects. These include the CIDR-g, a progesterone implant used to synchronize estrus cycles in sheep and goats. A study at North Dakota State using the CIDR-g resulted in 100 percent synchronization, the highest in comparison to any other technique. At this time, the project for sheep is nearly complete. Only the human food safety component remains to be accepted. The project for goats is earlier in its progress. The target animal safety study has been accepted, and a milk residue study is close to submission to CVM for review.

  Tulathromycin for respiratory disease in sheep and goats is also under study. The current status in goats is that the target animal safety study is nearing completion, protocols for effectiveness have been submitted for review, and the protocol for

(Continued, next page)

Semi-Annual Meeting *(Continued)*

the residue depletion study has been accepted. The Western region is working in partnership on this project and is currently concentrating on the analytical method.

Lasalocid is being studied for treatment of coccidiosis in ring-necked pheasants. The effectiveness study was completed at the University of Georgia last fall. The first draft of the study report was submitted this spring. The target animal safety protocol has been submitted, and the study was planned for the summer at the University of Georgia. The human food safety protocol will be submitted in the near future.

- **Southern Region:** Dr. Alistair Webb presented an overview of efforts in the Southern Region, focusing on project tracking, game bird projects, and the NRSP-7 Web site. This region is also completing the work for public master files for fenbendazole in pheasants and quail and for ivermectin for rabbits.

- **Western Region:** Dr. Lisa Tell began her presentation by reviewing the historical NRSP-7 accomplishments of the Western Region. Work in this region has led to approval of indications for drugs for reindeer, big horn sheep, sheep, finfish, goats, and honey bees.

  Current projects include erythromycin for treatment of bacterial kidney disease in salmonids, lincomycin for treatment of American foulbrood in honey bees, the CIDR-g for goats, and strontium chloride for skeletal marking of fish.

  Lastly, a detailed description was presented of the region's study of the pharmacokinetics of ceftiofur crystalline free acid (CCFA) in non-lactating domestic goats (*Capra aegagrus hircus*) following a single subcutaneous injection. The study demonstrated that a single subcutaneous injection of CCFA did not result in any adverse effects, and the serum concentration of CCFA remained above therapeutic concentrations for at least 4 days.

A Summary of the successes of the program

The NRSP-7 has published 33 Public Master Files that have supported 27 new animal drug approvals during its 25-year history; an average of 1.3 completed files per year. The approvals have been accomplished through strategic partnerships and the efficient use of resources so that the mean expenditure per approval is approximately $450,000, or 10 percent to 40 percent of the usual cost to industry.

Work done as part of the NRSP-7 led to five peer-reviewed publications in 2007. Publication of research is common for the members of the program.

NRSP-7 currently supports 14 active projects with 41 potential projects on the Animal Drug Request List. If adequate funding is secured, there is an opportunity for a great deal more to be done for the minor species that are so important and yet so underserved when it comes to availability of safe and effective products for their benefit.

The NRSP-7 Committee

John Babish	The National Coordinator (Cornell University)
Paul Bowser	Northeast Regional Coordinator (Cornell University)
Ronald Griffith	North Central Regional Coordinator (Iowa State University)
Lisa Tell	Western Regional Coordinator (University of California, Davis)
Alistair Webb	Southern Regional Coordinator (University of Florida)
Garry Adams	Chairman of Administrative Advisors (Texas A&M)
David Thawley	Administrative Advisor Western Region (University of Nevada)
John Baker	Administrative Advisor North Central Region (Michigan State University)
Kirklyn Kerr	Administrative Advisor Northeast Region (University of Connecticut) He was unable to attend this meeting.
Gary Sherman	USDA/CSREES Liaison (Washington, DC)
Meg Oeller	FDA Liaison (Rockville, MD)

Report from NRSP-7 Meeting...

Importance of Minor Species to Regional, U.S. Economy

by Dr. Meg Oeller, Director, Office of Minor Use and Minor Species Animal Drug Development, and Dr. John Babish, NRSP-7 National Coordinator

The members of the committee that runs the National Research Support Project #7 (NRSP-7) program invited stakeholders to attend their Spring 2008 meeting. This provided an opportunity to discuss the value of several minor species to national and regional economies and to identify some of the animal health products these species need.

The NRSP-7 Minor Use Animal Drug Program addresses the shortage of minor species animal drugs by funding and overseeing research to support the approval of New Animal Drug Applications. Data generated by NRSP-7 research are made available to the public. Pharmaceutical companies may then use these data at no cost as a way to encourage the development of drugs for minor species. NRSP-7 research is focused on species of agricultural importance.

At the Spring Meeting, held April 21-22, 2008, the stakeholders presented the following information demonstrating the regional and national value of their industries as well as specific therapeutic and other drug needs for their animals.

(See the table on page 11 for a quick reference to demonstrate the importance of minor species industries to the U.S. economy as well as the importance of NRSP-7 to these industries.)

Gamebirds

The North American Gamebird Association was represented by Dr. Eva Wallner-Pendleton of The Pennsylvania State University. She provided the following information about the economic impact, current research, and medication needs of gamebirds in the United States.

Gamebirds are raised in all 50 States. The birds raised include pheasants, bobwhite quail, Chukar partridges, mallards, wild turkeys, and Hungarian partridges. These birds support an estimated $5.0 billion in economic activity through production facilities and sport hunting preserves with an especially significant impact in rural areas. There are 14,000 game bird producers nationwide, with 25 percent deriving their full-time income from this business. Several farms produce 250,000 to 1.8 million birds annually. Associated businesses profit through feed sales, jobs, outdoor recreation, tourism, hunting fees, kennels, lodging, sale of birds, meat production, buildings, and energy sales. In addition, there are 16 million acres dedicated to habitat preservation.

The top game-bird-producing States are Texas, North Carolina, Pennsylvania, Kansas, Wisconsin, New York, Illinois, South Dakota, Florida, Minnesota, Iowa, Georgia, Missouri, Indiana, and Alabama.

Gamebird health is threatened by major disease challenges from bacterial infections and parasites. Coccidiosis alone is holding back game bird production by at least 10 percent to 25 percent.

Another problem is that few veterinarians are familiar with diseases in game birds and how to properly prescribe medications for them. Water treatments are difficult to administer to birds raised outdoors. Medicated feeds cannot be used outside their labeling. So, available medications are very limited.

Despite the challenges, the future is very bright for game bird industry growth. Research into safe and effective medications will play a huge role in helping this industry reach its full potential.

Rabbits

Dr. Chris Hayhow, representing the American Rabbit Breeders Association (ARBA), gave a presentation on the make-up of the rabbit industry in the United States and the therapeutic needs of rabbits and cavies.

The American Veterinary Medical Association reported that, in 2006, approximately 2 million households owned rabbits. In addition, approximately 600,000 households owned cavies. ARBA is the largest organization in the world devoted to rabbits and cavies. Its members raise rabbits and cavies as pets for show and for commercial use.

The rabbit industry includes the raising of lagomorphs for pets, meat, pelts, wool, animal by-products, and research. The market is divided into five major segments with common overlap: meat, fur, exhibition and breeding, pet, and laboratory businesses.

The rabbit industry employs a large and eclectic group of workers, including farmers growing crops for consumption by rabbits and cavies, feed mill workers, rabbit growers, pet supply personnel, lab personnel, family members who make a living selling rabbits or

(Continued, next page)

Importance of Minor Species... *(Continued)*

rabbit-related products, and end users, such as restaurant personnel.

Due to the lack of available drugs, only an extremely small percentage of rabbits and cavies receive preventive or therapeutic medications when needed. In some situations, the herd morbidity and mortality rates are very high. The resulting losses can be great, both financially and emotionally.

The limited availability of drugs to treat rabbits and cavies means that most animals either go untreated or treatment is delayed. Both situations lead to decreased treatment success. The result is increased suffering, loss of use, and loss of life for affected animals. The emotional impact of these losses is difficult to measure. The human-animal bond is strong and the emotional attachment to animals is tremendous.

The lack of approved medications also increases the risk of transmission of zoonotic diseases.

The meat industry: The meat production segment is very fragmented, and few producers can maintain a continuous supply of rabbits to meet slaughter demand. This fluctuation in animal numbers leads to producers contracting with other growers to fill orders and meet demand. The result is a product that lacks uniformity and quality at the retail level.

The NRSP-7 Minor Use Animal Drug Program addresses the shortage of minor species animal drugs by funding and overseeing research to support the approval of New Animal Drug Applications.

Fur and wool markets: The fur and wool markets have declined in recent years for numerous reasons. Whether the problem is consumer dissatisfaction due to price, quality of the product, pressure from foreign markets, or public perception of fur products, the negative impact has contributed to the decline of the rabbit fur industry.

Exhibition and breeding: Exhibition and breeding are fast growing segments of the rabbit industry. The ARBA has more than 28,000 members. At the 2007 Annual Convention and Show, more than 24,000 rabbits and cavies were exhibited. The number of rabbits exhibited at ARBA-sanctioned shows has increased from 595,960 in 1990 to 885,895 in 2006. These numbers do not include shows not sanctioned by the ARBA, such as 4-H and local fairs.

Pets: Rabbits represent one of the fastest growing types of pet ownership. Acceptance of rabbits as household pets is expected to continue to increase. Some rabbits are actually housebroken and trained to do tricks. This upward trend in rabbit ownership will lead to increased demand by clients for products to maintain rabbit health and treat disease problems.

Laboratory use: Laboratory use of rabbits is a well-developed business. With decreases in research funding and development of alternative animal models, the use of rabbits in research settings continues to decline. Most estimates put the decline at greater than 50 percent since the mid 1960s.

Therapeutic needs: It is obvious that the rabbit industry is very large. Rabbits face challenges similar to other animals raised in confinement, including infectious diseases, internal and external parasites, and production problems that require therapeutic agents.

Unfortunately, this minor species has few drugs that have been approved by FDA. Only three such products are available for use in rabbits in the United States—sulfaquinoxaline is used as an aid in the prevention of coccidiosis, lasalocid is used for the prevention of *Eimeria stiedea*, and tetracycline is used for increased growth and improved feed efficiency.

The U.S. market needs several products based on current management practices. Antibiotics for therapeutic use such as enrofloxacin and trimethoprim are broad spectrum, and could be used to treat infections due to *Pasteurella multocida* and other bacterial agents. Antiparasitics, such as amprolium, salinomycin, fenbendazole, and ivermectin, could be used to treat susceptible internal parasite infestations. Also, ivermectin could be used to treat susceptible external parasite infestations. Hormones, such as GnRHa for induction of ovulation for postpartum insemination, are needed. And an antifungal medication, such as griseofulvin, is also needed.

With very few approved products, and legal restrictions that limit the owners ability to treat animals with therapeutics not approved for over-the-counter use in rabbits, there are few alternatives. The Animal Medicinal Drug Use Clarification Act made it easier to obtain therapeutics through a veterinarian. Unfortunately, the economics of the rabbit industry do not allow for the widespread use of veterinarians. Owners tend to treat their own animals using mass medication via the feed or water.

(Continued, page 12)

Importance of Minor Species... (Continued)

Overview of Minor Species Industries, Leading States, Farm Gate Value and Economic Impact in the United States

Industry	*Leading States*	*U.S. farm gate value[1] (in millions)*	*U.S. economic impact[2] (in millions)*	*NRSP-7 Activity*	
				Approvals	***Active***
GAME BIRD	TX, NC, PA, KS, WI, NY, IL, SD, FL, MN, IA, GA, MS, IN & AL	$830.0	$5,000	*Chukar partridges* Sulfadimethoxine/Ormetoprim Lasalocid *Pheasants* Amprolium, Thiabendazole *Quail* Salinomycin, Bacitracin, Monensin	*Pheasants* Lasalocid Sulfadimethoxine/Ormetoprim Fenbendazole
RABBITS	CA, GA, OH, PA, & TX	$20.0	$831	Lasalocid	Ivermectin
HONEY BEES	ND, CA, SD, FL, MT, MN, TX, & WI	$153.0	$16,000	Tylosin	Lincomycin
CERVID	TX, PA, OH, FL, LA, IA, & KS	$894.0 (farming) $757.0 (hunting)	$3,000	*Bison* Ivermectin *Reindeer* Ivermectin	*Deer* Lasalocid *Fallow Deer* Fenbendazole
MEAT GOATS	TX, TN, CA, GA, OK, NC, KY, MO, FL, & AL	$173.2 $189.0 (breeding)	$1,039	Fenbendazole, Monensin, Decoquinate, Morantel tartrate	Lasalocid CIDR (progesterone), Tulathromycin
DAIRY GOATS	TX, OH, NY, PA, WI, WA, IN, CA, MD, MN, MI, FL, & KS	$58.3 $14.8 (export)	$439	Fenbendazole, Monensin, Decoquinate, Morantel tartrate	Lasalocid, CIDR (progesterone), Ceftiofur HCl (intramammary), Tulathromycin
SHEEP	TX, CA, WY, & CO	$750.0	$4,500	*Bighorn Sheep* Fenbendazole *Sheep* Decoquinate, Ceftiofur, Tilmicosin phosphate	*Sheep* CIDR (progesterone), Tulathromycin
CATFISH/AQUACULTURE	*Catfish* MS, AK, AL, & LA *Trout* WA, WI, PA, ID, NC, OR, NY, CA, & CO	Catfish: $480.0 Trout: $87.5	$2,880 $159	*Catfish* Sulfadimethoxine/Ormetoprim *Finfish* Formalin, Oxytetracycline *Lobster* Oxytetracycline	*Fish* Sulfadimethoxine/Ormetoprim, Florfenicol, Erythromycin, Carp, pituitary, Strontium chloride, Oxytetracycline
		Total = $4,406.8	Total = $33,848		

[1] In this table, the term "farm gate value" refers to the net value of an agricultural product when it leaves the farm after marketing costs have been subtracted.

[2] The "U.S. Economic Impact" reflects the value of the industry, including associated businesses. For example, the sale of milk and cheese from a goat farm profits the farm directly, but the economic effect is much broader when feed and equipment sales, worker salaries, and other goods and services are taken into account.

(Article continues on next page)

Importance of Minor Species... *(Continued)*

Honey bees

Troy Fore, representing the American Beekeeping Association, provided information on the value of bees in U.S. agriculture. He also presented information on the issues of Colony Collapse Disorder and American foulbrood in beekeeping culture.

The economic impact of bees in U.S. agriculture is considerable. The production of honey is actually only a small part of the importance of bees. By far their greatest role is through pollination of crops. Honey bees have their greatest economic impact in California, Florida, the Dakotas, Montana, Minnesota, Texas, and Wisconsin. The estimated annual economic value of the work of honey bees is $16 billion.

Colony Collapse Disorder is causing enormous losses in commercial colonies around the country. Efforts are ongoing to identify the cause and find a treatment for this devastating syndrome.

American Foulbrood is a disease that affects the developing bees in the hive. NRSP-7, in partnership with the U.S. Department of Agriculture Bee Lab, was able to complete a project that led to the approval of tylosin to treat American Foulbrood in honey bees. There is also a project in progress to support the approval of lincomycin for the same indication.

Deer

Shane Donely and Shawn Schafer, representing the North American Deer Farmers Association, and Scott Bugai of the Texas Deer Association, provided the following information regarding the cervid industry in the United States.

The cervid family includes whitetail deer, elk, fallow deer, reindeer, axis, sika, and red deer. In general, the production side of the industry is composed of breeding stock producers, trophy hunting preserves, commercial venison producers, and commercial scent collection. Across the Nation, the total number of cervid farms is 7,828, with Texas and Pennsylvania home to roughly 1,000 farms each.

Deer farming and hunting provide approximately $3 billion to the U.S. economy each year.

(Continued, next page)

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Importance of Minor Species... *(Continued)*

The most recent census shows that there are 3,015,000 goats in the United States. These are divided as follows: Angora goat – 210,000; dairy goat – 305,000; meat and other goats – 2,500,000.

Goats

Since 2006, U.S. meat goat numbers have increased by 9 percent with no projected drop in future growth. U.S. dairy goats show a 5 percent increase, and U.S. Angora goats show a 19 percent decline in population for the same period (USDA/National Agricultural Statistics Service numbers used).

The most recent census shows that there are 3,015,000 goats in the United States. These are divided as follows: Angora goat – 210,000; dairy goat – 305,000; meat and other goats – 2,500,000.

Meat goats

Marvin Shurley of the American Meat Goat Association presented information on meat goat production in the United States. He stated that 75 percent of the U.S. meat goat herd resides in 10 States: Texas, Tennessee, California, Georgia, Oklahoma, North Carolina, Kentucky, Missouri, Florida, and Alabama.

Dairy goats

A characterization of the American dairy goat industry was presented by Linda S. Campbell, president of the American Dairy Goat Association.

Dairy goat products include milk, cheese, meat, fiber, seed stock, browsing, and companionship. The breeding stock export market was $14.8 million in 2003, and dairy goat sales are valued at $250 million annually (2007).

Therapeutic and production needs of the dairy goat industry include products for estrus induction/synchronization, milk quality/mastitis treatments, anthelmintics, and products to promote animal welfare, such as those for pain management.

Sheep

Paul Rodgers of the American Sheep Industry joined the meeting via telephone and noted that sheep are most populous in Texas, California, Wyoming, and Colorado. The sheep industry contributes approximately $4.5 billion to the U.S. economy each year.

The sheep industry contributes approximately $4.5 billion to the U.S. economy each year.

Regulatory Activities . . . *(Continued)*

cooling canals and recirculated water supplies (21 CFR 113.60(b)); the firm failed to record all process deviations involving a failure to satisfy the minimum requirements of the scheduled process, as well as the actions taken by the firm to either fully re-process or set aside and evaluate that portion of the production involved in the process deviations (21 CFR 113.89); and the firm's recording thermometer charts and container closure records were not adequately reviewed by representatives of plant management (21 CFR 113.100(b) and (c)).

Recalls

A Class II firm-initiated recall is ongoing by Pfizer Inc. of Canada, Kirkland, Canada, for 1,441 50-blus bottles of Neo-Sulfalyte neomycin/sulfamethazine/electrolyte bolus. The products, which were distributed only within Canada, were recalled due to low potency for neomycin.

Land O'Lakes Purina Feed LLC, Statesville, NC, is conducting a firm-initiated Class III recall of 13,522 50-lb. bags of horse feed because of the presence of aflatoxin in the feed at unacceptable levels. The products were distributed in North Carolina, South Carolina, Virginia, and West Virginia.

A total of 154,313 units of Dr. Turtle Medication Block Card and Medication Bulk are the subject of an ongoing, firm-initiated Class III recall by Aquatrol, Inc., Anaheim, CA. The recall is being conducted because the products may not contain the specified level of sulfathiazole ingredient indicated on the labeling. Distribution took place nationwide and in Guam.

Comings and Goings

New Hires

OFFICE OF THE DIRECTOR

- Laura Bradbard, Health Communications Program Manager
- Shannon Cameron, Public Affairs Assistant
- Kathie Foley, Management Officer
- Kelly Covington, Program Support Specialist
- Denise Benton, Management Analyst

OFFICE OF MANAGEMENT

- Bryan Walsh, Program Support Assistant
- Scott Strunk, Program Support Assistant
- Heather Weiser, Program Analyst
- Shannon Bradbury, Program Analyst

OFFICE OF NEW ANIMAL DRUG EVALUATION

- Sarah Bates, Staff Fellow
- Warren Nesbit, Staff Fellow
- A'ndrea VanSchoick, Veterinary Medical Officer
- Tami Cloyd, Veterinary Medical Officer
- David Cooper, Staff Fellow
- Jennifer Kodak, Consumer Safety Officer
- York Lu, Office Automation Clerk
- Barbara Hamilton, Consumer Safety Officer
- Liju Fan, Biologist
- Heather Gennagios, Chemist

OFFICE OF SURVEILLANCE AND COMPLIANCE

- William Yowell, Program Support Assistant
- Sujaya Dessai, Consumer Safety Officer
- Sonya Barbee, Program Support Assistant
- Stacey Wilford, Veterinary Medical Officer

OFFICE OF RESEARCH

- Kristin Cameron, Microbiologist
- Jonathan Sabo, Microbiologist
- Sampa Mukherjee, Microbiologist
- Gina Weems, Program Support Assistant
- Karen Taylor, Program Support Assistant

Departures

OFFICE OF THE DIRECTOR

- Vashti Klein, Management Analyst
- Debbie Brooks, Management Analyst

OFFICE OF MANAGEMENT

- Rachel Bowman, Program Analyst
- Kathie Foley, Management Officer

OFFICE OF NEW ANIMAL DRUG EVALUATION

- Schuyler Winstead, Staff Fellow
- Sujaya Dessai, Consumer Safety Officer
- David Petullo, Mathematical Statistician
- Beverly Cook, Management Specialist

OFFICE OF SURVEILLANCE AND COMPLIANCE

- Philip Whitney, Consumer Safety Officer
- George Prager, Consumer Safety Officer

OFFICE OF RESEARCH

- Jurgen VonBredow, Pharmacologist

Approvals for June – August 2008

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

EXCENEL RTU EZ (ceftiofur hydrochloride) Sterile Suspension (NADA 141-288), filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., New York, NY. The approved NADA provides for the veterinary prescription use of EXCENEL RTU EZ (ceftiofur hydrochloride) Sterile Suspension for the treatment of various bacterial infections in swine and cattle. Notice of approval was published August 6, 2008.

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

TERRAMYCIN 200 for Fish (oxytetracycline dihydrate) Type A medicated article (supplement to NADA 38-439), filed by Phibro Animal Health, Ridgefield Park, NJ. The NADA provides for the use of TERRAMYCIN 200 for Fish Type A medicated article for the control of certain bacterial diseases in several species of fish and for skeletal marking of Pacific salmon. The supplement provides for use of oxytetracycline dihydrate in Type C medicated feeds for the control of mortality in freshwater-reared salmonids due to cold-water disease associated with *Flavobacterium psychrophilum* and for the control of mortality in freshwater-reared *Oncorhynchus mykiss* due to columnaris disease associated with *Flavobacterium columnare*. Notice of approval was published August 7, 2008.

COCCIPROL (amprolium) 9.6% Oral Solution (supplement to NADA 13-633), filed by Phibro Animal Health, Ridgefield Park, NJ. The NADA provides for the use of COCCIPROL 9.6% Oral Solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis; the approved supplemental NADA provides for label revisions associated with a previous change of sponsoring and other minor changes. Notice of approval was published August 6, 2008.

SYNANTHIC (oxfendazole) Bovine Dewormer Suspension (supplement to NADA 140-854), filed by Fort Dodge Animal Health, Division of Wyeth, Fort Dodge, IA. The NADA provides for the oral use of SYNANTHIC Bovine Dewormer Suspension in cattle for the removal of various internal parasites; the supplemental NADA provides for a revised warning statement, label formatting changes, and revised scientific nomenclature for parasite species. Notice of approval was published August 6, 2008.

VETISULID (sulfachloropyridazine sodium) Powder (NADA 33-373), filed by Fort Dodge Animal Health, a Division of Wyeth Holdings Corp., Fort Dodge, IA. The NADA is approved for the oral use of VETISULID Powder in calves and swine for the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis). The supplemental NADA provides for a revised warning statements and label formatting changes for oral use of sulfachloropyridazine in the milk replacer of ruminating calves. Notice of approval was published June 24, 2008.

DEPARTMENT OF
HEALTH & HUMAN SERVICES

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