FDA VETERINARIAN

Center for Veterinary Medicine

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CVM Proposes Rules on Drug "Designation" Under MUMS Act

On September 26th the Center for Veterinary Medicine (CVM) issued a proposed rule entitled "Designation of New Animal Drugs for Minor Uses or Minor Species." This rule is being proposed to implement section 573 of the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The intent of this section of the act is to provide incentives to pharmaceutical sponsors to encourage the development of new animal drugs for minor uses and minor species. These incentives are only available to sponsors whose drugs are "designated" by the Food and Drug Administration (FDA), under the criteria proposed in this rule, prior to approval.

The MUMS Act was passed by Congress with support from a coalition of animal health companies, animal health organizations, and animal producer groups, as a way to address the problem of making drugs legally available for the large number of animal species for which few drugs are currently approved.

Animal drug companies have been reluctant to seek costly FDA approvals for animal drugs that have a limited market. These include drugs for "Minor Uses," which are for diseases affecting a small number of animals in the major animal species (cattle, horses, swine, chickens, turkeys, dogs, and cats), and drugs for "Minor Species," which include all animals that do not belong to the major species categories. Minor species include zoo animals, and many common pets, such as ornamental fish, parrots, ferrets, and guinea pigs. Minor species also include animals of agricultural importance, including sheep, goats, catfish, and honey bees.

The MUMS Act has three major provisions, including "conditional approval," which allows drug sponsors to make a drug available on the market before the company has collected all the necessary effectiveness data; drug "indexing," which will allow legal marketing of an unapproved drug that a qualified expert panel determines to be safe and effective; and "designation."

The proposed rule for designation represents the first set of implementing regulations for the MUMS Act. Both designation and conditional approval became available to sponsors when the bill was signed. Drugs may not be

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U.S. Files Consent Decree in Animal Drug Residue Case

U.S. officials filed a Consent Decree of Permanent Injunction in July against a California dairy producer for delivering animals for slaughter that had illegal levels of animal drug residues.

Under the terms of the Consent Decree, the defendant, Carl M. Sousa, an individual doing business as White River Dairy, Stratford, CA, must implement systems to avoid illegal residues in the cattle sent to slaughter for human food. U.S. authorities believe the defendant's poor management of his operation led to the problems of drug residues.

The defendant is required to segregate, quarantine, and identify treated animals; identify each animal purchased or transported; maintain medication and treatment records; develop a system for drug inventory and accountability; and follow label directions for use of drugs, including their withdrawal times.

The U.S. Department of Agriculture's Food Safety and Inspection Service, which tests animals for drug residues at slaughter, found nine illegal tissue residues in animals from the defendant's dairy during the period February 1999 to December 2003. The illegal

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In This Issue

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

FDA Announces Fiscal Year 2006 Animal Drug User Fees

The Food and Drug Administration (FDA) announced rates for animal drug application, product, establishment, and sponsor fees for fiscal year 2006 in a notice published in the Aug.1, 2005, *Federal Register*.

The Animal Drug User Fee Act of 2003 (ADUFA) authorizes FDA to establish and collect user fees to enhance the performance of the animal drug review process.

ADUFA provides a formula for adjusting fees based on increases in costs due to inflation or changes in workload. The notice explains in detail how FDA calculated the rates and payment procedures.

The law permits FDA in fiscal year 2006 to collect up to $2,707,250 in fees under each of the four categories, for a total of $10,829,000. That figure represents a $2,500,000 base per category that is adjusted to reflect an 8.29 percent increase in inflation over the last two years. FDA also calculated a workload adjuster, but found that it does not alter the fee amount.

For fiscal year 2006, the fee is $151,800 per application for an animal drug application and $75,900 for a supplemental animal drug application for which safety or effectiveness data are required. The annual product fee is

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CVM Proposes Rules on Drug "Designation" Under MUMS Act *(Continued)*

indexed until regulations implementing that provision are finalized. Those regulations are scheduled to be published late in 2007.

The designation proposed rule was loosely modeled on the incentives included in the human orphan drug regulations. A significant incentive for drugs that are designated under the MUMS Act is that, at the time of approval or conditional approval, a designated drug will be granted seven years of marketing exclusivity. The exclusive marketing provision protects the drug from generic copying and from approval of another pioneer application for the same drug, in the same dosage form, for the same intended use.

The law also includes a provision that will allow Congress to appropriate funds for grants to defray the costs of safety and effectiveness testing for designated drugs. Such grants cannot be made available until final designation regulations are published late next year and funds are appropriated.

The preamble to the proposed rule discusses the difficult issue of defining "small numbers" of animals for "minor use" requirements. Congress defined minor use in major species as "an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually." Congress did not determine what would constitute small numbers, instead leaving that task up to FDA. The preamble discusses various aspects of the issues involved in determining small numbers and solicits public comment on this issue.

CVM will collect comments on the proposed rules for 75 days following the date the proposals were published. Written comments on the proposed rule may be submitted to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. Comments may be faxed to 301-827-6870. Electronic comments may be submitted to the Federal eRulemaking Portal *http://www.regulations.gov* or the FDA web site at *http://www.fda.gov/dockets/ecomments*. All comments on the draft rules should be submitted by December 12, 2005, and should be identified with the full title of the guidance, the Agency name (FDA), and Docket Number 2005N-0329.

U.S. Files Consent Decree... *(Cont.)*

residues included antibiotics such as penicillin, gentamicin, tylosin, and sulfadimethoxine.

The inspectors reported the findings to the Food and Drug Administration (FDA). FDA's San Francisco District Office conducted the investigation that led to the Decree. The Center for Veterinary Medicine's Division of Compliance, FDA's Office of the Chief Counsel, the U.S. Department of Justice's Office of Consumer Litigation, and the U.S. Attorney's Office in the Eastern District of California were responsible for processing and filing the case.

The Consent Decree was filed in the U.S. District Court for the Eastern District of California.

FDA VETERINARIAN

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International Activities

Visiting Chinese Scientists

In June and July, the Center for Veterinary Medicine's (CVM) Office of Research hosted two scientists from China's Institute of Veterinary Drug Control. The Institute of Veterinary Drug Control is considering developing a microbial monitoring system similar to the National Antimicrobial Resistance Monitoring System CVM helped establish in 1996.

The Chinese scientists spent six weeks learning the various techniques employed by scientists in the Office's Division of Animal and Food Microbiology to identify bacteria recovered from animals and from meats derived from animals. These techniques included isolation and identification of bacterial pathogens from retail meats, antimicrobial susceptibility testing using broth microdilution techniques in accordance with the methods described by the Clinical and Laboratory Standards Institute, Polymerase Chain Reaction, Pulsed Field Gel Electrophoresis, and DNA sequencing techniques. They were also shown how to develop and use a database that would facilitate data management for their monitoring system. Discussions were also held to design a valid sampling plan, to develop strategies to integrate laboratory and epidemiologic resources and to gain public support.

The Chinese visitors and their Office of Research hosts are:
In the back row, left to right, are: Zhang Xiuying, visiting scientist; Patricia Cullen, microbiologist; Sherry Ayers, microbiologist; Jason Abbott, microbiologist; Stuart Gaines, microbiologist; Dr. Terry Proescholdt, biologist, Ph.D., D.V.M.; Sonya Bodeis Jones, microbiologist; Dr. Robert D. Walker, Division Director, DAFM, Ph.D.; and Peggy Carter, microbiologist.
In the front row, left to right, are: Sharon Friedman, microbiologist; Dr. Marleen Wekell, Acting Director, Office of Research, Ph.D.; Song Li, visiting scientist; Dr. Heather Harbottle, microbiologist, Ph.D.; Sadaf Qaiyumi, microbiologist; Dr. Loretta Walker, Veterinary Medical Officer, D.V.M.; Althea Glenn, microbiologist; Susannah Hubert, microbiologist; and Charlotte Hatch, student intern.

FDA Announces Fiscal Year 2006 Animal Drug User Fees *(Continued)*

$3,905, the annual establishment fee is $49,200, and the annual sponsor fee is $44,400. FDA will not accept an application for filing unless the sponsor has paid all the fees it owes.

The notice also provides procedures animal drug sponsors should use to pay the fiscal year 2006 fees. The application fee rates are effective for applications received by FDA's Center for Veterinary Medicine (CVM) from Oct. 1, 2005, until Sept. 30, 2006. FDA will issue invoices for all other fiscal year 2006 fees by Dec. 30, 2005. Payments will be due on or before Jan. 31, 2006.

The *Federal Register* notice is available at *http://www.fda.gov/OHRMS/DOCKETS/98fr/05-15158.htm*.

For more information, contact Robert Miller, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7519 Standish Place, Rockville, MD, 20855, 240-276-9700. Send general questions to CVM at *cvmadufa@fda.gov*.

A Decade in the Director's Office: An Interview With CVM Director Dr. Stephen F. Sundlof

Part two of a two-part series

This is the second part of a two-part series based on an interview with Stephen F. Sundlof, D.V.M., Ph.D., Director of the Center for Veterinary Medicine, about the changes he brought to the Center when he became director more than 10 years ago. The first part of the series, published in our last issue, dealt with science and policy issues. In this second part, Dr. Sundlof talks about administrative changes at CVM.

When you first came to CVM more than a decade ago, you thought that improvements could be made in the way the Center works. Ten years ago, you said you envisioned a flatter management structure, and that you would have front-line reviewers offering improvements and taking ownership of the process. How would you describe the situation in the Center now compared with when you started?

Flattening, or reducing the layers, in CVM's management structure was part of the "Reinventing Government" initiative—a component of the managerial philosophy at that time, which encouraged development of less hierarchical organizations by removing management layers.

We started the flattening process by removing an entire layer of management. We completely eliminated supervisory branch chiefs, exchanging them for non-supervisory team leaders, who managed the day-to-day work of the team. All supervisory responsibilities were assigned to the division directors.

Now that we have considerable experience with the de-layered management structure, we are evaluating the strengths and weaknesses of this business practice. This evaluation is consistent with the current move toward rethinking government processes to determine what works best and is most efficient.

For example, we have discovered that as our review divisions became larger it was virtually impossible for the division directors to provide sufficient supervisory time to each individual staff member. Therefore, we are now in the process of converting team leaders back into supervisory branch chiefs. Live and learn.

Changing CVM's culture

What would you say has been the greatest challenge of your tenure at the CVM?

I think the greatest challenge has been trying to change the culture at CVM.

Shortly after I arrived at CVM, I began a strategic planning process. I hired two management consultants to help identify where the Center was strategically and where it should be headed.

The two conducted interviews and focus groups with nearly everyone in the Center and unearthed a litany of issues that people disliked about the organization. The consultants organized similar complaints in discrete groups and produced a thick book on the negative aspects of working at CVM. We called it the "Bluebook."

Armed with this new information, senior management set out to build a strategic plan aimed at addressing the various complaints that surfaced through the focus groups. After living with our new strategic plan for a couple of years, it became apparent that a plan which attempts to be all things to all people is in no way strategic, and is doomed to failure. It is difficult to develop a positive, forward looking plan if you just focus on what's wrong. Beware of consultants offering simplistic solutions to complex business problems. We decided to start again from scratch.

Shortly after joining the FDA in 1994, I enrolled in a leadership development program at the Federal Executive Institute in Charlottesville, VA. I was particularly influenced by a course titled Building High Performance Organizations. The course offered a much more holistic view of the organization than strategic planning could encompass. It emphasized sound business planning (including strategic planning) and management principles. But in addition, it focused on building a healthy work culture based in shared community values. I decided to explore the possibility of modeling CVM in accordance with the High Performance Organization (HPO) principles.

To begin the change process, we hired Dr. John Pickering, President of the Commonwealth Center for High-Performance Organizations, Inc., in Charlottesville. The Commonwealth Center for HPO is a management consulting firm that works with executive teams in both public and private sectors to improve

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A Decade in the Director's Office... *(Continued)*

organizational performance and manage large-scale organizational change. John Pickering, a former professor and senior-level Federal executive, was well positioned to help us move toward becoming a high performance organization.

Dr. Pickering and his associates at first found themselves referring to CVM as a good example of what not to do in management. One of his first recommendations, which was pivotal to the success of the culture change, was that we engage a fulltime, HPO-savvy, organizational development expert to help us. However, we quickly learned that there was not an oversupply of good organizational development consultants we could afford.

Dr. David Grau, who was then in charge of training at CVM, was identified as an excellent choice to become our HPO expert. Dr. Grau participated in the Organization Development and Leadership Coaching programs at Georgetown University, and has become CVM's instructor, spokesman, and leader for the HPO process.

Each staff member at CVM has knowledge to share with the rest of the organization. The senior leadership team wants to make the richness of that knowledge an integral part of our decision-making process.

I believe that the HPO model has been the key in building a vibrant and engaged work culture and solid business processes. Over the past six years, we have seen not only positive change, but a real sense that things are being done differently because of HPO.

In your interview 10 years ago, you also said that you wanted to build a workforce with a strong sense of the Center's strategic mission/vision. Has that happened?

A key to CVM's organizational values and our leadership philosophy is the belief that the people who work at FDA—and at CVM in particular—do so because they intrinsically value the Agency's mission. They are motivated by what the Agency does and by the fundamental nature of their work.

Each staff member at CVM has knowledge to share with the rest of the organization. The senior leadership team wants to make the richness of that knowledge an integral part of our decision-making process. Our goal is to make collaborative decisions at CVM, using the values and knowledge of all of our employees.

The HPO model has diversity and knowledge as centerpieces. Under the HPO model, decisions are made by a team reaching consensus, if possible. We revert back to the hierarchical mode only when necessary. It is important that decisions made by CVM's senior leaders—including those I make—take into account the perspectives of the diverse parts of our organization and are as fully informed as possible. To the extent possible, we try to take off our positional hats when we are in the decision-making mode so we can involve group members as equals in discussions and decisions.

Employer of choice

For the past six or seven years, we have been working hard to understand and apply this HPO model, and I think it has given us some real benefits.

One of the goals we identified through HPO is for CVM to be the "employer of choice" in government. HPO has been an important component in making CVM a desirable place to work. HPO has helped to make us more productive, has improved the the workplace environment, and has improved our ability to attract and keep highly qualified people.

FDA and CVM have employed a number of survey instruments to gauge employee satisfaction. The most recent is FDA's "Q12" survey, conducted by the Gallup Organization, the national polling firm. CVM's scores on the 12 questions in the survey were significantly higher than those for any other major FDA component. With 87 percent of the Center participating in the survey, employee engagement was high (defined as those involved in and enthusiastic about their work) as was satisfaction with the organization as a place to work. These results, in stark contrast to the results of the "Bluebook" interviews 10 years ago, are the result of years of dedicated effort toward becoming a high performance organization.

Turnover is another important measure of our success. I'm proud to say that we have a very low turnover rate—the lowest of any FDA center. Employee retention, which is a very telling sign, is excellent.

Management tools

What other management changes have you instituted?

Two other new initiatives we implemented are Activity Based Costing and Activity Time Reporting.

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A Decade in the Director's Office . . . *(Continued)*

We have expected productivity at CVM to increase over time, but until now, we have not had real ways to measure that. These initiatives are too early in their implementation to have generated enough data to reach any conclusion with regard to productivity, but early indications suggest that they are useful tools for collecting productivity measurement data.

Challenges of a regulator

What have you learned since coming to CVM that has had a significant impact on you and how you do your job?

I have to confess that prior to becoming CVM Director I did not fully understand the complexity of making scientific policy and regulating industries. I naively thought that policy decisions would be clearcut, based on unambiguous science. I quickly learned that was hardly the reality. Unambiguous science, it turns out, is a very rare commodity. Imperfect humans with imperfect technology are responsible for scientific research and technology. All science has some inherent uncertainty associated with it, and any decision based on science can be challenged because of that uncertainty.

A positive trend in the industry is the development of new drugs to treat companion animals. As people increasingly treat their pets as members of the family, they are more willing to spend their disposable income on products to improve the welfare of their pets. Companion animal medicine is an exciting area in which we are seeing some new product development.

In a regulatory setting, policy making sometimes takes on an adversarial quality, in part because different stakeholders hold differing values and assumptions. As a result, the Agency often finds itself at odds with industry or consumers because of disagreements about what the science says and how it should be applied in making policy.

Another factor that influences policy is the degree of risk we are willing to take. As regulators who are charged with protecting the public and animal health, we tend to be more risk averse than the regulated industry that is impacted by the cost of the risk reduction. Industry representatives often want to see evidence that harm will occur before the industry adopts more costly practices, whereas regulators seek to prevent any harm from occurring, thus barring the generation of direct evidence of harm.

Managing the resulting tension between the regulators and regulated industry is a large part of this job. I think that the honest debate that results is healthy and the result is usually good decision-making.

Industry trends

In your interview 10 years ago, you expressed concerns about the economic pressures on the animal pharmaceutical industry and what that might mean for the ability of companies to develop animal drugs. How would you describe the situation in the industry currently, and what might it portend for the future of the industry and the Center?

This is my interpretation, of course. But what I've seen in the last 10-plus years is a consolidation of the animal drug industry that mirrors the consolidation that has taken place elsewhere in the business world. We are now dealing with fewer and fewer companies, as mergers, consolidations, and divestitures from major pharmaceutical firms take place. The animal pharmaceutical industry has gotten more competitive. Some of the elements driving this change are financial and scientific. Recognizing that an unpredictable regulatory environment does not help that situation, we have been trying to make the regulatory process as transparent as possible.

In my opinion, the biggest driver has been the success of the human pharmaceutical industry and the great potential it has shown for generating profits. Major pharmaceutical companies can realize much greater profits by investing the same amount of money in human drugs rather than animal drugs.

Also, profit margins on agricultural commodities are very narrow. In order for a livestock producer to make a decision to use a drug in a large herd of animals, the cost needs to be offset by gains in production.

A positive trend in the industry is the development of new drugs to treat companion animals. As people increasingly treat their pets as members of the family, they are more willing to spend their disposable income on products to improve the welfare of their pets. Companion animal medicine is an exciting area in which we are seeing some new product development.

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Small Turtles Can Cause Illness, FDA Tells Consumers

In July, the Food and Drug Administration (FDA) issued an "Alert to Parents" telling them, as well as all consumers, that turtles are frequently contaminated with *Salmonella* bacteria and can pass the bacteria to anyone handling the turtles, making them sick. Children are especially susceptible.

FDA issued the alert because it has received reports that parents buy baby turtles as pets for their children.

Turtles naturally carry *Salmonella* bacteria. When the turtles shed the *Salmonella*, children or others handling the turtles can become infected. *Salmonella* bacteria cause salmonellosis in humans, which is an infection of the digestive tract. Symptoms include nausea, diarrhea, stomach pain, vomiting, fever, and headache.

Anyone can become infected, but the risk is higher in children, as well as the elderly and individuals with lowered immunity.

The turtles themselves are not affected by *Salmonella*. And when they are infected, they may not shed it all the time, so a negative *Salmonella* test does not indicate that a turtle is free of the bacteria.

To protect the public health, FDA enforces a regulation that prohibits the sale as pets of turtles with shells 4 in. long or smaller. The regulation has been in effect since 1975. Anyone convicted of selling the baby turtles can be fined up to $1,000 and sentenced to jail for up to a year for each offense.

The "Alert to Parents" also recommends that parents and anyone who takes care of children should be aware of the *Salmonella* risk when taking children to petting zoos that contain turtles. Children and others handling the turtles can protect themselves from salmonellosis by carefully washing their hands after handling the turtle or its housing.

A Decade in the Director's Office . . . *(Continued)*

CVM successes

What successes have come from the challenges of the past 10-plus years?

When we developed our CVM Strategic Plan, we called it "Back to Basics." As new issues arose, e.g., international trade, counterterrorism, etc., we were being pulled away from our core functions—pre-market review of animal drugs, post-market surveillance of animal drugs, feed safety, and enforcement and compliance. We needed to refocus our attention on our core functions, and refrain from taking on new issues unless it was absolutely necessary. We still have to deal with crises, such as bovine spongiform encephalopathy, for example, but we are trying to compartmentalize that crisis to the extent possible so it does not affect how we carry out the core functions of CVM. I think we have been successful, as our recent successes with the Animal Drug User Fee Act and the Minor Use and Minor Species Health Act would suggest. We had to rely on the back-to-basics focus in our strategic plan to make these recent successes possible.

Now that you have seen the Center inside and out, how have your views changed?

I must say that after more than 10 years I still believe in the importance of CVM. I always thought CVM was a great organization with a vital mission. The only real change—after working with people in CVM for more than a decade—has been an increase in my respect for the Center and the people who work here. Being a part of CVM has been a wonderful experience. My fundamental attraction to CVM has not changed over the past 10 years—the mission of FDA and CVM.

The mission of FDA—protecting the public—is one to which I am deeply committed. This position allows me to make a meaningful contribution in protecting the public and in dealing with animal health and safety. In addition, the high level of scientific expertise at FDA and the organization's strong grounding in science made it very attractive for me to leave academia to come to this regulatory agency.

As a veterinarian, I am very interested in making sure the health care needs of animals are met. There are not many places where your work as a veterinarian affects not only individual animals, but all animals. This is very rewarding to me.

Finally, how would you sum up CVM's progress after more than a decade in the Director's chair?

My primary goal was to make the organization stronger than it was when I arrived. I think all the Center Directors who preceded me have made improvements. I wanted to continue to improve on that record of progress. When I look at the Center after more than a decade in this role, I see a significantly better organization than 10 years ago.

I am very proud of the work that CVM does. It is a privilege to sit in the Director's seat.

BSE INSPECTION UPDATE

CVM Reports BSE Inspection Figures as of June 11

As of June 11, 2005, the Food and Drug Administration (FDA) had received more than 37,000 reports of inspections done under the ruminant feed rule designed to prevent the establishment and spread of bovine spongiform encephalopathy (BSE) in the United States.

Approximately 68 percent of the inspections were conducted by State officials under contract to FDA, with the remainder conducted by FDA officials.

Inspections conducted by State and FDA investigators are classified to reflect the compliance status at the time of the inspection, based upon whether objectionable conditions were documented. Based on the conditions found, inspection results are recorded in one of three classifications:

- **OAI (Official Action Indicated)** when inspectors find significant objectionable conditions or practices and believe that regulatory sanctions are warranted to address the establishment's lack of compliance with the regulation. An example of an OAI classification would be findings of manufacturing procedures insufficient to ensure that ruminant feed is not contaminated with prohibited material. Inspectors will promptly reinspect facilities classified OAI after regulatory sanctions have been applied to determine whether the corrective actions are adequate to address the objectionable conditions.
- **VAI (Voluntary Action Indicated)** when inspectors find objectionable conditions or practices that do not meet the threshold of regulatory significance, but warrant an advisory to inform the establishment that inspectors found conditions or practices that should be voluntarily corrected. VAI violations are typically technical violations of the 1997 BSE Feed Rule. These violations include minor recordkeeping lapses or conditions involving non-ruminant feeds.
- **NAI (No Action Indicated)** when inspectors find no objectionable conditions or practices or, if they find objectionable conditions, those conditions are of a minor nature and do not justify further actions.

(Note: The following figures are as of June 11.)

Renderers

These firms are the first to handle and process (i.e., render) animal proteins. After they process the material, they send it to feed mills and/or protein blenders for use as a feed ingredient.

- **Number of active firms whose initial inspection has been reported to FDA** – 263
- **Number of active firms handling materials prohibited from use in ruminant feed** – 176 (67 percent of those active firms inspected)

  Of those 176 firms:

  ❖ 2 (1.1 percent) were classified as OAI

  ❖ 8 (4.5 percent) were classified as VAI

Licensed feed mills

In the inspection report database, FDA lists medicated feed licensed feed mills separately from non-licensed feed mills. But the licensing has nothing to do with handling prohibited materials under the feed ban regulation. FDA requires feed mills to have medicated feed licenses to manufacture and distribute feed using certain potent drug products, usually those requiring some pre-slaughter withdrawal time, to produce certain medicated feed products.

- **Number of active firms whose initial inspection has been reported to FDA** – 1,069
- **Number of active firms handling materials prohibited from use in ruminant feed** – 411 (38 percent of those active firms inspected)

  Of those 411 firms:

  ❖ 1 (0.2 percent) was classified as OAI

  ❖ 7 (1.7 percent) were classified as VAI

Feed Mills Not Licensed by FDA

These feed mills are not licensed by the FDA to produce medicated feeds.

- **Number of active firms whose initial inspection has been reported to FDA** – 5,145
- **Number of active firms handling materials prohibited from use in ruminant feed** – 1,920 (37 percent of those active firms inspected)

  Of those 1,920 firms:

  ❖ 2 (0.1 percent) were classified as OAI

  ❖ 27 (1.4 percent) were classified as VAI

Protein blenders

These firms blend rendered animal protein for the purpose of producing feed ingredients used by feed mills.

- **Number of active firms whose initial inspection has been reported to FDA** – 329
- **Number of active firms handling materials prohibited from use in ruminant feed** – 117 (36 percent of those active firms inspected)

  Of those 117 firms:

  ❖ 0 were classified as OAI

(Continued, next page)

CVM Reports BSE Inspection Figures... *(Continued)*

- 3 (2.6 percent) were classified as VAI

Renderers, feed mills, protein blenders

This category includes any firm that is represented by any of the above four categories, but includes only those firms that manufacture, process or blend animal feed or feed ingredients using prohibited materials.

- **Number of active renderers, feed mills, and protein blenders whose initial inspection has been reported to FDA** – 6,550
- **Number of active renderers, feed mills, and protein blenders processing with prohibited materials** – 553 (8.4 percent of those active firms inspected)

Of those 553 firms:

- 5 (0.9 percent) were classified as OAI
- 20 (3.6 percent) were classified as VAI

Other firms inspected

Examples of such firms include ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers, distributors, retailers and animal feed transporters.

- **Number of active firms whose initial inspection has been reported to FDA** – 12,575
- **Number of active firms handling materials prohibited from use in ruminant feed** – 3,288 (26 percent of those active firms inspected)

Of those 3,288 firms:

- 8 (0.2 percent) were classified as OAI
- 90 (2.7 percent) were classified as VAI

Total Firms

- **Number of active firms whose initial inspection has been reported to FDA** – 15,676
- **Number of active firms handling materials prohibited from use in ruminant feed** – 4,093 (26 percent of those active firms inspected)

Of those 4,093 firms:

- 10 (0.2 percent) were classified as OAI
- 98 (2.4 percent) were classified as VAI

(NOTE: A single firm that has more than one function can be listed in different industry segments, which also means that the total may be less than a combination of all the segments.)

FDA Seeks Nominations for Veterinary Medicine Advisory Committee

The Food and Drug Administration (FDA) is seeking nominations for a voting member with expertise in biostatistics to serve on the Veterinary Medicine Advisory Committee. The Committee reviews and evaluates data concerning the safety and effectiveness of new animal drugs, feeds, and devices for use in the treatment and prevention of animal diseases and increased animal production, and makes recommendations regarding scientific issues and regulatory policies.

Persons nominated for membership on the committee should have specialized training and experience necessary to qualify the nominee as an expert. Qualified experience may include veterinary medical practice, teaching, and/or research relevant to the field of activity of the committee.

Any interested person may nominate one or more qualified persons for membership on the advisory committee. Self-nominations are also accepted.

The term of committee membership is four years. Information regarding the committee can be found on the CVM home page at *http://www.fda.gov/cvm/FOI/vmactoc.htm*.

Nominations must include the name of the committee, complete curriculum vitae of each nominee, current business address and telephone number. The nomination must state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of any potential conflict of interest.

FDA also anticipates a vacancy on the VMAC in the specialty area of Animal Science in November 2006. Nominations for that vacancy are also being accepted at this time.

FDA has a special interest in ensuring that women, minority groups, and the physically challenged are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

All nominations and curricula vitae should be sent to Aleta Sindelar, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9004, e-mail: *asindela@cvm.fda.gov*.

How FDA Takes Care of Animals: AAALAC Accreditation Achieved and Maintained

by Mack A. Holt, D.V.M., Director, CVM Office of Animal Care and Use

The Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC, International) is a private, nonprofit organization that promotes the humane treatment of animals used in science.

AAALAC accreditation is achieved through institutional voluntary submission to assessment and accreditation of animal care and use programs. Achievement of "fully accredited" AAALAC status is considered to be the "Gold Standard" in laboratory animal care and use. This symbolizes to the public and biomedical research communities that the accredited program is operating at standards that epitomize quality animal care and use.

Currently, more than 670 animal care and use programs in 24 countries have earned the "Gold Standard" of accreditation. These programs include academic institutions, commercial organizations, agricultural research programs, government agencies, hospitals, nonprofit organizations, biotechnology, and pharmaceutical companies. Once initial accreditation is achieved, the accredited program is site visited or peer reviewed once every three years.

All of the animal care and use programs in the Food and Drug Administration (FDA) are operating under the "Gold Standard" of accreditation. FDA scientists participating in research and testing using *in vivo* test systems understand the critical relationship between quality animal care and quality science.

The first two FDA animal care and use programs that achieved accreditation did so in 1977. Those programs were the Center for Biologics Evaluation and Research and the National Center for Toxicological Research. Over a period of 25 years during the evolving stages of FDA animal care and use programs, "full accreditation" status has been achieved and maintained for all of the Agency's programs using *in vivo* test systems. The chronology of these accreditations has been as follows: Center for Veterinary Medicine (CVM), 1993; Center for Drug Evaluation and Research (CDER), 1999; Center for Devices and Radiological Health (CDRH), 2000; Center for Food Safety and Applied Nutrition, 2001; and Office of Regulatory Affairs, 2003. Since the initial accreditations, all programs have had multiple site visits and have maintained "fully accredited" status.

AAALAC accreditation is achieved through institutional voluntary submission to assessment and accreditation of animal care and use programs.

As part of a long-range plan by FDA to construct facilities and consolidate multiple FDA entities as the FDA/Federal Research Center at White Oak, in Silver Spring, MD, the animal-research based programs of CDER and CDRH were consolidated under a Memorandum of Agreement. These consolidated programs became the White Oak Animal Program in December 2003. Inasmuch as the animal care and use programs of CDER and CDRH had achieved and maintained "full accreditation" status, AAALAC International granted permission to FDA to let both programs function as a single consolidated program under the "Gold Standard."

When new buildings are constructed that are to accommodate animals used in research, testing and teaching, a question often asked is whether the buildings will be AAALAC accredited. An AAALAC evaluation considers all aspects of an animal care and use with buildings being a part of the overall program. Such an evaluation would include an organization's procedures and overall performance in the area of animal care and use in research, education, testing, or breeding. The basic components that are evaluated include institutional policies, animal husbandry, veterinary care, and physical plant. AAALAC evaluations emphasize performance-based measures that make allowance for greater flexibility in the achievement of desired outcomes in animal use.

AAALAC does not impose prescriptive measures in the achievement of desired outcomes. The evaluation process takes into consideration the fact that each animal care and use program is unique. Differences between programs may be a function of program mission, types of animals involved, or outcomes desired. FDA's AAALAC accredited programs are all unique. This uniqueness can best be illustrated in the CVM AAALAC accredited Office of Research animal care and use program. It conducts applied research in support of regulatory decision-making in a state-of-the-art research complex. This program does not include just one category of animals. Instead, the Office of Research complex is facilitated to accommodate small laboratory animals, a variety of agricultural animals, aquatic species, and companion animals.

FDA is proud that all of its animal care and use programs are counted among the programs operating under the "Gold Standard" status. The emphasis and commitment given to the derivation of quality regulatory decisions must parallel that of quality animal care and use. If data generated from use of *in vivo* test systems is utilized to support or validate regulatory science-based decisions, its source must be of "Gold Standard" origin.

FDA Recognizes Industry Expert for MUMS Legislative Push

by Richard L. Arkin, Assistant Editor

Dr. John R. "Randy" MacMillan, an industry fisheries specialist, was awarded the Food and Drug Administration (FDA) Commissioner's Special Citation in a ceremony May 6 for his work in supporting animal drug availability and in leading the coalition that was instrumental in securing passage last year of the Minor Use and Minor Species (MUMS) Animal Health Act.

Dr. MacMillan, Vice President for Research and Environmental Affairs, Clear Springs Foods, Inc., Buhl, ID, was presented the award at the FDA Honor Awards Ceremony in Gaithersburg, MD, by FDA Commissioner Dr. Lester M. Crawford and Center for Veterinary Medicine (CVM) Director Dr. Stephen F. Sundlof.

The award cited Dr. MacMillan "for outstanding effort and perseverance in support of animal drug availability culminating in passage of the Minor Use and Minor Species Animal Health Act of 2004."

The MUMS Animal Health Act is intended to be a mechanism to provide FDA-authorized drugs for use in "minor" species and to provide common food and companion animal or "major" species with needed therapeutics for uncommon indications or "minor uses." The major species are cats, dogs, horses, cattle, swine, turkeys, and chickens. Minor species are all other animals, including sheep, goats, game birds, emus, ranched deer, alpacas, llamas, deer, elk, rabbits, guinea pigs, pet birds, reptiles, ornamental and other fish, shellfish, wildlife, zoo and aquarium animals.

"After all, it is a truism that minor uses and minor species are, well, minor," Dr. MacMillan explained. "There are seven major animal species, meaning that all the rest are minor," he added, "including, for example, the 35 species of fish raised for food and more than 800 ornamental fish species commonly in distribution."

Dr. MacMillan said that an industry-wide effort was necessary to deal with legislative solutions. "Industry, zoos, and others interested in increasing drug availability for minor uses and minor species needed a broad coalition to draft the legislation and do the legwork necessary to get it passed," he explained.

The award cited Dr. MacMillan "for outstanding effort and perseverance in support of animal drug availability culminating in passage of the Minor Use and Minor Species Animal Health Act of 2004."

"We were a bit naïve at first," Dr. MacMillan later commented. "We thought the need was so clear and that our legislative initiatives were so simple and straightforward that Congress would agree right away. It turned out that a multi-year, sustained effort was necessary to educate Congress and the public."

Dr. MacMillan chaired the MUMS Coalition, an organization formed to support the MUMS legislation, which was made up of animal health industry organizations and representatives from across the industry. A diverse group of veterinarians, animal owners and producers, and developers of animal products, the MUMS Coalition's 43 member organizations represent those involved in the care of terrestrial, aquatic, domestic, and wild animals, those kept as pets, livestock, zoological and aquarium collections. Members of the MUMS Coalition include the American Veterinary Medical Association, American Farm Bureau Federation, Animal Health Institute, American Pet Product Manufacturers Association, American Feed Industry Association, and National Aquaculture Association.

Dr. MacMillan called the group "a broad-based" coalition that worked with other interest groups and CVM over a six-year period to provide technical assistance, education, and other support to Congress in drafting and passing MUMS legislation. The process of drafting and ultimately passing particularly novel drug legislation is often quite long and arduous, and that was especially true for MUMS legislation, in part because of the difficulty of meshing complicated science and policy issues, and in part because of the complexity of the legislative process, he said.

The dedication and perseverance of Dr. MacMillan and other members of the coalition paid off when MUMS Animal Health Act became law last year, creating a climate that will ultimately lead to an increase in the number of approved animal drugs for species and ailments for which treatment options have traditionally been limited.

As the Senate report accompanying the MUMS Animal Health Act stated, the legislation was necessary because of a severe shortage of approved new animal drugs for use in minor species and for treating animal diseases and conditions that occur infrequently or in limited geographic areas. Because of the small market shares for these products, low-profit margins involved, and capital investment required, it has generally not been economically feasible for new animal drug applicants to pursue approvals for drugs to treat these species, diseases, and conditions. Additionally, because the populations for

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FDA Recognizes Industry Expert... *(Continued)*

which such new animal drugs are intended may be small and conditions of animal management may vary widely, it has often been difficult to design and conduct studies to establish drug safety and effectiveness under traditional new animal drug approval processes, the report said.

In passing the MUMS Act, Congress decided that the public interest and the interest of animal welfare required the provision of special procedures to allow the lawful use and marketing of certain new animal drugs for minor species and minor uses that take into account these special circumstances and that ensure that such drugs do not endanger animal or public health, the Senate report said.

Legislation

To address these issues, the legislation provided for:

- Creation of a conditional approval mechanism for new animal drugs for minor uses and minor species that allows for early marketing while effectiveness studies are completed;
- Formulation of an index of legally marketed unapproved new animal drugs for non-food minor species and non-food life stages of food-producing minor species under limited circumstances; and
- Initiation of a process for classifying certain new animal drugs for minor uses and minor species as "designated" new animal drugs to qualify them for incentives, including grants and exclusive marketing rights, to help compensate drug sponsors for clinical testing expenses to encourage them to develop new MUMS animal drugs.

The legislation maintains all pre-existing FDA requirements for the approval of animal drugs including antimicrobials, however. Only indexed drugs will be made available under a different standard.

The MUMS Animal Health Act also provided for the organization of a new Office of Minor Use and Minor Species Animal Drug Development within CVM. This Office is responsible for designating minor use and minor species animal drugs, for administering grants and contracts, for reviewing minor species drug index listing requests, and for serving as liaison to other government agencies interested in minor use and minor species animal drug development. The legislation also requires FDA to issue proposed and final regulations and establish deadlines for these to be published.

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Some provisions of the new law went into effect immediately after the bill was signed. These include conditional approval and designation. Indexing cannot be implemented until the publication of the final regulations, due in August of 2007.

"Team effort"

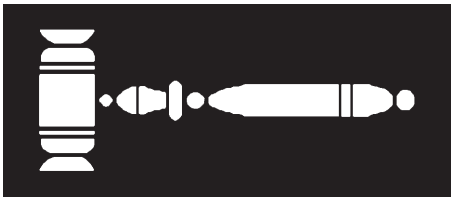
Dr. MacMillan called the push to pass the MUMS legislation "a team effort." He added: "In my view, getting the MUMS bill passed took the combined efforts of FDA, CVM, and the entire MUMS Coalition," Dr. MacMillan stated. "It was a great team effort, and we all stuck together," he said. "Now that the legislation is law, we're looking for continuing collaboration because we still have a long way to go" in making therapeutic drugs available for minor uses and minor species, Dr. MacMillan added.

Dr. MacMillan has been Clear Springs Foods' Vice President of Research and Environmental Affairs since 1998. In that role, he is responsible for the company's research and development, environmental stewardship of natural resources, and quality assurance programs. In addition to the MUMS coalition, which he continues to lead, Dr. MacMillan is president of the National Aquaculture Association and was chair of the joint National Association of State Aquaculture Coordinators-National Aquaculture Association Committee on National Aquatic Animal Health Management Plan Development. He is also Chairman of the Idaho Board of Environmental Quality and immediate Past Chairman of the Upper Snake River Basin Advisory Group.

Before assuming his current post at Clear Springs Foods, Dr. MacMillan served as that company's Director of Research. Previously, he was an Associate Professor at Mississippi State College of Veterinary Medicine, an extension fisheries specialist in Mississippi, a research biologist for the U.S. Fish and Wildlife Service in Seattle, WA, and a Senior Research Fellow at the University of Washington School of Medicine.

Dr. MacMillan received his Ph.D. from the University of Washington in 1980. He also holds a Master of Science degree from Michigan State University and a Bachelor of Science degree from the University of Maryland.

Regulatory Activities



The following individuals and firms received Warning Letters for offering animals for slaughter that contained illegal tissue residues:

- James G. Rankel, owner, Elder Grove Dairy Farm, Colby, WI
- Art R. Mills and Roger A. Mills, co-owners, Bar-B-R Farm, Andover, NY
- Horton Mitchell, owner, Mitchell Farms, Adairsville, GA
- Arthur H. Chickering, III, cattle dealer, Westmoreland, NH
- David Galton, principal owner, Ridgecrest Dairy, LLC, Genoa, NY
- Douglas B. Handley, owner, Do-Rene Dairy, Clovis, NM
- Paul S. Weber, president, Idyl Wild Farms, Inc., Londonville, OH
- Eric W. Daale, owner/partner, Heritage Dairy, Clovis, NM
- Barney G. Prince, Hamilton, NY
- James M. Klever, part-owner, Klever Holstein Farms, Ltd., Fredricktown, OH

The above violations involved neomycin in bob veal calves, sulfadimethoxine in dairy cows, gentamicin in a bull calf, penicillin in cows, and tilmicosin in a cow.

A Warning Letter was issued to Priscilla D. Shaw, owner, A & A Services, Kapolei, HI, because inspection at this animal feed distribution operation found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations (CFR), Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). The use of protein derived from mammalian tissues, as defined by 21 CFR 589.2000(a)(1), as an animal feed ingredient or in animal feeds must comply with the requirements of 21 CFR 589.2000. Products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed (prohibited material) must be labeled with the cautionary statement, "Do not feed to cattle or other ruminants." The inspection found that the operation was not labeling the products distributed to swine farms that contain food waste from restaurants and hospital cafeterias with this caution statement. The inspection also found that the same containers were being used to hold both prohibited materials to be used for feed for non-ruminants and non-prohibited materials to be used for feed ruminants. However, the firm failed to provide written procedures specifying clean-out procedures or other measures to avoid cross-contamination of the feed products to be used for ruminants.

Products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed (prohibited material) must be labeled with the cautionary statement, "Do not feed to cattle or other ruminants."

A Warning Letter was issued to Don Cloud, CEO, West Feeds, Inc., Billings, MT, because an inspection conducted at his medicated feed mill located at Miles City, MT, found significant deviations from Current Good Manufacturing Practice (cGMP) regulations for medicated feeds. The deviations included a failure to possess a medicated feed license for the use of Category II, Type A medicated articles amprolium, sulfamethazine, and chlortetracycline in the manufacture of medicated feeds at the Miles City facility; and the failure to conduct on an annual basis periodic assays on at least three samples of medicated feeds requiring a medicated feed mill license for each drug or drug combination used. Specifically, the facility in Miles City has manufactured medicated supplements containing the Category II, Type A medicated articles amprolium, sulfamethazine, and chlortetracycline since October 2003 without performing the required annual assays.

A Warning Letter was issued to Jose M. Homen and Durvalina Homen, co-owners, Homen Dairy Farms, LP, Merced, CA, because investigations found they were offering animals for slaughter that contained illegal tissue residues. This violation involved the drug penicillin in dairy cows. In addition, their extralabel use of Penicillin G Procaine and Oxytetracycline Hydrochloride caused these drug products to become adulterated within the meaning of Section 501(a)(5) of the Food, Drug, and Cosmetic Act, because they failed to use the drugs in conformance with their approved labeling.

A Warning Letter was issued to Francisco Torres Quijano, president of the Board, Asociación de Productores de Leche Camuy-Quebradillas, Camuy, PR, for selling and dispensing veterinary prescription drug products without a lawful order from a licensed veterinarian, which caused the products to be misbranded within the meaning of Section 503(f)(1)(C) of the

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Regulatory Activities *(Continued)*

Act. Examples of veterinary prescription drugs dispensed without the order from a licensed veterinarian include gonadorelin diacetate tetrahydrate sterile solution, dinoprost tromethamine injection, and isoflupredone acetate sterile aqueous suspension. In addition, these prescription veterinary drugs were misbranded within the meaning of 502(f)(1) because they did not bear adequate directions for use, and they do not fall into an exception to that requirement. FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended."

A Warning Letter was issued to Michael J. Langenhorst, president, Anamax Corporation, Green Bay, WI, because inspection at his rendering plant in South St. Paul, MN, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations (CFR), Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of BSE. The use of protein derived from mammalian tissues, as defined by 21 CFR 589.2000(a)(1), as an animal feed ingredient or in animal feeds must comply with the requirements of 21 CFR 589.2000. Products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed (prohibited material) must be labeled with the cautionary statement, "Do not feed to cattle or other ruminants." The inspection found that the operation failed to provide for measures to prevent commingling or cross-contamination in that the plant failed to maintain written procedures or to use clean-out procedures adequate to prevent carryover of protein derived from mammalian tissues into feeds that may be used for ruminants. The inspection also found failure to label products with the cautionary statement, "Do not feed to cattle or other ruminants." For example, the company's Feather Meal and Stabilized Poultry By-Product Meal lacked this statement, even though the absence of sufficient measures to avoid commingling or cross-contamination may result in these products containing protein derived from mammalian tissues.

Approvals for March Through June 2005

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

SPECTRAMAST DC (ceftiofur hydrochloride) Sterile Suspension (NADA 141-239), filed by Pharmacia & Upjohn, a Division of Pfizer, Inc. The NADA provides for the veterinary prescription use of ceftiofur hydrochloride suspension, by intramammary infusion, for the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with *Staphylococcus aureus*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*. Notice of approval was published April 18, 2005.

CYDECTIN (moxidectin) Injectable Solution for Beef and Nonlactating Dairy Cattle (NADA 141-220), filed by Fort Dodge Animal Health. The NADA provides for use of an injectable moxidectin solution for the treatment and control of various internal and external parasites of cattle (i.e., gastrointestinal roundworms, lungworms, cattle grubs, mites, and lice). Notice of approval was published June 23, 2005.

TRIBUTAME Euthanasia Solution (embutramide; chloroquine phosphate, U.S.P.; and lidocaine, USP) (NADA 141 245), filed by Phoenix Scientific, Inc. The NADA provides for veterinary prescription use of the solution by intravenous injection for euthanasia of dogs. Notice of approval was published June 23, 2005.

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Approvals for March Through June 2005 *(Continued)*

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

- COMBI-PEN-48 (Penicillin G Benzathine and Penicillin G Procaine Injectable Suspension) (NADA 065-506), filed by Cross Vetpharm Group Ltd. The supplemental NADA provides for a change in the proprietary name on the OTC label product from COMBICILLIN-AG to COMBI-PEN-48 and the addition of the statements "A withdrawal period has not been established for the product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section of the product labeling. Notice of approval was published April 28, 2005.

- RALGRO (zeranol) (NADA 038-233), filed by Schering-Plough Animal Health Corp., a subcutaneous implant used in cattle and in sheep for improved feed efficiency and/or increased rate of weight gain. The supplemental NADA provides for the establishment of a tolerance for residues of zeranol in edible tissues of sheep. Accordingly, the analytical method for detecting residues of zeranol in uncooked edible tissues of sheep is being removed from the animal drug regulations 21 CFR Part 556. Notice of approval was published March 29, 2005.

- Pyrantel Pamoate Paste (pyrantel pamoate) (NADA 200-342), filed by Phoenix Scientific, Inc. The supplemental provides for oral use for the removal and control of mature infections of tapeworms (*Anoplocephala perfoliata*) in horses and ponies. Notice of approval was published May 23, 2005.

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

- Tiamulin Soluble Antibiotic (tiamulin hydrogen fumarate) (ANADA 200-344), filed by Phoenix Scientific, Inc. The supplemental ANADA provides for use of tiamulin soluble powder to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia. Phoenix Scientific, Inc.'s Tiamulin Soluble Antibiotic is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s DENAGARD (tiamulin) Soluble Antibiotic approved under NADA 134-644. Notice of approval was published March 18, 2005.

- Carprofen Caplets (ANADA 200-366), filed by IMPAX Laboratories, Inc. The ANADA provides for veterinary prescription use of Carprofen Caplets (carprofen) in dogs for the relief of pain and inflammation associated with osteoarthritis. IMPAX Laboratories, Inc.'s Carprofen Caplets is approved as a generic copy of Pfizer, Inc.'s RIMADYL Caplets, approved under NADA 141-053. Notice of approval was published May 27, 2005.

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