



## Consent Decree of Permanent Injunction Filed Against X-Cel Feeds, Inc. Based on Violations of 1997 Animal Feed Rule

On July 11, 2003, FDA announced the filing of a Consent Decree of Permanent Injunction against X-Cel, Feeds Inc., and individual officers based on violations of the Food, Drug, and Cosmetic Act. In the Consent Decree, the Firm and officers admitted liability for introducing adulterated and mis-branded animal feeds into interstate commerce and agreed to implement measures to correct the violations under FDA's supervision.

X-Cel, a feed manufacturer headquartered in Tacoma, Washington, failed to comply with FDA regulations (the 1997 Animal Feed Rule) designed to prevent the establishment and spread of Bovine Spongiform Encephalopathy (BSE, also known as "Mad Cow Disease") should it ever be found in the United States and FDA regulations concerning the manufacture of medicated feeds.

"No case of BSE has ever been documented in the U.S., despite aggressive surveillance, said FDA Commissioner Mark B. McClellan, M.D., Ph.D. "FDA's animal feed regulations provide a firewall against BSE, and we are committed to strictly enforcing the rules that protect Americans from this disease."

The Department of Justice, Civil Division, Office of Consumer Litigation and the United States Attorney's Office of the Western District of Washington filed the Consent Decree in the United States District Court of the Western Dis-



Photo by Catherine Brown

FDA Commissioner Mark B. McClellan, M.D., Ph.D. says "FDA's animal feed regulations provide a firewall against BSE, and we are committed to strictly enforcing the rules that protect Americans from this disease."

trict in Tacoma, Washington. It permanently enjoins X-Cel from manufacturing animal feeds in violation of the Food, Drug, and Cosmetic Act and requires the firm, its officers, and employees to take specific steps to avoid future violations including, implementing clean-out procedures, obtaining protein supplier certifications and implementing standard operating procedures for compliance until it satisfies FDA that it has corrected its problems.

FDA's animal feed regulations protect the United States from the potential threat of BSE by prohibiting the use of cer-

tain proteins derived from mammalian tissue in the feed for cattle and other ruminant animals.

In addition, FDA and the State regulatory agencies have increased the number of inspections of renderers, animal feed manufacturers, and other firms responsible for keeping prohibited mammalian protein out of cattle and other ruminant feed. U.S. industry compliance with the 1997 Animal Feed Rule currently exceeds 99 percent.

In order to prevent the establishment and spread of BSE in the United States the Animal Feed Rule requires animal feed manufacturers to: (1) take measures (including cleaning) to prevent contamination of ruminant feeds with mammalian proteins prohibited in ruminant feeds; (2) maintain sufficient records to track the mammalian proteins prohibited in ruminant feeds through their receipt, processing, and distribution; and (3) label animal feeds that contain mammalian proteins prohibited in ruminant feed with the required cautionary statement "Do not feed to cattle or other ruminants."

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## FDA Presents Award to State of Iowa

FDA was proud to present the Iowa Department of Agriculture's Feed and Fertilizer Bureau with the Federal Leveraging/Collaboration Award in recognition of their exemplary efforts in performing contract inspections including BSE ('mad-cow') inspections in light of a difficult budget situation in 2002. The citation read: *For your exemplary and creative efforts in overcoming significant resource constraints to accomplish work plan and performance goals.*

In FY 2002, FDA's Office of Regulatory Affairs (ORA) requested the field offices to conduct targeted BSE inspections of 100% of all renderers and feed mills handling prohibited material. A review of the national BSE/medicated feed inventory indicated that nearly 45% of the firms were located in the Kansas City District Office's (KAN-DO) area of responsibility. In order to meet ORA's performance and work plan performance goals, FDA's Kansas City District Office and their State partners needed to conduct a total of 740 inspections. Fifty-six percent (412 inspections) were located in the State of Iowa, and 77% of those inspections (318 inspections) were contracted to be conducted by the Iowa Department of Agriculture and Land Stewardship (IDALS) personnel.

In October 2001, the State of Iowa encountered significant budget cuts resulting in the loss of 50% of its staff who performed contract inspections, including BSE inspections, as well as the loss of key supervisory personnel, including the Bureau Chief. The changes left only one State investigator in the field with 318 inspections assigned. However, the State notified FDA that it could not meet its contractual obligations given the State's severe budget situation.

**The citation read: For your exemplary and creative efforts in overcoming significant resource constraints to accomplish work plan and performance goals.**



From left to right: Terry Jensen, Gerald Vandevor, Kevin Klommhaus, Patty Judge – Iowa Secretary of Agriculture, Bill Sedgwick – District Director, Kansas City District Office, John Danielson, Neal Vaughn, Jeff Eichenberger, and John Whipple .

Robert Wilson, Supervisory Consumer Safety Officer in FDA's Kansas City District Office (KAN-DO), encouraged State officials to be creative in their approach to obtaining additional resources to perform inspections. He committed himself and his staff to work closely with the State to accomplish inspections and fulfill contractual requirements, and meet FDA's performance goals. Through extraordinary efforts in work planning and streamlining of inspectional approaches, the Kansas City District, the Iowa Department of Agriculture and Land Stewardship and another State agency successfully completed 318 medicated feed/BSE inspections in addition to 38 tissue residue investigations for KAN-DO.

Bill Sedgwick, FDA Kansas City District Director, presented the award in

Des Moines. In his remarks, Director Sedgwick said the Iowa Department of Agriculture's feed and fertilizer inspectors are "a top-notch crew" and even under serious budget constraints "did an exceptional job of completing their inspections, and without their hard work, we could not have obtained our goals. Iowa should be proud."

### FDA VETERINARIAN

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## CPG Available on Compounding of Drugs

FDA announced the availability of a revised Compliance Policy Guide (CPG) section 608.400 entitled "Compounding of Drugs for Use in Animals" in the July 14, 2003, *Federal Register*. The purpose of the revised CPG is to ensure that the Agency's enforcement policy regarding the compounding of drugs intended for use in animals is consistent, to the extent practicable, with its enforcement policy regarding the compounding of drugs intended for use in humans.

In addition, FDA is revising its previous animal drug compounding CPG to ensure it is consistent with the current animal drug compounding regulations, which are codified at Title 21, Part 530 of the *Code of Federal Regulations* ([http://www.access.gpo.gov/nara/cfr/waisidx\\_03/21cfr530\\_03.html](http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr530_03.html)). The CPG represents the Agency's current thinking on the enforcement of the Federal Food, Drug, and Cosmetic Act with regard to drug products compounded for use in animals.

This CPG is intended to provide guidance and instructions to FDA staff, industry, and the public for obtaining information to help fulfill the Agency's plans regarding the compounding of drugs for use in animals. The CPG does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA)

***This CPG is intended to provide guidance and instructions to FDA staff, industry, and the public for obtaining information to help fulfill the Agency's plans regarding the compounding of drugs for use in animals.***

or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

A copy of the CPG is available on the FDA Home Page at: [http://www.fda.gov/ora/compliance\\_ref/cpg/](http://www.fda.gov/ora/compliance_ref/cpg/). Individuals who prefer a paper copy may submit written requests for single copies of the

CPG to the Director, Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please send one self-addressed adhesive label to assist in processing the request.

Comments on the CPG may be submitted any time to: Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments should be identified with the full title of the CPG and Docket Number 2003D-0290.

Additional information about the CPG may be found in the July 14 *Federal Register* notice. Technical questions concerning this CPG should be directed to Dr. Neal Bataller, Center for Veterinary Medicine, HFV-230, Food and Drug Administration, 7500 Standish Place, Rm. E441, Rockville, MD 20855, 301-827-0163, [nbatalle@cvm.fda.gov](mailto:nbatalle@cvm.fda.gov).

## Reminder to Scientists Involved in Research with Genetically Engineered Animals

FDA has sent letters to all Land Grant universities reminding those involved in research involving genetic engineering in animals that such research may need to be performed under the authority of an investigational new animal drug (INAD) exemption or a similar provision. The INAD regulations are published in the *Code of Federal Regulations*, Title 21, Part 511.1(b)—[http://www.access.gpo.gov/nara/cfr/waisidx\\_02/21cfr511\\_02.html](http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr511_02.html). As part of the INAD submission, those conducting this type of research must document their plans regarding the disposition of all investigational animals after their participation in the

study is completed. This is important in the case of animal species commonly used for food.

FDA sent these letters to help prevent another situation similar to one that occurred at the University of Illinois at Champaign-Urbana. FDA has determined that pigs involved in certain genetic engineering studies at the University were not properly disposed of, and instead, entered the food supply (<http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01197.html>).

To date, FDA has not permitted genetically engineered animals to be placed into the human food supply. Likewise, only in certain circumstances has

the FDA allowed animals from genetic engineering investigations to be rendered and incorporated into animal feed.

Researchers who have questions about their responsibilities may contact John Matheson at [jmatheso@cvm.fda.gov](mailto:jmatheso@cvm.fda.gov), (301) 827-6649, for further information. They also may want to consult the FDA Center for Veterinary Medicine (CVM) Biotechnology Home Page at [http://www.fda.gov/cvm/biotechnology/bio\\_drugs.html](http://www.fda.gov/cvm/biotechnology/bio_drugs.html). A copy of the letter sent to Land Grant universities is posted on this same page.

# CVM Ombudsman Annual Report 2002

by Marcia Larkins, D.V.M.

The Ombudsman position was established in the Center for Veterinary Medicine (CVM) in November of 1999. The CVM Ombudsman 1) handles complaints and helps to resolve disputes involving science and policy issues for products regulated by CVM and 2) is a point of contact for response to inquiries and requests for general information and for information on specific issues involving science, policy, and procedures or for referral to the appropriate resource within the Center. Additionally, the Ombudsman advises the Office of the Center Director (OD) concerning any trends in the reoccurrence of specific issues or problems that may have an impact on Center policy and makes recommendations for change or improvement.

The information presented in this article is a summary of the CVM Ombudsman's Annual Report for 2002. The complete detailed report will soon be available on the CVM Home Page.

## Background

There were a total of 104 complaints and inquiries handled by the CVM Ombudsman during the 2002 calendar year which is a 16% increase over the number for the year 2001. The majority (91%) of these originated outside the Center from consumers, scientists and other professionals, private industry and other Federal agencies. Nine percent (9%) of the inquiries originated from inside CVM. Several (14%) of the complaints or inquiries were referred to the Ombudsman either from within CVM, another Center Ombudsman, or the Office of the FDA Ombudsman (OO). The Ombudsman was generally contacted directly by e-mail and by telephone.

## General Categories and Subjects

The issues handled by the CVM Ombudsman during 2002 can be categorized generally as 1) complaints concern-

ing the availability of specific important products regulated by CVM, 2) complaints/comments about the interpretation or implementation of existing FDA/CVM policies, 3) inquiries and questions about FDA policy regarding specific issues/products, and 4) requests for general information on the review/approval process. These categories covered the following subjects/areas:

- Adverse Drug Experiences
- Animal Feeds
- Animal Research
- Aquaculture
- Center Contacts/Direct Referrals
- Compliance Issues
- Contract Research Organization
- Current Legislation
- Dietary Supplements
- Dispute Resolution
- Drug Importation
- Drug Withdrawal/Restricted Use
- Establishment Inspection Report (EIR) Information
- External requests for "Ombud" input
- Extra-Label Use
- Food Safety/Hygiene
- Green Book
- INAD/NADA Process
- International Inquiry
- Internet Pharmacies
- Manufacturing Issues
- Minor Species
- Neutraceuticals
- Pet Food/Products
- Proprietary Trade Names
- Quality Assurance
- Veterinary Biologicals
- Veterinary Devices
- Veterinary Research
- Veterinary Medicine Advisory Committee (VMAC)

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## 2002 Animal Drug Approvals

FDA published 57 documents in FY 2002, relating to significant New Animal Drug Application and Abbreviated New Animal Drug Application approvals in the *Federal Register*. Significant approvals included: 4 new chemical entities, 7 products for use in new animal species, 4 new combinations, and 2 new dosage forms. The new

chemical entities approved are listed in the table below.

A complete list of all FY 2002 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 2002

Drug	Species	Sponsor	NADA Number
Albuterol Sulfate .....	Horses	Boehringer Ingelheim	141-180
Deracoxib .....	Dogs	Novartis Animal Health	141-203
Danofloxacin Mesylate .....	Beef Cattle	Pfizer	141-207
Imidacloprid, Ivermectin .....	Dogs	Bayer	141-208

# CVM Proposes Rules for Liquid Medicated Feed

FDA is proposing to change the regulations for liquid medicated feed and free-choice medicated feed. By changing the regulations for liquid medicated feed, FDA intends to clarify: what data are required to demonstrate chemical and physical stability of a drug in liquid feed, how such data may be submitted for use in the new animal drug approval process, and which liquid medicated feeds may be manufactured in a feed manufacturing facility that has not obtained a medicated feed mill license from FDA. By changing the regulations for free-choice medicated feed, FDA wants to ensure that they are consistent with the requirements for liquid medicated feed, and that provisions for free-choice medi-

cated feed and liquid medicated feed comply with the terms of the Animal Drug Availability Act (ADAA) of 1996 (<http://www.fda.gov/cvm/index/adaa/adaatoc.html>).

This proposed rule was published in the May 28, 2003, *Federal Register* (<http://www.fda.gov/OHRMS/DOCKETS/98fr/03-12974.html>) Single copies of the proposed rule may be obtained by writing to the Communications Staff, FDA/Center for Veterinary Medicine, 7519 Standish Place, HFV-12, Rockville, MD 20855. Please send a self-addressed adhesive label to assist in processing your request.

Submit written comments on the proposed rule 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.fda.gov/dockets/ecomments>. FDA will consider all comments received by August 26, 2003. Comments on the proposed rule must be identified with Docket Number 93P-0174.

Additional information is available in the May 28, 2003, *Federal Register* and from Dr. Dragan Momcilovic, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-0169, e-mail: [dmomcilo@cvm.fda.gov](mailto:dmomcilo@cvm.fda.gov).

## CVM Ombudsman Annual Report 2002 (Continued)

### Systemic Issues

Overall, the complaints and inquiries received/handled by the Ombudsman reflected primarily four systemic issues as follows:

#### 1. Timeliness in Response to Data Submissions, Letters, Phone Calls or E-mails

This issue is a carry-over from the year 2001 and has increased from 8% to 14%. The complainants requested the Ombudsman's assistance when there was no response to repeated requests for submission status or after specific stated timeframes had past. Complainants were especially concerned if there was no response or acknowledgement when they considered their request to be an emergency.

#### 2. Adverse Drug Experience (ADE) Issues

There were more concerns and complaints about potential and reportable adverse reactions occurring in drugs currently under regulatory discretion

status than for approved drugs. This is a change from the previous trend (CVM Ombudsman 2001 Annual Report), which focused more on the process involved in making these drugs available for veterinary use.

#### 3. Communication Problems

The Ombudsman was requested to intervene for parties both inside and outside the Center due to difficulties encountered in communicating with a rude or difficult employee or outside caller. For these situations the Ombudsman exercised diplomacy and/or assisted in handling the administrative aspects of case with follow-up by the appropriate Center staff.

#### 4. Quality of Information Dissemination (QID) Issues

The FDA information quality guidelines became effective on October 1, 2002. The guidance describes the type of information disseminated by FDA and explains FDA's standards, policies, and procedures for ensuring the quality of that information. It also

explains the Agency's administrative complaint procedures that are in place to enable persons to seek and obtain correction of information that they believe does not comply with the OMB and HHS guidelines and the FDA guidance.

In 2002 there were three challenges to information disseminated by CVM that fit under the QID guidelines:

- A. the accuracy of the information in the ADE database
- B. the availability of certain "public" information on the Home Page
- C. interpretation of the personal import policy

All calls and inquiries to the Ombudsman are confidential. For further information about the activities of the Ombudsman's office, please visit the CVM Home Page at <http://www.fda.gov/cvm/index/ombudsman/ombudsman1.htm>. For printed copies of the full report, please contact Dr. Larkins at 301-827-4535.

*Dr. Larkins is the CVM Ombudsman.*



## International Activities

### CVM Receives HHS Award for NARMS Expansion in Mexico

The Center for Veterinary Medicine was recently awarded the Department of Health and Human Services Secretary's Award for Distinguished Service for establishing a program in Mexico to detect resistance in pathogens that may contaminate food imported to the U.S. and also pose a hazard to U.S. travelers.

The global expansion of food markets has intensified the risk of transmitting infectious agents across borders. The North American Free Trade Agreement promotes agricultural trade between the United States and Mexico, and importation of meat and poultry has increased since its implementation. U.S. consumers as well as U.S. travelers to Mexico are exposed to animals reared under very different laws and conditions relating to antimicrobial drug use in food animals. Antimicrobial usage is known to select for antimicrobial resistance and food animal reservoirs of human pathogens can be subjected to this selection pressure from food animal use. To respond to this public health hazard, the team members developed a system to monitor resistance in enteric pathogens by collaborating with Mexican investigators at four sites within Mexico in areas of high agricultural activity.

The project began in January 2002 by establishing surveillance of antimicrobial resistance in foodborne patho-

gens in human, food and veterinary isolates at the four participating sites in Mexico. All the investigators underwent training in the U.S. prior to the project's initiation in order to standardize methods for isolation, identification, and antimicrobial susceptibility testing at the four sites. The Mexico project goals include: 1) development of effective surveillance of antimicrobial resistance in foodborne pathogens in human, food, and veterinary laboratories at the four participating sites, 2) standardization of the methods for isolation, identification, and antimicrobial susceptibility testing of foodborne pathogens at the four sites, 3) determination of the prevalence of *Salmonella*, *Campylobacter*, and quinolone-resistant *E. coli* in asymptomatic and ill humans, poultry, pork, beef, and healthy food animals on farms, and 4) identification and comparison of the susceptibility profiles of the *Salmonella*, *Campylobacter* and *E. coli* isolates. Goals 1 and 2 are accomplished: Goals 3 and 4 are on-going. The project has fostered collaboration among Mexican and U.S. microbiologists and epidemiologists and has strengthened the Mexican national capacity in the surveillance of foodborne disease and resistant pathogens.

The surveillance system is designed to identify outbreaks of foodborne illness, in particular those that are multi-drug resistant, in time to respond to public health hazards with mitigations designed to stop the spread of the resistant pathogens. For example, we have already identified quinolone-resistant *E. coli* infections among children in day-care centers in the Yucatan. The principal investigator at the Yucatan site has implemented procedures to determine the etiology of the resistance and is providing follow-up care for the affected children. The Team has presented the data gathered from the project at several international meetings and an article on "Risk Factors for Quinolone-Resistant *Escherichia coli* in Mexican Children" which published in *Antimicrobial Agents and Chemotherapy* in June.

(Continued, next page)



DHHS Award Winners Dr. David White, Dr. Robert Walker, Dr. Patrick McDermott, RADM Linda Tollefson, Dr. Charles Eastin, and Ms. Sonya Bodeis



## International Activities (Continued)

### ***CVM Receives HHS Award for NARMS Expansion in Mexico (Continued)***

#### **Team Members**

##### *FDA/Center for Veterinary Medicine*

- RADM Linda Tollefson  
Deputy Director
- Ms. Sonya Bodeis  
Office of Research
- CAPT Marcia L. Headrick  
NARMS Coordinator
- Patrick F. McDermott, Ph.D.  
Office of Research
- David G. White, Ph.D.  
Office of Research
- Robert Walker, Ph.D.  
Director, Division of Animal and Food Microbiology  
Office of Research

##### *USDA/Agricultural Research Service Employees*

- Paula J. Fedorka-Cray, Ph.D.  
NARMS Project Officer  
Athens, GA
- Jovita Hermosillo  
Athens, GA
- Scott Ladely  
Athens, GA

##### *International – Mexico*

- Mussaret Zaidi, M.D., M.P.H.  
Principal Investigator
- Hospital O’Horan  
Merida, Yucatan



## Draft Guidance Released on Dispute Resolution Procedures

FDA has released a draft guidance for industry entitled “Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM).” This draft guidance document (Guidance Document #79) describes dispute resolution procedures by which sponsors, applicants, or manufacturers of FDA regulated products for animals may request review of science-based decisions. This draft guidance does not address procedures for handling issues associated with FDA’s new initiative to enhance pharmaceutical good manufacturing practices.

Draft guidance #79 is posted on the FDA/Center for Veterinary Medicine Home Page at: <http://www.fda.gov/cvm/guidance/dguide79.pdf>. Single copies of the draft guidance may be obtained by contacting the *FDA Veterinarian*.

Dr. Marcia Larkins, CVM’s Ombudsman says the document is significant be-

cause “it represents CVM’s compliance with the FDAMA requirement for a dispute resolution procedure in accordance with Section 562 of the Act. It updates, expands (and will replace) the current policy and procedure for formal appeals by giving stakeholders

***This draft guidance document (Guidance Document #79) describes dispute resolution procedures by which sponsors, applicants, or manufacturers of FDA regulated products for animals may request review of science-based decisions.***

the additional option of requesting review by VMAC, and it includes the ombudsman function to facilitate the process.”

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 03D-0167. Written comments on the draft guidance may be submitted at any time; however, comments should be submitted by August 4, 2003, to ensure their adequate consideration in preparation of the final document.

Additional information about this draft guidance may be found in the May 19, 2003, *Federal Register* (<http://www.fda.gov/OHRMS/DOCKETS/98fr/03-12369.htm>) and from Dr. Marcia Larkins, Center for Veterinary Medicine (HFV-7), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 301-827-4535, e-mail: [mlarkins@cvm.fda.gov](mailto:mlarkins@cvm.fda.gov).

## FDA Approves First Injectable Solution for Sterilization in Dogs

FDA has approved the first product for chemical sterilization of 3 to 10 month old male puppies. The drug, Neutersol Injectable Solution (zinc gluconate neutralized by arginine), provides an alternative to surgical castration and may prove to be a valuable aid in efforts to control burgeoning dog populations.

Neutersol, administered by direct injection into the testicles, is a necrotizing agent that has a local effect when injected into the testicle. Based on histopathology, one or more of the following actions accounts for the drug's effectiveness: 1) Atrophy of the testicles, epididymides, seminiferous tubules, and prostate gland and 2) Scar tissue formation which prevents movement of sperm from the seminiferous tubules to the epididymis. Neutersol does not require the use of general anesthesia, though sedation is recommended to prevent the dog from moving during injection.

The effectiveness of Neutersol was evaluated in a field study of 270 male puppies between 3 and 10 months of age. Of the 270 puppies enrolled, 224 completed the study to month 6 and were included in the analysis. One injection of Neutersol in each testicle produced successful chemical sterilization

in 223/224 (99.6%) puppies, as determined by serial semen analyses. In a study conducted in laboratory beagles, effectiveness was confirmed up to 24 months post-injection.

Proper injection technique and post-injection care are critical for the safe use of the product. According to Dr. Elizabeth Luddy, veterinary medical officer at CVM, "The most serious reaction we saw in laboratory and field testing was ulceration of the scrotum at the injection site, associated with incorrect injection technique, movement of the needle during injection or the dog licking or biting the area after injection." To help educate veterinarians and dog owners about these and other safety issues and to prevent the occurrence of serious adverse events, the approved labeling includes an instructional videotape demonstrating the proper injection technique, and a client information sheet explaining the importance of post-injection monitoring and care.

Unlike surgical castration, dogs treated with Neutersol become sterile without removal of the testicles and, therefore, testosterone is not completely eliminated. Veterinarians and dog owners should be aware that diseases which

occur as a result of or in conjunction with testosterone hormones (prostatic disease, testicular or perianal tumors) may not be prevented with this procedure. As with surgical castration, secondary male characteristics (roaming, marking, aggression, or mounting) may be displayed.

Neutersol is manufactured by Meridian Medical Technologies, Inc. for Technology Transfer, Inc., Columbia, MO and is available for use only by or on the order of a licensed veterinarian. ■

## Feed Grade Biuret

On May 22, 2003, a notice was published in the *Federal Register* to amend the food additive regulations to provide for the safe use of feed grade biuret in lactating dairy cattle feed. Feed grade biuret is produced by the partial hydrolysis of urea and consists of a mixture of biuret, urea, cyanuric acid, and more limited amounts of triuret and other homologs.

Feed grade biuret is incorporated into animal diets as a source of non-protein nitrogen (NPN). NPN is commonly used to supplement ruminant animal diets low in protein, such as with poor quality forages. The currently approved use for feed-grade biuret in the rations of cattle as a NPN source does not provide for use in lactating dairy cattle. ADM Alliance Nutrition, Inc. submitted a food additive petition to amend the current regulation and to provide for the safe use of biuret in lactation dairy rations.

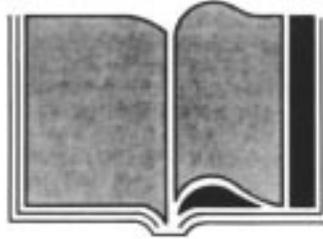
The FDA concluded that the information submitted was sufficient to establish safety and functionality for the proposed use. An environmental assessment or environmental impact statement was not required under Title 21, *Code of Federal Regulations*, Part 25.32(r). The food additive regulation for feed-grade biuret (21 CFR 573.220) was amended by removing paragraph (c)(1)(iii). ■



Photo by Karen Kandia

Neutersol provides an alternative to surgical castration for male puppies between 3 and 10 months of age.

## CVM'ers Collaborate on New Books



CVM Deputy Director Dr. Linda Tollefson and Division of Epidemiology staff member Dr. Joe Paige have authored a chapter on "Veterinary Products: Residues and Resistant Pathogens" in a book entitled *Food Safety: Contaminants and Toxins*.

This is a comprehensive book (452 pages) that is organized into four parts: Biotoxins, Anthropogenic Contaminants, Case Studies, and Conclusion. The conclusion is written by the editor J.P.F. D'Mello of Edinburgh UK.

The book is published by CABL Publishing, a division of CAB International, Oxon UK. The cost of the book is \$145.00

In another new collaboration, *Microbial Food Safety in Animal Agriculture*, Dr. Mary Bartholomew, along with

former CVM staffer Dr. Kathy Hollinger and CVM Consultant Dr. David Vose wrote Chapter 30, "Characterizing the Risk of Antimicrobial Use in Food Animals: Fluoroquinolone-Resistant *Campylobacter* from Consumption of Chicken;" CVMers Dr. David White, Dr. Pat McDermott and Dr. Bob Walker wrote Chapter 5, "Antimicrobial Susceptibility Testing Methodologies;" and Dr. Tollefson, along with CVM's Dr. Bill Flynn and Dr. Marcia Headrick, wrote Chapter 7, "Regulatory Activities of the U.S. Food and Drug Administration Designed to Control Antimicrobial Resistance in Foodborne Pathogens."

## Draft Guidance on Use of Material From Deer and Elk in Animal Feed; CVM Updates on Deer and Elk Withdrawn

FDA has announced the availability of a draft guidance for industry entitled "Use of Material from Deer and Elk in Animal Feed." This draft guidance document (GFI #158), when finalized, will describe FDA's current thinking regarding the use in animal feed of material from deer and elk that are positive for Chronic Wasting Disease (CWD) or that are at high risk for CWD.

CWD is a neurological (brain) disease of farmed and wild deer and elk that belong in the cervidae animal family (cervids). Only deer and elk are known to be susceptible to CWD by natural transmission. The disease has been found in farmed and wild mule deer, white-tailed deer, North American elk, and farmed black-tailed deer. CWD be-

longs to a family of animal and human diseases called transmissible spongiform encephalopathies (TSEs). TSEs are very rare, but are always fatal.

This draft Level 1 guidance, when finalized, will represent the Agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

Draft guidance #158 is posted on the FDA/Center for Veterinary Medicine Home Page. Single copies of the draft guidance may be obtained from the *FDA Veterinarian*.

## Report Issued by Office of Research

Dr. Renate Reimschuessel and her colleagues from CVM's Office of Research have conducted a multi-laboratory study to develop uniform methods for antimicrobial susceptibility testing of bacteria from aquatic sources. These methods are detailed in a special report entitled *Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated from Aquatic Animals: A Report*. This report was published by the National Committee for Chemical Laboratory Standards (NCCLS) in May 2003, and it provides the most up-to-date techniques for disk diffusion susceptibility testing of aquatic bacteria isolates, as well as quality control ranges used for monitoring the performance of study conditions and experimental deviations.

"This is a major step forward for aquatic animal diagnostics and for the monitoring of antimicrobial susceptibilities of microorganisms in the aquatic environment," says Dr. Reimschuessel. NCCLS is a globally recognized, voluntary consensus standards-developing

***"This is a major step forward for aquatic animal diagnostics and for the monitoring of antimicrobial susceptibilities of microorganisms in the aquatic environment," says CVM'S Dr. Reimschuessel.***

organization that enhances the value of medical testing within the healthcare community through the development and dissemination of standards, guidelines, and best practices. NCCLS is comprised of more than 2,000 member organizations worldwide from government, industry, and the professions.

The report can be purchased directly from the NCCLS website at <http://subservice.nccls.org/edds/webstore.htm>, for a cost of \$35 by NCCLS members, and \$65 for non-members.

## FARAD – Resource for Residue Problem Avoidance

The Food Animal Residue Avoidance Databank (FARAD) is a computer-based decision support system originally designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminant residue problems. However, FARAD also offers emergency response assistance for accidental or deliberate chemical exposures to food animals. Since 1982 the FARAD has provided emergency hotline assistance to State and Federal agencies dealing with chemical contamination in food animals.

FARAD is a collaboration between USDA, FDA, and three Universities (North Carolina State University, University of Florida, and University of California, Davis). FARAD was authorized by Congress in 1998 (Public Law 105-185). Dr. Jim Riviere, Professor, North Carolina State University, College of Veterinary Medicine says one of FARAD's functions is "to provide withdrawal time guidance in support of extra-label drug use under AMDUCA." Dr. Riviere adds, "They also provide such information to the FDA-supported Veterinary Antimicrobial Decision Support System (VADSS) program on Prudent Antimicrobial Use and internationally to the Commonwealth Agricultural Bureau, International (CABI), which is a global storehouse and disseminator of agricultural databases."

FARAD personnel at the University of California, Davis and the University of Florida comb through numerous sources of residue avoidance information and extract information that will be of greatest use. These data are reviewed by residue experts to ensure accuracy and consistency, and further analysis is done by FARAD personnel at North Carolina State University to explore novel ways in which the data may be used to prevent residue problems. FARAD maintains an up-to-date computerized compilation of:

- Current label information including withdrawal times on all drugs approved for use in food animals in the United States and on hundreds of products used in Canada, Europe and Australia.
- Official tolerances for drugs and pesticides in tissues, eggs and milk.
- Descriptions and sensitivities of rapid screening tests for detecting residues in tissues, eggs and milk.
- Data on the fate of chemicals in food animals.



Photo by Karen Kamstra

*FARAD is a valuable resource for residue avoidance.*

FARAD maintains the largest database of animal pharmacokinetic data in the world. These data describe the time-course of chemical (drugs, pesticides, environmental contaminants and toxins) depletion in the tissues and products of animals. FARAD is also sanctioned to provide these estimates to the United States Pharmacopeia-Drug Information (USP-DI) Veterinary Medicine Advisory Committee. As a cooperative multi-state program, FARAD is available nationwide to offer advice about residue avoidance.

### Where to Call FARAD

FARAD expert-mediated assistance is available from two Regional Access Centers that can be accessed by this single toll-free telephone number:

**1-888-USFARAD (1-888-873-2723)**

WESTERN REGIONAL ACCESS CENTER

**Fax** ..... (530)752-0903

**Email** ..... [farad@ucdavis.edu](mailto:farad@ucdavis.edu)

EASTERN REGIONAL ACCESS CENTER

**Fax** ..... (919)513-6358

**Email** ..... [farad@ncsu.edu](mailto:farad@ncsu.edu)

### When to Call FARAD

Anyone who has a question about how to prevent residues in animal-derived foods is encouraged to call FARAD for assistance. Food animal veterinarians and Extension specialists are currently the major users of FARAD information. The FARAD Regional Access Centers operate during normal business hours. Most questions can be answered immediately; however, complex response may require a couple of days.

For more information, please visit FARAD's web site at <http://www.farad.org>.

## Consent Decree Against California Dairy

On March 19, 2003, the United States District Court for the Central District of California entered a Consent Decree of Permanent Injunction against the defendant James Bootsma Jr., an individual, doing business as Jim Bootsma Jr. The Consent Decree is founded on the numerous illegal drug residues caused by the firm and the failure of Mr. Bootsma to maintain controls to prevent illegal residues in animals delivered for slaughter.

Jim Bootsma Jr. dairy livestock business is located in Lakeview, California. The business maintains a herd of approximately 2,000 animals, including a milking herd of about 1,500 cows. Since 1987, Jim Bootsma Jr. has engaged in the sale and consignment of cattle that are slaughtered for use as human food. Mr. Bootsma's poor management practices have been the primary source of these illegal drug residues in spite of the relentless efforts by FDA, the U.S. Department of Agriculture (USDA), and the California Department of Food and Agri-

culture to gain compliance at this firm through inspections and written warnings.

Under the terms of the Consent Decree Mr. Bootsma agrees to be permanently restrained and enjoined from: (1) introducing or delivering for introduction into interstate commerce any livestock or their edible tissues; (2) administering to cattle any articles of new animal drug while held for sale after shipment in interstate commerce, except in a manner that conforms to such drug's approved conditions for use or to the specific written instructions of a licensed veterinarian, until the corrective actions enumerated in the decree are established and implemented.

The FDA's Los Angeles District Office conducted the investigation that led to this Consent Decree. Center for Veterinary Medicine Division of Compliance, the FDA's Office of the Chief Counsel, and the United States Department of Justice Office of Consumer Litigation were responsible for the case processing and legal procedures. ■

## Pew Initiative Releases Proceedings

Proceedings of the conference titled "Animal Cloning and the Production of Food Products—Perspectives from the Food Chain," are now available on the Pew Initiative's web site at <http://www.pewagbiotech.org>.

Over 150 participants attended the conference, held September 26, 2002. Co-hosted by the Pew Initiative on Food and Biotechnology and FDA. Attendees included scientists, industry and government representatives, animal welfare advocates, consumer rights representatives and policy analysts. Speakers addressed the potential uses of ge-



netically engineered animals, ethical and animal welfare considerations, human health and environmental concerns, the state of the technology and future trends, marketing issues, and regulation of transgenic and cloned animals.

Dr. Stephen Sundlof, Director of the Center for Veterinary Medicine, said "The Center for Veterinary Medicine co-sponsored last year's conference on animal cloning along with the Pew Initiative to inform regulators, scientists, and consumers about the science behind the cloning of food-producing animals." ■

## Comings and Goings

### NEW HIRES

*Office of the Center Director (OCD)*

- Kristina Goddard, Staff Specialist

*Office of New Animal Drug Evaluation (ONADE)*

- Dr. Michael Oehlsen, Staff Fellow
- Dr. Diane Heinz, Biologist
- Dr. Margaret Bowman, Staff Fellow
- Dr. Kyunghye Song, Mathematical Statistician
- Dr. Xikui Chen, Chemist
- Dr. Estella Z. Jones, Veterinary Medical Officer

*Office of Surveillance and Compliance (OS&C)*

- Jeanette Brown, Biologist

### RETIREMENTS

- Margaret Klock, OCD
- Dr. Nicholas Weber, ONADE

### DEPARTURES

- Dr. Shabbir Simjee, Office of Research
- Dr. Pamela Chamberlain, OS&C

## CLA Petition – Correction

In the May/June 2003 issue of the *FDA Veterinarian*, it was erroneously reported that a food additive petition for Conjugated Linoleic Acid (CLA) was approved. The notice filed on March 11 was a notice of filing and not an approval. The petition is still under review. Therefore, CLA is **not** approved for use in animal feed. ■

## Regulatory Activities

by Karen A. Kandra

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

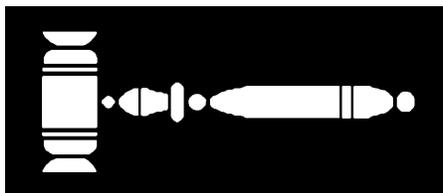
- John G. O'Hearn, Co-owner, O'Hearn Irish Dairy, Reedsville, WI
- Jerimy Craig, Owner, Box Canyon Dairy, Wendell, ID
- Mark G. Hohlmann, Owner, Lakeview Farms, St. Cloud, WI
- David Vander Schaaf, Owner, David Vander Schaaf Dairy, Ontario, CA
- Randy R. Stewart, Owner, Cottonwood Cattle Company, Sioux Falls, SD
- James S. Lipiec, Little Falls, NY
- David Hudson, Flintville, TN
- Michael D. Geerlings, Owner, Scenic View Dairy, LLC, Fennville, MI
- Michael E. Musser, Partner, Shady Grove Dairy, Ontario, CA

The above violations involved illegal residues of gentamicin in a cow; penicillin in a calf heifer; penicillin in a heifer; oxytetracycline in a culled dairy cow; multiple residues of gentamicin, sulfadimethoxine, oxytetracycline, penicillin, sulfamethazine, and tilmicosin in cattle; penicillin in a cow; sulfadimethoxine in a cow; neomycin in a dairy cow; and penicillin in a cow.

A warning letter was issued to Dr. Keith A. Budder, Rio Vista Veterinary Hospital, Painted Post, NY, for prescribing drug products for extralabel use resulting in illegal tissue residues in two animals offered for slaughter for human food. These include residues of flunixin and penicillin in cows.

A warning letter was issued to Robert D. DeGregorio, President, Land O'Lakes Farmland Feed LLC, Arden Hills, MN, for selling Category II, Type A Medicated Articles to a feed mill that does not have a valid FDA Medicated Feed Mill License.

A warning letter was issued to Steve L. Denk, President, Barr Animal Foods, Greenwood, WI, for 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. The inspection revealed that the firm was not labeling 50-pound blocks of frozen beef and bulk loads of beef bone chips and rendering waste, that are intended for animal feed, with the caution statement, "Do not feed to cattle or other ruminants." This statement is required on products that contain or may contain

protein derived from mammalian tissues and are intended for use in animal feed.

A warning letter was issued to John F. Turner, Owner, Manager, Millstone Agri Distributors, Maryville, TN, for significant deviations from Title 21 CFR 589.2000. Violations included failure to separate the receipt, processing, and storage of products containing prohibited material from products not containing prohibited material; failure to establish written procedures, including clean-out and flushing procedures, to avoid commingling and cross-contamination of common equipment; failure to maintain records sufficient to track prohibited materials; and, failure to label non-ruminant products with the required cautionary statement "Do not feed to cattle or other ruminants." ■

## Extralabel Drug Use – Clarification

In answering a question regarding extralabel drug use in its "Ask CVM" section in the May/June issue of the *FDA Veterinarian*, the Center stated its position on extralabel use in a potentially confusing manner. The answer derived from a statement in the "FDA and the Veterinarian" booklet which is, unfortunately, also somewhat obscure.

It appears that CVM was trying to draw a distinction between preventive use in which a thoughtful decision is made by a veterinarian regarding the likelihood of harm to animals in the absence of prophylaxis and "preventive" use when such is not the case—calling the latter "routine prevention". However, all aspects of extralabel use require the thoughtful determination of potential harm in the absence of treatment or control or prevention and, in that context, all of these uses are acceptable under the regulations. Therefore, there is no reason to single out preventive use in this regard and lump some ill-defined portion of it in with production claims as prohibited.

The phrase "routine prevention" will be removed from the "FDA and the Veterinarian" booklet at the next printing and readers are advised to discount it in the meantime.

We also note that the list of drugs prohibited from extralabel use that accompanied the answer discussed above failed to include some recent changes. The current list follows:

- (1) Chloramphenicol;
- (2) Clenbuterol;
- (3) Diethylstilbestrol (DES);
- (4) Dimetridazole;
- (5) Ipronidazole;
- (6) Other nitroimidazoles;
- (7) Furazolidone.
- (8) Nitrofurazone.
- (9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxyypyridazine);
- (10) Fluoroquinolones;
- (11) Glycopeptides; and
- (12) Phenylbutazone in female dairy cattle 20 months of age or older.

## Ask CVM

The CVM Home Page receives quite a bit of mail. The questions and answers featured here are composites of multiple questions the Home Page has received on the same topic. If you would like to send a question to the CVM Home Page, please visit [www.fda.gov/cvm](http://www.fda.gov/cvm) and select "contact CVM" or write us directly at [CVMHomeP@cvm.fda.gov](mailto:CVMHomeP@cvm.fda.gov).

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*We are a manufacturer of human medical devices. We want to expand our business and develop medical devices for pets. Please let me know if there are any regulations for pet medical devices. If so, where can I find the detailed information?*

While FDA does not require pre-approval of veterinary medical devices, we do ask that you submit a copy of all labeling and promotional materials for review. Please see <http://www.fda.gov/cvm/index/consumer/regofdevices.htm> for additional information.

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*I purchased a bag of my regular dog food and it is spoiled. How do I file a complaint about this product?*

You should contact the Complaint coordinator at the FDA District Office in your area. A listing of the complaint coordinators can be found at <http://www.fda.gov/opacom/backgrounders/complain.html>.

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*I am interested to know if the FDA has legislation/codes/guidelines determining how a veterinary medicine may be distributed? As such, what criteria do you use to decide if the product should be confined to veterinary surgeons or made available over the counter?*

FDA has the responsibility for determining the marketing status (prescription, over-the-counter, or Veterinary Feed Directive) of animal drug products based on whether it is possible to prepare "adequate directions for use" under which a layperson can use the drugs safely and effectively. An animal drug which is not safe for animal use except under the professional supervision of a licensed veterinarian because of:

- (1) its toxicity or other potential for harmful effects, or
- (2) the method of its use, or
- (3) the collateral measures necessary for its use

is an Rx drug if it is not possible to prepare "adequate directions for use" under which a layperson can use the drugs safely and effectively. Such products can be dispensed only by or upon the lawful written order of a licensed veterinarian. Products for which adequate directions for lay use can be written must be labeled for over-the-counter (OTC) use under existing law. Safe use includes safety to the animal, safety of food products derived from the animal, safety to the persons associated with the animal, and safety in terms of the drug's impact on the environment.

Effective use of a drug product assumes that an accurate diagnosis can be made with a reasonable degree of certainty, that the drug can be properly administered, and that the course of the disease can be followed so that the success or lack of success of the product can be observed.

The same drug substances can be marketed in a number of different dosage forms, intended for use by different routes of administration, and in different species of animals. Thus, these drug products may be appropriately labeled Rx in some cases and OTC in others. Rx products must bear the legend: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

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*I would like to know if the heartworm medications that I can buy from Internet pharmacies are FDA-approved and not imported.*

Before dealing with internet pharmacies you should see the information on FDA's Home Page ([www.fda.gov/oc/buyonline/default.htm](http://www.fda.gov/oc/buyonline/default.htm)). We recommend that you only deal with a reputable pharmacy that can assure you that the products you are purchasing are approved for sale in the United States. We do not have jurisdiction over products produced overseas and you have no guarantees that these products have been made to the same standards as drugs produced (and approved) for sale in the U.S.

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*I would like to know what I have to do to import shampoo, conditioner, perfume, soap to use in dogs and cats. Does it need approval or can I just bring it? Does it need to be regulated or tested here?*

The animal counterpart of a cosmetic is commonly referred to as a "grooming aid." The Act defines a cosmetic as pertaining only to human use (201(i)). Therefore, products intended for cleansing or promoting attractiveness of animals are not subject to FDA control. However, if such products are intended for any therapeutic purpose or if they are intended to affect the structure or function of the animal, they are subject to regulation as new animal drugs under the FD&C Act.

Therefore, unless they are intended for any therapeutic purpose, i.e., for treatment of a disease, or intended to affect the structure or function of the animal, you do not need approval to bring these products into the U.S. ■

## Award for Counter/Bioterrorism Preparedness

The "FDA Counter/Bioterrorism Preparedness Team" has been awarded the DHHS Secretary's Award for Distinguished Service. The Team is comprised of several groups of employees throughout FDA who contributed to FDA's counter/bioterrorism preparedness efforts. CVM's representative is Dr. Charles Eastin. The Team was recognized for "demonstrating outstanding leadership in FDA's counter/bioterrorism preparedness efforts to protect the Nation's public health and food supply from biological, chemical and radiological threats and to respond more effectively to threats following the tragic events of September 11, 2001." ■

## New Animal Drug Approvals

<i>Company</i>	<i>Generic and (Brand) Names</i>	<i>Indications</i>	<i>Routes/Remarks</i>
Pfizer, Inc. (NADA 141-199)	Carprofen (Rimadyl®) RX	Dogs. For relief of pain and inflammation associated with osteoarthritis.	<b>SUBCUTANEOUS</b> —The NADA provides for the veterinary prescription use of carprofen solution in dogs, by subcutaneous injection, for the relief of pain and inflammation associated with osteoarthritis. <i>Federal Register</i> 05/15/03
Technology Transfer, Inc. (141-217)	Zinc Gluconate Neutralized by Arginine (Neutersol®) RX	Dogs. For chemical sterilization.	<b>INTRATESTICULAR</b> —The NADA provides for use of Neutersol Injectable for chemical sterilization of 3- to 10-month-old male dogs by intratesticular injection. <i>Federal Register</i> 05/19/03
Schering-Plough Animal Health Corp. (NADA 141-193)	Tepoxalin (Zubrin) RX	Dogs. For the control of pain and inflammation.	<b>ORAL</b> —The NADA provides for veterinary prescription use of Zubrin Tablets for the control of pain and inflammation associated with osteoarthritis in dogs. <i>Federal Register</i> 06/11/03

## Supplemental New Animal Drug Approvals

<i>Company</i>	<i>Generic and (Brand) Names</i>	<i>Indications</i>	<i>Routes/Remarks</i>
Bayer Corp. Agriculture Division, Animal Health (141-007)	Praziquantel, Pyrantel Pamoate Febantel (Drontal Plus)	Dogs. For the removal of several species of internal parasites.	<b>ORAL</b> —The supplement provides for the use of a larger size of tablet. <i>Federal Register</i> 04/28/03
Intervet, Inc. (NADA 128-620)	Fenbendazole (Safe-Guard®)	Goats. For removal and control of stomach worms.	<b>ORAL</b> —The supplement provides for a change to over-the-counter marketing status for the oral use of fenbendazole suspension in goats. <i>Federal Register</i> 05/15/03
Lloyd, Inc. (NADA 139-236)	Xylazine (Cervizine 300) RX	Elk and Wild Deer. To produce sedation.	<b>INTRAMUSCULAR</b> —The supplemental NADA provides for use of a 300 milligram per milliliter strength of xylazine hydrochloride solution in elk and wild deer to produce sedation, accompanied by a shorter period of analgesia. A revised food safety limitation and cautionary statement are added. <i>Federal Register</i> 05/15/03
Intervet, Inc. (NADA 141-034)	Bambermycins (Gainpro®)	Cattle. For increased rate of weight gain.	<b>MEDICATED FEED</b> —The supplemental NADA provides for use of bambermycins Type A medicated articles to make Type B and Type C medicated feeds used to increase rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) when consumed free-choice or hand-fed at the rate of not less than 10 mg nor more than 40 mg bambermycins per head/day. <i>Federal Register</i> 05/21/03

(Continued, next page)

## Supplemental New Animal Drug Approvals (Continued)

<i>Company</i>	<i>Generic and (Brand) Names</i>	<i>Indications</i>	<i>Routes/Remarks</i>
Intervet, Inc. (NADA 131-675)	Fenbendazole (Safe-Guard® 20%)	Horses. For the control of gastrointestinal worms.	<b>MEDICATED FEED</b> —The supplemental NADA provides for use of SAFE – GUARD Type A medicated article to make Type B and Type C medicated horse feeds. The medicated feeds are used for the control of large strongyles, small strongyles, pinworms, and ascarids. <i>Federal Register</i> 06/10/03
Pfizer, Inc. (NADA 141-199)	Carprofen (Rimadyl®) RX	Dogs. For relief of pain and inflammation associated with osteoarthritis.	<b>SUBCUTANEOUS</b> —The supplemental NADA provides for a once daily, 2-mg/lb dosage of carprofen solution by subcutaneous injection. <i>Federal Register</i> 06/11/03
Alpharma, Inc. (NADA 96-298)	Lasalocid (Bovatec® 68)	Cattle. For increased rate of weight gain.	<b>MEDICATED FEED</b> —The supplemental NADA provides for the use of lasalocid Type A medicated article to make free-choice, loose mineral Type C medicated feeds used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). The regulations are also being revised to provide current references for the amounts of selenium and ethylenediamine dihydroiodide (EDDI) permitted in other free-choice cattle feeds. <i>Federal Register</i> 06/19/03

## Abbreviated New Animal Drug Approvals

<i>Company</i>	<i>Generic and (Brand) Names</i>	<i>Indications</i>	<i>Routes/Remarks</i>
Pennfield Oil Co. (ANADA 200-314)	Chlortetracycline/Sulfamethazine (Pennchlor S 700™)	Beef cattle.	<b>MEDICATED FEED</b> —The ANADA provides for the use of a fixed-combination Type A medicated article to make two-way combination drug Type C medicated feeds for beef cattle. PENNCHLOR S 700 is a generic copy of Alpharma, Inc.'s AUREO S 700 approved under NADA 35-805. <i>Federal Register</i> 04/28/03
Phoenix Scientific, Inc. (ANADA 200-322)	Butorphanol Tartrate RX	Horses. For relief of colic and postpartum pain.	<b>INTRAVENOUS</b> —The ANADA provides for use of Butorphanol Tartrate injection for the relief of colic and postpartum pain in adult and yearling horses. Phoenix Scientific's Butorphanol Tartrate injection is a generic copy of Fort Dodge Animal Health's TORBUGESIC® approved under NADA 135-780. <i>Federal Register</i> 04/29/03

(Continued, next page)

## Abbreviated New Animal Drug Approvals (Continued)

<i>Company</i>	<i>Generic and (Brand) Names</i>	<i>Indications</i>	<i>Routes/Remarks</i>
Phoenix Scientific, Inc. (ANADA 200-347)	Penicillin G Potassium	Turkeys. For the treatment of erysipelas.	<b>ORAL</b> —The ANADA provides for use of Penicillin G Potassium, USP, in the drinking water of turkeys for the treatment of erysipelas caused by <i>Erysipelothrix rhusiopathiae</i> . Phoenix Scientific's Penicillin G Potassium is a generic copy of Fort Dodge Animal Health's Penicillin G Potassium, USP, approved under NADA 55-060. <i>Federal Register</i> 05/15/03
Phoenix Scientific, Inc. (ANADA 200-319)	Acepromazine Maleate	Dogs, cats, horses. For use as a tranquilizer.	<b>SUBCUTANEOUS or INTRAMUSCULAR</b> —The ANADA provides for the use of Acepromazine Maleate as a tranquilizer. Phoenix Scientific's Acepromazine Maleate Injection is a generic copy of Fort Dodge Animal Health's PROMACE approved under NADA 015-030. <i>Federal Register</i> 06/06/03
Cross Vetpharm Group, Ltd. (ANADA 200-350)	Pyrantel Pamoate (Exodus)	Horses and Ponies. For the removal and control of certain internal parasites.	<b>ORAL</b> —The ANADA provides for use of EXODUS paste for the removal and control of certain internal parasites in horses and ponies. Cross Vetpharm Group, Ltd's EXODUS is a generic copy of Pfizer, Inc.'s STRONGID Paste approved under NADA 129-831. <i>Federal Register</i> 06/10/03

### DEPARTMENT OF HEALTH & HUMAN SERVICES

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