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FDA VETERINARIAN

LESTER M. CRAWFORD, JR. NAMED FDA DEPUTY COMMISSIONER

HHS Secretary Tommy G. Thompson today named Lester M. Crawford, Jr., D.V.M., Ph.D., to serve as deputy commissioner of the Food and Drug Administration. Dr. Crawford begins in the position immediately.

As deputy commissioner, Dr. Crawford will be the senior official at FDA, pending the installment of a permanent commissioner of food and drugs.

"Lester Crawford has devoted his career to promoting safer products for the public, and he brings to the FDA valuable experience and leadership skills," Secretary Thompson said. "With his help, the FDA will continue to build on its successes in ensuring the safety of foods, drugs and medical products for all Americans."

Dr. Crawford takes over from Bernard A. Schwetz, D.V.M., Ph.D., a career FDA executive who has served as acting principal deputy commissioner since Jan. 21, 2001. Dr. Schwetz, senior advisor for science, will continue to work on public health and FDA issues within the agency.

"Dr. Bern Schwetz has led the FDA during a challenging year, when the nation faced its first bioterrorism attack," Secretary Thompson said. "Forward-looking actions by FDA, like early and rapid approval of effective drugs against anthrax, played a crucial role in saving lives. I thank Bern for his service over the past year."

Dr. Crawford most recently served as head of the Center for Food and Nutrition Policy at Virginia Tech. He also served as administrator of the U.S. Department of Agriculture's Food Safety and Inspection Service from 1987 to 1991 and as director of the FDA's Center for Veterinary Medicine from 1978 to 1980, and again from 1982 to 1985.

Dr. Lester M. Crawford

He received a Doctor of Veterinary Medicine from Auburn University in 1963 and a Ph.D. in pharmacology from the University of Georgia in 1969. During his career, he has also served as executive director of the Association of American Veterinary Medical Colleges, executive vice president of the National Food Processors Association, as chairman of the University of Georgia's Department of Physiology-Pharmacology and as a practicing veterinarian.

This statement was issued by HHS on February 25, 2002. □

DR. CLIFFORD I. JOHNSON SELECTED AS DIRECTOR OF CVM'S OS&C

Dr. Clifford I. Johnson has been selected to fill the position as Director, Office of Surveillance and Compliance (OS&C) in FDA's Center for Veterinary Medicine (CVM.) He joined the Center on February 25, 2002.


Dr. Clifford I. Johnson

During his more than 30-year career, Dr. Johnson has held significant positions in both the military and State government. He comes to CVM from his position as the Maryland State Public Health Veterinarian and Acting Chief, Center for Immunization. In that position, Dr. Johnson managed veterinary and immunization activities for the State of Maryland, and provided consultation services for twenty-four health officers/health

(Continued, next page)

In This Issue

AAFCO Mid-Year Meeting 2
CVM's Office of Research 2001 Highlights 3
Proposal to Withdraw Poultry Enrofloxacin Approval 9
New Director for OMAC 12

DR. CLIFFORD I. JOHNSON SELECTED AS DIRECTOR OF CVM'S OS&C (Cont.)

commissioners and their staffs at the local health departments. He has led Maryland's Epidemiology and Disease Control Program, including providing guidance for the annual site reviews for each local health department.

Prior to that position, Dr. Johnson was Chief, U.S. Army Veterinary Corps, as well as Director, Department of Defense Veterinary Services Activity, Assistant Surgeon General for Veterinary Services. Dr. Johnson served as senior veterinary consultant to the Assistant Secretary of Defense (Health Affairs), Director, Defense Research and Engineering, and the Surgeons General, Army, Navy and Air Force. He served in the military at the general officer level as a Colonel.

Dr. Johnson received both his B.S. and D.V.M. degrees from Tuskegee University and his M.P.H. in Epidemiology from the University of Michigan. □

VMAC SEEKS NOMINATIONS

The Center for Veterinary Medicine is seeking nominations for three vacancies on the Veterinary Medicine Advisory Committee (VMAC) in the specialty areas of pharmacology, Minor Species/Minor Use Veterinary Medicine, and pathology. Nominations for the VMAC Chairperson are also solicited. Information regarding the committee can be found at the CVM Home Page *http://www.fda.gov/cvm/index/vmac/vmactoc.htm*. Nominations for new committee members and Chair should be submitted by **May 15, 2002**, to:

EXECUTIVE SECRETARY
Aleta Sindelar
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855 □

PET FOOD, BSE, DISCUSSED AT AAFCO MID-YEAR MEETING

by Rod Noel, John Breitsman, and Sharon Senesac

The Association of American Feed Control Officials (AAFCO) held its mid-year meeting in Austin, Texas on January 27-30, 2002. There were representatives from 23 States, Canada, U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and industry.

An Environmental Nutrition Symposium was conducted on Sunday, January 27, 2002. Dr. Floyd Byers, USDA/ARS, spoke on Environmental Nutrition – Focus and Future in Food Animal Production and Dr. L. Wayne Greene, Texas A&M gave a presentation entitled "Feeding Management, Beef Cattle – Perspective". "Biological Assays for Amino Acid Bioavailability in Animal Feeds" was the title of Dr. Steven C. Ricke's presentation, and the symposium ended with Dr. Kyle Newman, Venture Laboratories, discussing "Mannan Oligosaccharides: Defining Structure with Function".

The National Academy of Sciences held an open forum to discuss planned changes to the NRC Dog & Cat Nutrient Requirements Series on Tuesday, January 22, 2002. A new addition to the mid-year meeting was a members-only session where the AAFCO Board discussed important issues with the AAFCO members. This was well-received and will be continued at future meetings.

AAFCO's BSE Task Force held an open session that included an update by CVM's Gloria Dunnavan on FDA's revised BSE inspection checklist and the Agency's activities involving BSE. Dr. Svetlik, a representative from USDA, provided a report on the Harvard Risk Assessment on BSE. Gloria Dunnavan also led a discussion on improving communications between the States and FDA on sharing inspection information and other pertinent information. The BSE Task Force recently completed developing a BSE educational/informational brochure that is now available for distribution. FDA will provide copies of this brochure to the States for distribution in their continuing education effort to achieve full compliance with 21 CFR Part 589.2000.

During the Feed Manufacturing Committee (FMC) meeting, a discussion was held concerning adoption by the members of the "Guidance/Framework for Best Management Practices for Manufacturing, Packaging and Distributing Animal Feeds and Feed Ingredients." A small working group had developed a preamble to the document that provides the intent and purpose of this document. The guidance document was adopted by the membership at the General Session on January 23, 2002. This committee also decided to develop a checklist for use in evaluating and measuring the implementation of this guidance by industry and regulators. As part of the AAFCO's Feed/Food Safety Initiative and with the support of the AAFCO Board and members, the FMC will move forward with the development of process controls for all feeds and feed ingredients. It will start working on principles that would be applicable to all feed manufacturing. Efforts will be made to secure industry cooperation and participation in this project. The FMC must make a decision to pursue these changes as a proposed Federal regulation or as changes to AAFCO's Model Bill & Regulations to be adopted by individual States or

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FDA Veterinarian

Lester M. Crawford, D.V.M. , Ph.D.
Deputy Commissioner of Food and Drugs

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Center for Veterinary Medicine

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FAX (301) 827-4065 or write to:
FDA Veterinarian (HFV-12)
7519 Standish Place
Rockville, MD 20855

both. Finally, the Voluntary Self Inspection Program (VSIP) for medicated feeds was discussed. FDA hopes to launch a pilot program in the very near future and the FMC has offered to assist the agency in that effort.

The Enforcement Strategy for Marketed Ingredients (ESMI) Working Group produced a planned coordinated strategy to address unapproved feed/pet food ingredients and approved ingredients distributed for unapproved purposes. Model regulatory letters and a fact sheet have been developed and are currently available for use in the enforcement of both Federal and State statutes and regulations. With the assistance of CVM, an ingredient will be identified for the State members to take a coordinated uniform enforcement action later this year. To assist in this event, one day of the AAFCO's Feed Administrators Seminar in April will be devoted to training administrators in the background and mechanics for this regulatory event.

The AAFCO Surf Day Working Group discussed the results from its follow-up surf day effort. The information collected during the surf days will be further compiled and distributed to the States, FDA and USDA for possible enforcement actions. The feed industry and AAFCO members have identified e-commerce as an ongoing regulatory issue.

The Pet Food Committee meeting had a full slate of issues. Dr. Bill Burkholder, CVM, presented a proposal to make some changes to the AAFCO Feeding Protocols. These included recording all pet food weights during the trials and limiting the number of years that a feeding protocol would be valid. Five years was the suggested timeframe. Dr. Burkholder also updated everyone on certain label claims such as dental, hairball and FUS. A discussion on the use of the term "Human Grade" on labels was held. Other issues discussed were salvage/distressed pet foods, species name on label, educating the public about pet

. . . AAFCO members have identified e-commerce as an ongoing regulatory issue.

food labels, organic pet foods and requiring additional guarantees on labels.

The Botanicals and Herbs Committee recommended to the AAFCO Board of Directors that it be disbanded and a single investigator be established. The committee has received no submissions for ingredient definitions since its inception. The AAFCO Board of Directors accepted the recommendation and decided to establish an investigator at such time as there is interest in pursing ingredient definitions in this category.

The Lab Methods & Services Committee continues to work on improving consistency and uniformity in analytical methodology. The Feed Labeling Committee is nearing completion of the feed labeling handbook that is intended to assist both the feed industry and government regulators with understanding labeling requirements. The Feed Labeling Committee is also working on finding a resolution to accurately labeling and monitoring salt guarantees in animal feeds. The Environmental Issues Committee is working on developing a bio-security policy statement for AAFCO and will be gathering existing State bio-security plans. The Ingredient Definition Committee (IDC) has proposed a number of new definitions and proposed changes to others. The IDC is also discussing the status of the animal protein products collective term and if changes are needed. The Collaborative Check Sample Committee has recommended to the AAFCO Board of Directors to support funding a web-based program for processing the data. The Board has agreed to support this recommendation.

A small working group from the Inspection and Sampling Committee and the Feed Manufacturing Committee is working on developing the structure for a Certifying Body (CB) that would oversee the process by which Federal and State inspectors could be certified in the area of animal feed regulation. Members of the CB would consist of key AAFCO members and FDA staff. Discussions are under way with the Division of Federal-State Relations (DFSR) and others in ORA about ORA University serving as the possible Certifying Organization (CO) to implement the inspector certification.

This year's AAFCO mid-year meeting was very productive as the association moves forward with initiatives to address serious regulatory compliance issues, BSE, GMP's for all feed, unapproved feed ingredients, and e-commerce. Solutions to these issues are best achieved in a cooperative effort between Federal and State regulatory agencies, industry and the public. AAFCO meetings provide the forum so that the partnerships can be developed with the impacted parties.

For more information concerning AAFCO, please visit their web site at *www.aafco.org*.

Rod Noel is AAFCO Secretary-Treasurer. John Breitsman is AAFCO President, and Sharon Senesac is AAFCO Assistant Secretary-Treasurer. □

CVM'S OFFICE OF RESEARCH 2001 HIGHLIGHTS

The Office of Research (OR) is the laboratory-based research arm of FDA's Center for Veterinary Medicine (CVM). OR's research priorities are ever changing, being driven by the needs of other CVM offices—i.e., the Office of New Animal Drug Evaluation (ONADE) and the Office of Surveillance and Compliance (OSC) and by FDA-wide requirements to thoroughly assess the latest food safety concerns. To meet these needs, OR is staffed by researchers with diverse

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scientific backgrounds—microbiology, biochemistry, toxicology, analytical chemistry, pharmacology, etc.—as well as scientists with specialist training—e.g., aquatic science specialists and antimicrobial resistance geneticists.

To give the reader an idea of the broad array of research studies conducted by OR scientists, this section briefly describes some of OR's recent studies. These studies are organized by the three OR Divisions in which they were conducted—Division of Residue Chemistry (DRC), Division of Animal Research (DAR) and Division of Animal and Food Microbiology (DAFM).

Division of Residue Chemistry

OR's Division of Residue Chemistry has been responsible for developing, and validating monitoring methods used in FDA's highly effective milk safety programs. More recently, DRC has been focused on developing methods to measure antibiotic residues in various tissues. They also have been conducting surveys to examine possible misuse of antibiotics, particularly fluoroquinolones, to prevent the emergence of antibiotic-resistant bacteria.

Aquaculture Crop Grouping

There is a vital need to expand the repertoire of therapeutic drugs for veterinary use in aquaculture. Compared with traditional farm species, few drugs are currently approved by FDA for use in aquaculture species. In order to facilitate the drug approval process for multiple cultured fish species, it is desirable to establish crop (species) grouping based on similar drug metabolic profiles and drug residue patterns between species. Similarities (and dissimilarities) between metabolic profiles and species residue depletion will determine the likelihood of deriving species groupings.

DRC scientists in collaboration with DAFM scientists conducted studies to determine metabolic profiles and depletion pattern of albendazole in muscle tissue of cold water (rainbow trout) and warm water (tilapia) fish. The preliminary results indicate that albendazole is metabolized by both species and also a similar depletion pattern was observed for its pharmacologically active metabolite albendazole sulfoxide in fish, rainbow trout and tilapia. This suggests there is a potential for crop (species) grouping of cold and warm water fish for this model compound.


Photo by Stan Serfling

Dr. Renate Reimschuessel, here working with Dr. Badaruddin Shaikh, directs CVM's aquaculture research.

DRC scientists have developed and are completing the validation of a multiresidue confirmatory method for aminoglycoside antibiotics in tissues. This study builds on previous DRC work on confirmation of aminoglycosides in milk. It utilizes liquid chromatography-ion trap mass spectrometry. This approach yields highly specific residue identification. The method is capable of confirming nine different aminocyclitol and aminoglycoside antibiotics at or below their U.S. tolerances: spectinomycin, streptomycin, dihydrostreptomycin, hygromycin, amikacin, kanamycin, apramycin, gentamicin, and neomycin. It has been demonstrated to work in a variety of tissues: bovine kidney, liver and muscle; swine kidney, liver, and muscle; chicken kidney and muscle; rabbit and horse kidney. CVM's method is intended to be used by USDA's Food Safety and Inspection Service (FSIS) in their tissue residue monitoring programs. Currently, FSIS is unable to take action with some potentially adulterated carcasses because their screening and microbiological assays will not distinguish individual drugs within a class. As part of the validation of DRC's mass spectrometry method, FSIS sent DRC numerous bovine kidney samples that had screened presumptive positive for either streptomycin, gentamicin, or neomycin. DRC scientists were able to confirm the identity of aminoglycoside in nearly all of these tissues. In several of the tissues, the presence of two or more distinct drug residues was confirmed.

CVM's method is intended to be used by USDA's Food Safety and Inspection Service (FSIS) in their tissue residue monitoring programs.

Drug-Dose Regimen Requirements in Bovine Production Classes

A comparative pharmacokinetic study of four different drugs in both steers and lactating dairy cows indicate a significant difference in the elimination half-life of the extensively metabolized drugs enrofloxacin and fendbendazole and no difference in elimination half-life phenylbutazone and ivermectin which are not metabolized. The data provide support for extensive pharmacokinetic review and drug dose regimen development in steers and dairy cows for drugs that are metabolized and the minimization of this

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requirement to one production class for drugs that are eliminated without extensive metabolization.

Division of Animal Research

The Division of Animal Research has been heavily involved in investigating the safety of animal feeds. These investigations included developing methodology for detecting prohibited substances in ruminant animal feeds as part of the Center's bovine spongiform encephalopathy (BSE) prevention program.

BSE – Methods for Detecting Prohibited Substances

In an attempt to prevent the emergence of BSE in U.S. beef cattle, FDA established a ban on ruminant materials in feed for ruminant animals. However, CVM did not have an analytical method to detect the prohibited substances in animal feeds. Previous efforts at OR established the validity of bovine specific PCR primers to detect bovine-derived materials in complete feed. Current efforts have established that a set of "universal" PCR primers is capable of detecting DNA from cattle, sheep, goats, deer, elk, horse and swine. Other than horse and swine, these primers do not detect any other exempt species. We have established sets of primers for swine, poultry and dog that detect only each individual species. We are currently focusing on developing sets of PCR primers that detect only horse and only cat. Once these are completed, CVM will conduct a method validation trial using these new primers. After validation, the Center will be able to analyze a feed sample using PCR methodology with the universal set of primers and the swine and horse primers to determine if the feed contains material from a prohibited species.

The second approach to the problem is the development of an ELISA test capable of discriminating between prohibited and exempt materials. The initial efforts have centered on bovine-derived materials. CVM researchers have separated and are in the process of identifying four heat stable proteins found in bovine meat and bone meal (BMBM) that are not present in blood and milk. (The gelatin which is always present in BMBM is removed by ammonium sulfate precipitation.) Efforts are underway to purify enough of these proteins to permit preparation of polyclonal and monoclonal antibodies for development of an ELISA test. In addition, CVM will attempt to identify and isolate unique heat-stable proteins from other prohibited species to include in our ELISA work.

Photo by Richard R. Peabody II

Keesla Moulton treats a calf at OR.

Division of Animal and Food Microbiology

Currently, one of the FDA's most important tasks is to ensure the safety of foods from microbial hazards, particularly from antibiotic-resistant bacteria. The increase in the incidence of human infections caused by resistant foodborne bacterial pathogens has raised concerns about the increased possibility of therapeutic failures in animals and humans. Under the direction of Dr. Robert Walker, DAFM's research goals are to characterize and reduce microbial hazards associated with all phases of animal food production and to address the effects of therapeutic and non-therapeutic antimicrobials used in food-producing animals on commensal bacteria and foodborne bacterial pathogens.

Antimicrobial Resistance

To achieve these public health goals, DAFM collaborates on and has initiated a number of research studies, both internally and externally funded, aimed at developing approaches to support the safe use of antimicrobials in food animals, including aquatic species. This research focuses on strategies designed to provide greater understanding of the mechanisms of antibiotic resistance in order to reduce the prevalence of antibiotic resistant bacteria in the human food chain.

Improving Reliability of Microbiological Tests

Currently, many microbiological tests suffer from poor reproducibility,

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poor comparability, and lack of agreement among microbiologists as to which tests are reliable and should be used by all investigators. Recognizing these shortcomings, Dr. Walker and his team coordinated an experiment involving investigators from the U.S., Canada, and Europe, and were able to demonstrate that when performing antimicrobial susceptibility testing on *Campylobacter* species the agar dilution testing method provided the intra-and interlaboratory reproducibility required by the NCCLS to be accepted as an NCCLS standardized testing method. The DAFM team recently performed comparison studies of two widely used antimicrobial susceptibility testing methods for *Campylobacter*—the concentration gradient (Etest) and agar dilution testing methods.

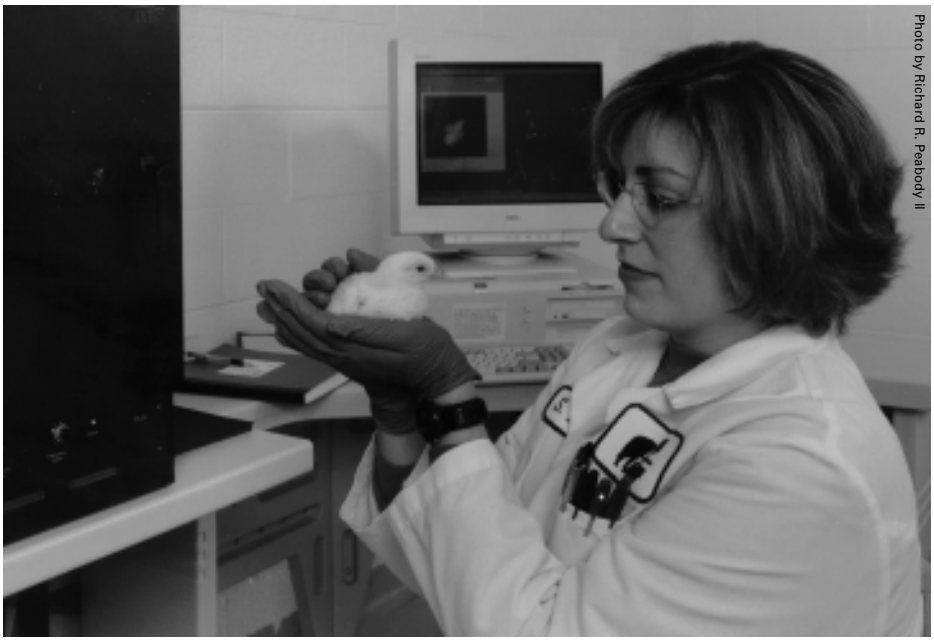
Photo by Richard R. Peabody II

Sonya Bodeis uses the Xenogen In Vivo Imaging System (IVIS) to look at colonization of various luminescent labeled pathogens within the chicken in OR's lab.

PulseNet-Genetic Fingerprinting of Antibiotic-Resistant Bacteria

PulseNet, a national computer network of DNA fingerprinting database for foodborne pathogens, was established in 1996 through a collaborative effort of CDC, FDA, USDA, and State Health Departments. The program uses pulsed-field gel electrophoresis (PFGE) as the DNA fingerprinting method to pinpoint an exact source of foodborne illness outbreak. PulseNet has already been highly successful in preventing and reducing foodborne outbreaks. In the past, PulseNet was focused on foodborne pathogens isolated from patients and foods because foodborne pathogen isolates from animals are limited. In a collaboration with the National Antimicrobial Resistance Monitoring System (NARMS), DAFM researchers obtain approximately 600 *Salmonella* isolates each year from NARMS, which are isolated from a variety of animals, including cattle, swine, chicken, turkey, equine, cat, and dog. All isolates are subtyped by PFGE and the DNA fingerprinting patterns are submitted to PulseNet. The patterns are compared to human clinical isolates through PulseNet. The study will reveal if there is a clonal spread of resistant isolates between animals and humans or widespread dissemination of unrelated strains. Also, *Salmonella* isolates are screened for the presence of class1 antibiotic resistance integron. Integrons are antibiotic resistance gene "cassettes" and play an important role in the dissemination of resistance genes. This study will help us to understand the genetic diversity of *Salmonella*, the link of *Salmonella* strain between animals and humans, and how antibiotic usage in animal husbandry can influence antimicrobial resistance in foodborne pathogens as well as the mechanism of resistance gene transfer between animal and human bacterial pathogens. In addition to *Salmonella*, the DNA fingerprinting database of *E. coli* 0157:H7 and *Campylobacter* are also established at CVM/OR.

STEC and Salmonella *Antibiotic Resistance in Cattle*

DAFM is collaborating with Dr. David Acheson at University of Maryland, Baltimore, MD to examine Shiga-toxin producing *E. coli* (STEC), e.g., *E. coli* 0157:H7, and *Salmonella* in cattle. These studies will determine the epidemiology of antimicrobial resistance phenotypically and genotypically in *Salmonella* and STEC as the organisms move longitudinally from feed into animals.

Prevention of Waterborne E. coli *Transmission*

DAFM collaborates with Dr. Charles Kaspar at the University of Wisconsin - Madison, on a study examining the waterborne transmission of *E. coli* 0157:H7 in cattle. Molecular subtyping of *E. coli* isolates will also be done to assess possible development of new *E. coli* strains. This information will be used in developing prevention scheme strategies for on-farm control of *E. coli* transmission.

Surveillance

Assessment of the dissemination of antibiotic resistant bacteria in food and within the food animal environment has been an important component of the DAFM mission. Preliminary data were developed in conjunction with NARMS on the prevalence of resistant enterococci, *Salmonella*, *Campylobacter*, and *E. coli* associated with animal-derived food. This work was preliminary to the development of an annual national survey, which will be initiated

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in FY02 and will be a collaboration between CVM and the Centers for Disease Control and Prevention.

The survey of animal feed commodities was also initiated as a pilot project during FY01 and will be expanded in FY02 in conjunction with FDA's Office of Regional Operations. This work forms part of CVM's ongoing risk assessment activities and is being conducted in concert with NARMS. The rationale is based on the potential for feed commodities to serve as vectors for the dissemination and maintenance of antibiotic resistant determinants within animal production environments.

During FY01, CVM was in the midst of conducting a formal risk assessment on the potential human health impact of Enterococci serving as a vector for transferring synercid resistance to humans through the food supply. This potential risk arises from the long-term use of virginiamycin, a Synercid analog, as a growth promoter in animal production. DAFM has been significantly involved in this risk assessment activity by providing microbiological analytical support through data collection and analysis.

DEVELOPMENT OF FLUOROQUINOLONE RESISTANCE IN CAMPYLOBACTER *JEJUNI*

Historically, antimicrobials approved for use in food animals have been evaluated based on their efficacy against the animal pathogen. There is increasing concern about their effect on resistance development within non-target, foodborne bacteria that are pathogenic to humans. These studies examined the effect of the veterinary-specific fluoroquinolones against the foodborne pathogen, *Campylobacter jejuni*. A series of experiments were conducted in broiler chickens using sarafloxacin and enrofloxacin. The results demonstrated that the use of fluoroquinolones in chickens, under label indications, generates a rapid increase in the fluoroquinolone minimum inhibitory concentrations (MICs) of resident *C. jejuni* (from 0.250 to 32 µg/mL), appearing within the treatment time frame and persisting long after treatment is stopped. No resistant isolates were detected in the non-treated control groups. In the case of *C. jejuni* from animals treated with sarafloxacin, an increased proportion of susceptible isolates appeared beginning at day 12. At day 26 (3 weeks after ending treatment), 72% of the isolates tested displayed MICs ≥32 µg/mL. In contrast, 100% of isolates analyzed from the enrofloxacin-treated animals displayed ciprofloxacin MICs of 32 µg/mL throughout the experiment, which ended 16 days after ending treatment. These results highlight the potential of inducing resistance in non-target bacterial species.


Photo by Richard R. Peabody II

Stan Serfling dispays an Atlantic Salmon in OR's aquaculture lab.

There is increasing concern about their effect on resistance development within non-target, foodborne bacteria that are pathogenic to humans.

The above represent just a few of the ongoing highly successful research studies being conducted by DAFM scientists. These studies are achieving The President's Food Safety Initiative goal of helping to reduce the incidence of foodborne disease to the greatest extent possible. □

CVM HOME PAGE INCREASES IN POPULARITY

by Stephanie W. Dove

The Center for Veterinary Medicine's (CVM's) Internet Home Page at *http://www.fda.gov/cvm* was increasingly popular in 2001. There were an average of two-million "hits" per month. A hit is a term used to describe how often someone accesses a site on the Internet. This is a major increase over the hits for previous years. In 2001, the number of hits ranged from a low of 1,627,955 in September to a high of 2,352,637 in March. In contrast, the number of hits in April 2000 was 620,000, and the number for September 1999 was only 8,809.

The increasing number of hits recorded for year 2001 is testimony to the plethora of pivotal information on our site. Statistics for the "Most Visited Pages" revealed a consistent pattern. Each month with little variation, users regularly visited the following

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CVM HOME PAGE INCREASES IN POPULARITY (Continued)

pages: What's New, The Green Book, Guidance Documents, Index, Vacancies, FOI's, Antimicrobial Resistance, BSE, Bio-engineered Foods, and Adverse Drug Experience Reports.

All CVM employees working on the Home Page do everything they can to ensure that people who visit our Internet Home Page receive the information they need on CVM-related issues. This can include everyone from a student doing a report to a veterinarian making crucial decisions regarding treatment options.

The CVM Home Page has undergone three major re-designs since 1998. The focus of the first re-design was to improve navigation and to reconfigure the entire file structure. The second re-design focused on content management and an updated look using professional stock photography. With the third re-design, we paid special attention to Section 508, Compliance for Handicapped Accessibility. The CVM Web Team's primary mission is to make the information on the Home Page easy to find, easy to retrieve, and easy to access cutting edge information.

The CVM Internet Home Page is growing at a phenomenal rate both in user access and as a repository for veterinary health information. Presently, the CVM Internet Home Page is undergoing a new re-design, expected for release in the near future. The latest revision is to help the Web Team keep pace with various changes necessary for updating the site. The CVM Web Team welcomes your comments about the Home Page. Please send your comments by e-mail to *sdove@cvm.fda.gov*.

Stephanie W. Dove is CVM's Web Master.

□

DRAFT GUIDANCE AVAILABLE FOR COMMENT

The Food and Drug Administration (FDA) is announcing the availability for comment of draft guidance for industry entitled "Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora" (Guidance #52). This draft guidance is a revision of guidance document #52 entitled "Microbiological Testing of Antimicrobial Drug Residues in Food," which was implemented in 1996. In this draft guidance, the Agency recommends a pathway approach for assessing the microbiological safety of antimicrobial drug residues in food, rather than the approach described in the 1996 version of the guidance. FDA's decision to revise this guidance is based on new information available to the Agency.

In this draft guidance, the Agency recommends a pathway approach for assessing the microbiological safety of antimicrobial drug residues in food . . . .

An electronic copy of draft guidance may be found on the FDA/Center for Veterinary Medicine Home Page. Single copies of the guidance may be obtained by writing to the *FDA Veterinarian.*

Written or electronic comments on the guidance may be submitted at any time. However, comments should be submitted by March 27, 2002, to ensure their incorporation during the next meeting of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Microbial Safety Task Force.

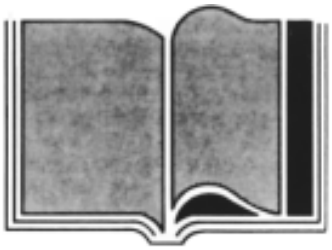
Comments on the draft guidance should be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

All comments should be identified with the full title of the draft guidance and docket number 93D-0398. The Agency will not implement this revised guidance until it has considered comments and prepares a final guidance. FDA will announce the availability of a final guidance in the *Federal Register*.

Additional information about this draft guidance document may be found in the December 27, 2001, *Federal Register* and from Dr. Haydee Fernandez, Center for Veterinary Medicine (HFV-150), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20850, 301-827-6981.

□

PUBLICATIONS



FDA Veterinarian Index Available

A topical index for the 2001 *FDA Veterinarian* is now available on the CVM Internet Home Page at *http://www.fda.gov/cvm/index/fdavet/2001/01index.pdf*. Readers who wish to obtain a paper copy of the Index may call or write the *FDA Veterinarian*.

Booklet Available

The Center for Veterinary Medicine has recently published "Judicious Use of Antimicrobials for Poultry Producers." Copies are available on the CVM Web Site: *www. fda.gov/cvm*, or by contacting the *FDA Veterinarian*.

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UPDATE ON FY 2001 ANIMAL DRUG APPROVALS

FDA published 38 documents relating to significant New Animal Drug Application and Abbreviated New Animal Drug Application approvals in the *Federal Register*. Significant approvals included: 2 new chemical entities, 6 products for use in new animal species, 9 new combinations, and 2 new dosage forms. The new chemical entities approved in FY 2001 are listed in the table below.

A complete list of all FY 2001 animal drug approvals is available from the *FDA Veterinarian*. Additional information about FDA-approved veterinary drugs is included on the Center's Home Page at *http://www.fda.gov/cvm/fda/greenbook/greenbook.html*.

New Chemical Entities Approved in FY 2001

Drug	*Species*	*Sponsor*	*NADA Number*
Nitenpyram	Dogs, Cats	Novartis	141-175
Ponazuril	Horses	Bayer	141-188

□

STAFF COLLEGE DIRECTOR HIRED

CVM welcomes Faith S. Williamson, Ed. D. as Director of the CVM Staff College. Dr. Williamson comes to CVM from the Department of Health and Human Services where she worked as a career development program specialist for the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration).

Dr. Williamson is extensively qualified to lead CVM's Staff College efforts. She obtained a B.S. degree in business education from Wilkes College, Wilkes-Barre, PA, and a M.S. degree in counseling psychology from Angelo State University, San Angelo, TX. Prior to joining the Federal Civil Service, Dr. Williamson earned her Ed. D. degree in adult and continuing education from Virginia Polytechnic Insititute and State University.

At DHHS, Dr. Williamson served as coordinator of the Senior Executive Service Candidate Development Program and coordinated and implemented the grand opening of the Program Support Center's Career Counseling Program.

After lengthy planning and development, the CVM Staff College will soon be up and running. The Center continues the development of a competency-based learning management system that will enhance the science base and the introduction of the new training facility to support the infrastructure of the CVM Staff College. In addition, the development of several in-house scientific/reviewer training programs, seminars and workshops are forthcoming to increase the science-based knowledge of the CVM Review Staff. □

Dr. Faith Williamson

FDA TO HOLD PUBLIC HEARING ON PROPOSAL TO WITHDRAW POULTRY ENROFLOXACIN APPROVAL

The Food and Drug Administration (FDA) will hold a hearing on the safety of enrofloxacin for use in poultry following CVM's proposal to withdraw approval for use of the product in poultry water. Enrofloxacin is in the class of antimicrobials known as fluoroquinolones; ciprofloxacin is the comparable human drug in this class. Baytril, the trade name of enrofloxacin, is indicated for the control, in chickens, of mortality associated with *Escherichia coli (E.coli)* and in turkeys, of mortality associated with *E.coli* and *Pasterella multocida*. Baytril is the product of Bayer Corp., Shawnee Mission, KS, which has requested the hearing.

The hearing will address CVM's determination that the use of fluoroquinolones in poultry causes the development of fluoroquinolone-resistant *Campylobacter* species in poultry, that these fluoroquinolone-resistant organisms are transferred to humans and cause the development of fluoroquinolone-resistant *Campylobacter* in humans, and fluoroquinolone-resistant *Campylobacter* infections in humans are a health hazard. These determinations provided the basis for the Center's proposal in October 2000 to withdraw the approval for the animal drug use in poultry.

The supporting data for CVM's proposal includes:

- an association between the approval of fluoroquinolones for use in poultry in the United States in October 1996 and an increase in fluoroquinolone-resistant *Campylobacter* infections in humans in the U.S.;
- a comparison of fluoroquinolone use in poultry with other possible causes of fluoroquinolone-resistant infections; and
- a risk assessment that determined that in 1999, an estimated 9,261 persons infected with campylobacteriosis and prescribed a

(Continued, next page)

FDA TO HOLD PUBLIC HEARING . . . (Cont.)

fluoroquinolone in the United States had a fluoroquinolone-resistant illness due to the use of fluoroquinolones in chickens.

CVM has concluded that such patients, especially if they have underlying health problems, may suffer a prolonged illness or complications, and that therefore the approval for use of the drug in poultry should be withdrawn.

Additional information about the hearing is contained in a notice that appeared in the February 20, 2002, *Federal Register*, *http://www.fda.gov/OHRMS/DOCKETS/98fr/022002b.htm* or can be obtained from Robin Thomas Johnson, Office of Policy (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3480. □

EDUCATIONAL EVENTS

2002 Mid-Atlantic Conference for Bovine Practitioners

The Maryland Veterinary Medical Association (MVMA) announces the following continuing education course for veterinarians: 2002 Mid-Atlantic Conference for Bovine Practitioners, April 4-5, 2002, at the Holiday Inn, Frederick, Maryland. The two-day seminar will include lectures from nationally recognized experts, interactive case studies, practice tips, and opportunities for fellowship. Meals are included in the registration. Topics include Nutrient Management, Johne's Disease Update, Bio-security, Dairy Quality Management Program, Johne's Disease Certification Training, Leptospirosis, Bovine Leukemia Virus, Salmonellosis, and Evaluating Paper and Computer Herd Records.

The cost (including meals) is $150 for both days, or $90 for one day. Veterinary students or technicians may attend at half price. Please make checks payable to "MVMA" and mail to P.O. Box 918, Bel Air, MD 21014. For further information, please contact the MVMA office at 1-888-884-6862. □

FDA AMENDS RULES ON ADE RECORDS AND REPORTS

FDA's Center for Veterinary Medicine is amending the requirements for records and reports of adverse experiences (ADE) and other information for approved new animal drugs. This interim final rule more clearly defines the kinds of information to be maintained and submitted by new animal drug applicants for a new animal drug application (NADA) or an abbreviated new animal drug application (ANADA). In addition, the interim final rule revises the timing and content of certain reports to enhance their usefulness. The regulation will provide for protection of public and animal health and reduce unnecessary recordkeeping and reporting requirements. This interim rule is effective August 5, 2002.

This interim final rule was published in the February 4, 2002, *Federal Register* and may be found on the FDA Home Page at: *http://www.fda.gov/OHRMS/DOCKETS/98fr/020402a.htm*. Single copies of the guidance may be obtained by writing to the Communications Staff, FDA/Center for Veterinary Medicine, 7519 Standish Place, HFV-12, Rockville, MD 20855, 301-827-3800. Please send one self-addressed adhesive label to assist in processing your request.

Written or electronic comments on new information on the interim final rule and the information collection requirements should be submitted by April 5, 2002. Please note, the Agency will not consider any comments that have been previously submitted and considered during this rulemaking. Written comments should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Electronic comments should submitted at *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*. All comments should be identified with Docket Number 88N-0038.

Further information on the Interim Final Rule may be found in the February 4, 2002, *Federal Register* and from Dr. William C. Keller, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6641, or *wkeller@cvm.fda.gov <mailto:wkeller @cvm.fda. gov>*. □

FDA PROHIBITS NITROFURAN DRUG USE

FDA is issuing an order prohibiting the extralabel use of topical nitrofuran animal and human drugs in food-producing animals. This order is based on evidence that extralabel use of topical nitrofuran drugs in food-producing animals may result in the presence of residues that are carcinogenic and have not been shown to be safe. The Agency finds that such extralabel use presents a risk to the public health for the purposes of the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994.

AMDUCA amended the Federal Food, Drug, and Cosmetic Act to allow licensed veterinarians to prescribe extra-label uses of approved animal drugs and human drugs in animals. Section 2(a)(4)(D) of the AMDUCA provides that the Agency may prohibit an extra-label drug use in animals if, after affording an opportunity for public comment, the Agency finds that such use presents a risk to the public health.

In the past, FDA permitted two approved topical nitrofurans to be used in cattle. These products were:

1. Furazolidone aerosol powder (trade names such as Topazone and Furox aerosol.)
2. Nitrofurazone topical powder for pinkeye and wounds (trade names such as NFZ Puffer and P.E. 7.)

A carbon-14 (C-14) radio-label residue depletion study conducted by

(Continued, next page)

FDA PROHIBITS NITROFURAN DRUG USE (Continued)

the FDA showed that detectable levels of nitrofuran derivatives are present in edible tissues (milk, meat, kidney, liver) of cattle treated by the ocular (eye) route. The study indicates that use of these nitrofuran products may pose a risk to public health because residues of known carcinogens are present in edible tissues.

The current list of prohibited drugs includes furazolidone and nitrofurazone, but it contains the parenthetical statement (except for approved topical use). FDA plans to remove this parenthetical statement. Once this prohibition is in place, the revised list will state that the following drugs (both animal and human), families of drugs, and substances are prohibited for extra-label uses in all food-producing animals.

1. Chloramphenicol;
2. Clenbuterol;
3. Diethylstilbestrol (DES);
4. Dimetridazole;
5. Ipronidazole;
6. Other nitroimidazoles;
7. Furazolidone, Nitrofurazone, other nitrofurans;
8. Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine);
9. Fluoroquinolones; and
10. Glycopeptides.

FDA will consider all comments on this order that the Agency receives by April 8, 2002. Written comments should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Electronic comments may be submitted to *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm* . All comments should include Docket number 01N-0499. The order will become effective May 7, 2002, unless FDA revokes or modifies the order or extends the comment period.

Additional information on this prohibition is contained in the February 6, 2002, *Federal Register* (<*http://www.fda.gov/OHRMS/DOCKETS/98fr/020602b.htm*>). Questions about this prohibition may be directed to: Gloria J. Dunnavan, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-1168, e-mail: gdunnava@cvm.fda.gov <*mailto:gdunnava@cvm.fda.gov*>. Please note that the address and telephone number for Ms. Dunnavan in the February 6, 2002, *Federal Register* is incorrect. □

SOZINHO DAIRIES PAY $140,000 TO SETTLE CONTEMPT COMPLAINT

The Food and Drug Administration announced that a California dairy operation agreed to pay the United States $140,000 in settlement of the Government's motion to have them found in contempt of a Federal court mandated permanent injunction. The firms were Joe Sozinho Dairy #1 and #2 in Hanford, California, and are owned and operated by Joe Sozinho, Sr., Danny Sozinho, and Dimas Sozinho.

Meat from Sozinho cattle tested positive for antibiotic residues in 1994, 1996, 1999, and 2000. The United States Department of Justice, along with the Office of the United States Attorney for the Eastern District of California, filed for an injunction against the dairies in February last year.

The United States District Court in Fresno issued a permanent injunction on July 30, 2001, prohibiting the Sozinhos from selling cattle until the dairies complied with the animal drug regulations of the Federal Food, Drug, and Cosmetic Act. These regulations are designed to prevent excessive levels of antibiotic and animal drug residues in meat and milk sold for human consumption.

Despite this court injunction, the Sozinho's failed to take adequate corrective action and continued selling cattle. According to a stipulation filed in court, the Sozinhos admitted that they delivered at least 56 head of cattle for slaughter during the first 36 days after the injunction. They also admitted that they continued to make medication errors. These errors included using inaccurate meat and milk withdrawal periods and administering more than the recommended amount of medications to their animals. They also admitted that their medication records were inaccurate. □

IN MEMORIAM

Dr. Edison Monk died January 15, 2002, at his home after a battle with brain cancer. Dr. Monk was a reviewer in CVM's Office of New Animal Drug Evaluation for 24 years. Born May 29, 1945, in Culloden, West Virginia, Dr. Monk graduated from Berea College in Kentucky, and received his Masters and Doctorate from Purdue University. Dr. Monk is survived by Helen, his wife of 34 years, his mother Nina, and three children, Julie, Eric, and Mark, and three grandchildren, and seven brothers and sisters. □

NEW DIRECTOR FOR OMAC

CVM is pleased to announce that Mr. Don Peterson has agreed to succeed Bob Sauer as Director of CVM's Office of Management and Communications (OMAC). Don has a Master of Business Administration degree from George Washington University. He has 20 years of Federal service at USDA, and six with the FDA. Don joined the FDA in June 1995, as Director, Office of Financial Management. He served with distinction in that role until he was selected to be the Director, Office of Management, CBER. For the last nine months, Don has served as the Acting Deputy to Mr. Jeff Weber, Senior Associate Commissioner for Management Systems, FDA's Office of the Commissioner. Don's knowledge of the Agency and how it operates administratively, make him ideally suited to become CVM's Executive Officer. Don is spending several weeks with CVM's program offices, meeting the employees, and learning about CVM's major issues. Don will assume his new position as Director of OMAC prior to Mr. Sauer's retirement on March 31, 2002. □

Don Peterson, Director of CVM's OMAC

DRAFT GUIDANCE ON PHARMACOVIGILANCE AVAILABLE

The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms" (#143.) This draft guidance has been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance addresses the process for developing a controlled list of terms to assure that terms are used consistently in adverse event reports and to allow comparison between products and across product classes. This draft guidance is limited to developing a controlled list of terms describing

(Continued, next page)

FDA OFFERS WORKSHOP ON SWINE MYCOPLASMAL PNEUMONIA

The Food and Drug Administration (FDA) is holding a Swine Mycoplasmal Pneumonia Technical Workshop. The topic to be discussed at this public workshop is how to evaluate drug effectiveness against swine mycoplasmal respiratory disease.

The public workshop will be held on March 6 and 7, 2002, at the DoubleTree Hotel Kansas City, 1301 Wyandotte St., Kansas City, MO 64105, 816-474-6664. The workshop will be held from 8:30 a.m. to 5:00 p.m. on Wednesday, March 6 and from 7:00 a.m. to 3:30 p.m. on Thursday, March 7.

FDA is seeking scientific input from a broad public forum to help the Agency determine an acceptable method, in light of the current state of scientific knowledge, for evaluating drug effectiveness against swine mycoplasmal respiratory disease. Mycoplasma hyopneumoniae is a major pathogen in "porcine respiratory disease complex" (PRDC). PRDC is a significant problem in the swine industry in the United States and abroad. This workshop will provide a necessary forum for leveraging scientific resources, including top experts in swine mycoplasmal pneumonia. The workshop is part of CVM's leveraging initiative aimed at increasing interaction with industry, academia, practitioners, and other government agencies.

Registration is required for the meeting, and space is limited. Registration will be on a first come, first served basis, and there is no registration fee. Electronic registration for the workshop is available at *<http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm>* (see Docket No. 02N-0027.) Alternatively, please send registration information (including name, title, firm name, address, telephone, and fax number) to Irma Carpenter, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-7580, FAX 301-594-2298. If you need special accommodations due to a disability, please contact the DoubleTree Hotel Kansas City at least seven days in advance at 816-474-6664 and Irma Carpenter at 301-827-7580.

Written or electronic comments on this workshop may be submitted by May 6, 2002, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*. All comments should include Docket No. 02N-0027.

Additional information about the workshop, including a preliminary agenda, is contained in the February 6, 2002, *Federal Register*, *http://www.fda.gov/OHRMS/DOCKETS/98fr/020602f.htm*. For general information about the workshop, contact: Dr. Gillian A. Comyn, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-7568, FAX 301-594-2298. As it becomes available, additional information about the workshop will be posted on the Internet at the Center for Veterinary Medicine (CVM) Web site at *http://www.fda.gov/cvm/index/conferences/calendar.html*.

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veterinary medicinal products (VMPs), animals, clinical signs, and associated body systems and organs for reporting an adverse event associated with the use of a VMP.

Draft guidance #143 is posted on the FDA/Center for Veterinary Medicine Home Page at: *http://www.fda.gov/cvm/guidance/published.htm#documents*. Single copies of the draft guidance may be obtained by writing to the Communications Staff, FDA/Center for Veterinary Medicine, 7519 Standish Place, HFV-12, Rockville, MD 20855, 301-827-3800. Please send one self-addressed adhesive label to assist in processing your request.

Written comments on the draft guidance may be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Electronic comments may be submitted to *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*. Comments should be identified with the full title of the draft guidance and Docket number 02D-0005. To ensure their adequate consideration in preparation of the final document, comments should be submitted by March 8, 2002. General comments on Agency guidance documents are welcome at any time.

Additional information on the draft guidance document may be found in the February 6, 2002, *Federal Register* (*http://www.fda.gov/OHRMS/DOCKETS/98fr/020602h.htm*) and from Dr. William C. Keller, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-6642, e-mail: *wkeller@cvm.fda.gov <mailto:wkeller@cvm.fda.gov>*.

□

ILLEGAL COMPOUNDING OF CLENBUTEROL

In 1998, FDA approved a new animal drug application (NADA) for Ventipulmin® Syrup, which contains a small amount of clenbuterol, as a restricted use prescription-only drug for treating horses affected with airway obstruction. When FDA approved the NADA for Ventipulmin® (sponsored by Boehringer Ingelheim Vetmedica, Inc.), several controls were put in place to ensure that this drug would not be misused in food-producing animals.

Ventipulmin® is the only clenbuterol drug product approved for use in the U.S. Ventipulmin® may only be used in horses not intended for food. FDA has special concern with clenbuterol, a beta-agonist drug that has been used illegally in the U.S. to enhance production of food animals. The use of clenbuterol in other countries has resulted in documented adverse reactions in humans who ingested meat containing residues of clenbuterol.

In recent years, availability of illegal clenbuterol formulations, produced as "compounded" drug product has increased steadily. The Animal Medical Drug Use Clarification Act (AMDUCA) permits compounding under very limited circumstances. Compounding must be done only on the order of a licensed veterinarian, based upon a valid veterinarian/client/patient relationship from approved human or veterinary drugs. In addition, other criteria must be met including establishing the need for a compounded product, and prohibitions against use of some drug products in food-producing animals. AMDUCA (*http://www.fda.gov/cvm/index/amducca/amducatoc.htm*) does not permit compounding from bulk drugs. Bulk clenbuterol should only be available for use by Boehringer Ingelheim Vetmedica, Inc. in the production of the approved clenbuterol product.

When an approved product is available, a compounded product is not permitted to be used unless it meets the criteria in AMDUCA. Since there is an approved clenbuterol product available, only limited compounding from approved Ventipulmin® is permitted. Clenbuterol products that mimic the approved product are unapproved new animal drugs and are not legal for preparation, sale, and use.

Veterinarians and animal owners should be aware that these unapproved clenbuterol products have not been shown to be safe and effective and may not be prepared under conditions that are controlled to produce a consistent, quality product. Prescribing, purchasing, or distributing "compounded" clenbuterol is in violation of Federal law. Veterinarians ultimately assume responsibility for the efficacy, safety, and composition of drugs prescribed in this manner.

Prescribing, purchasing, or distributing "compounded" clenbuterol is in violation of Federal law.

During the past two years Boehringer Ingelheim Vetmedica, Inc., working cooperatively with the FDA, has been investigating this activity and has provided information demonstrating the existence of compounded clenbuterol products are merely copies of the safe and effective FDA approved veterinary drug product readily available to veterinarians. FDA will consider enforcement action for any preparation, advertising, sale, and use of unapproved clenbuterol.

Responsible compounding pharmacies have the potential to provide a necessary service to veterinarians and their clients by providing useful drug formulations in the absence of FDA-approved pharmaceuticals that meet the specific therapeutic needs of the patient. While some compounded drugs may have a place in veterinary practice, compounded clenbuterol, except in very limited circumstances, does not. A FDA-approved clenbuterol hydrochloride product is available. □

NATIONAL PET WEEK

This year National Pet Week is scheduled for May 5-11, 2002. The theme, "People, Pets, & Veterinarians . . . a Winning Team" highlights the successful partnerships formed by owners, pets, and their veterinarians. Pet owners depend on their veterinarians for the most current health information available to care for their beloved family pets. National Pet Week is an opportunity to raise awareness of health issues facing pets, and emphasizes the importance of regular check-ups to maintain healthy pets and quality of life for years to come.

National Pet Week 2002 is co-sponsored by the American Veterinary Medical Association (AVMA, *http://www.avma.org*), the Auxiliary to the AVMA, (*http://www.avmaaux.org*) the American Animal Hospital Association (AAHA, *http://www.healthypet.com*), and the North American Veterinary Technician Association (*http://www.avma.org/navta*).

For more information about this annual celebration, please visit the above web sites. CVM is proud to endorse this worthwhile campaign. □

REGULATORY ACTIVITIES

by Karen A. Kandra

The following firms/individuals received warning letters for offering animals for slaughter that contained illegal drug residues:

- Dr. Rhodnick B. Lowe, Rowan Animal Clinic, Salisbury, NC
- James A. Van Haitsma, Van Haitsma Dairy Farm, Falmouth, MI
- Alger H. Vos, President, Vos Dairy, Inc., Arlington, WA
- Bennett J. Palmer, Jr., Co-Owner, Palmer Farms, Holland, NY
- J. Randall Mayes, Pulaski, TN
- Dr. Wyatt C. Galbraith, Animal Clinic, Pulaski, TN
- David W. Goodrich, Owner, Goodrich Farms, LLP, Deer Park, WI

These violations involved illegal residues of phenylbutazone in a dairy cow, gentamicin in a dairy cow, tylosin in a dairy cow, penicillin in dairy cows, gentamicin in a dairy cow, and penicillin in a dairy cow.

A warning letter was issued to Robert T. Shinn, Owner, The Feed Bucket, Mooresville, NC, for violations related to 21 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).

Violations included failure to label products with the required cautionary statement "Do Not Feed to Cattle or Other Ruminants." Also, customer records were not sufficient to track the distribution of products that contain, or may contain, prohibited material.

William Neuberg, Owner, Shamrock Technologies, Inc., Dayton, NJ, received a warning letter for significant deviations from the Current Good Manufacturing Practices Regulations (cGMPs), 21 CFR 210, 211, related to his firm's manufacture of veterinary drug products. Significant observations included: no assurance that the veterinary drug products Androhep Plus and Androhep Lite are not contaminated with various industrial products, such as waxes, polyterafluoroethylene and polyethylene mixes made in the same blender. The firm does not have validated cleaning procedures and does not perform any testing on the veterinary drug products for the presence of industrial products. In addition, the manufacturing process for the above products is not validated, i.e., there is no documentation to support the manufacturing parameters, the order and amount of components, and blending time used to manufacture the finished veterinary drug products. The firm also fails to perform any testing or receive a Certificate of Analysis (COA) to verify the identity of the active raw materials, Gentamicin Sulfate and Neomycin Sulfate. The firm fails to store the finished products Androhep Plus and Androhep Lite according to the temperature conditions stated on the product label.

Shamrock Technologies has responded that they will not produce any drug products in its Newark plant. Based on this statement, FDA has cancelled their drug registration.

Fred Rogers Adams, Jr., President, Cal-Maine Foods, Inc., Jackson, MS, received a warning letter for significant deviations from Current Good Manufacturing Practices regulations for medicated feeds, 21 CFR 225. Violations included failure to maintain correct documentation of actual drug usage during production, failure to conduct required potency assays on at least three representative samples of each feed at periodic intervals during the calendar year, failure to manufacture medicated feeds in accordance with the master file formula, failure to maintain a daily inventory of each drug used, and, failure to maintain complete master record files and production records. □

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPROVALS

Company	*Generic and (Brand) Names*	*Indications*	*Routes/Remarks*
Agri Laboratories (ANADA 200-066)	Oxytetracycline Hydrochloride (Agrimycin™ 343)	Turkeys and swine. For treatment of various bacterial diseases of livestock.	**ORAL**—The supplement provides for a revised, zero-day, withdrawal time after use of oxytetracycline hydrochloride in the drinking water of turkeys and swine. *Federal Register* 02/06/02 □


Photo by Norman Watkins

SUPPLEMENTAL NEW ANIMAL DRUG APPROVALS

Company	*Generic and (Brand) Names*	*Indications*	*Routes/Remarks*
Intervet, Inc. (NADA 140-992)	Trenbolone Estradiol (Revalor® -200)	Feedlot cattle (heifers). For increased rate of weight gain and improved feed efficiency.	**SUBCUTANEOUS**—The supplement provides for an additional dose of trenbolone acetate and estradiol implant for use in feedlot heifers for increased rate of weight gain and improved feed efficiency. *Federal Register* 02/07/02 □


Photo by Norman Watkins

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