THE FARAD NEWSLETTER

An electronic publication from the Food Animal Residue Avoidance Databank (FARAD) for veterinarians, animal scientists, extension specialists and the regulatory community.

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Issue # 1

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IN THIS ISSUE:

1. FROM THE EDITOR

Dear FARAD Supporters,

In November Congress approved $800,000 for FARAD for the 2002-2003 fiscal year, this is the second year running that Congress has singled out FARAD in the Agriculture Appropriations Bill. It is hoped that this marks the start of stable funding for FARAD. However FARAD's supporters should be aware that a line-item is an annual appropriation and subject to budget cuts and that only inclusion in the USDA Budget gives the program the needed stability. As you might expect the fluctuations in funding have wreaked havoc on the program and we lost many highly trained, committed professionals. For the last two years having only a skeleton staff, FARAD has been fielding 3 to 4 emergency calls a week, a service level far reduced from it's previous average of 3 to 4 calls per day.

With this year's appropriation we will be resuming full service as quickly as our infrastructure can be reestablished. The FARAD toll-free hot-line, 888-873-2723 (888-US-FARAD) is again operational. While our goal is to respond to callers within 24 hours, we are requesting that our clients be patient as we train new staff. With funding for programmers, the FARAD interactive web site (www.farad.org) will become operational in the near future. The web site will make available a database containing all OTC and prescription animal drugs and will be searchable by compound, trade name or species.

With this year's appropriation we are also initiating The FARAD Newsletter. This electronic publication will pertain to a wide variety of issues, all involved with prevention of toxin and drug residues in food animals. Animal drug label changes, regulatory advisories, brief case histories and availability of other food safety resources are examples of the type of information that will be found in this newsletter. We will also keep readers apprised of FARAD's funding status.

The newsletter will, on occasion, also supply FARAD recommendations concerning extra label drug use in food animals. The clear intent of the federal Animal Medicinal Drug Use Clarification Act (AMDUCA) is that veterinarians supervise all extra-label drug use by producers. It is for this reason that a primary intended audience of the newsletter is practicing veterinarians. Others that could benefit from the information contained in the publication include extension specialists, animal scientists and state and federal regulatory staff. The newsletter will be published on an "as needed" basis dependent on the amount or urgency of the material.

In order to not encourage extra label use by producers, we ask that portions of this newsletter not be forwarded to producers or producer list-serves or used in producer newsletters (electronic or print). The material within this newsletter is copyrighted and requests for permission to reproduce portions of the newsletter may be made by calling the FARAD hot-line: 888-873-2723 (888-US-FARAD). However if your colleagues would like to receive their own copy of the news letter tell the to send their request to farad@mail.vetmed.ufl.edu including their name, address and phone number and we can add them to the list.

Before rolling up our sleeves and getting back to work, we need to thank all those who have been in our corner during the last several years. The list of those that have spoken and written on our behalf is too long to print here but includes practicing, academic and regulatory veterinarians, producer and vet association staff and members of congress. We would be remiss however if we did not direct a special thanks to the AVMA's Governmental Relations Division and their own Dr. Bernadette Dunham who have been largely responsible for FARAD's continued survival.

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2. CEFTIOFUR APPROVED FOR MEAT AND DAIRY GOATS

Pharmacia (previously Upjohn) Animal Health has gained a label addition for ceftiofur sodium (Naxcel® Sterile Powder) which allows for its use in the treatment of caprine respiratory disease (goat pneumonia). When given on-label to dairy or meat goats at 0.5 to 1.0 mg/lb, IM, once a day for up to 5 days, neither a milk discard nor a pre-slaughter withdrawal period is required. Naxcel® is a prescription product and prescribing veterinarians must meet labeling requirements for product left on the farm or dairy. Ceftiofur is the first systemic antibiotic approved for use in goats and the first goat drug specifically approved for use in dairy goats. The approval of Naxcel® for goats was accomplished in part through the National Research Support Project #7 (NRSP-7), the Minor Use Animal Drug Program. This cooperative university, federal and pharmaceutical industry program's mission is approval of animal health products for minor uses and species. The program provides financial support for efficacy, animal safety, food safety and environmental impact studies necessary for approval in species whose market would normally be insufficient to justify costly research expenditures by the private sector. For example, of the seven drugs previously approved for use in goats in the US, four (morantel tartrate, fenbendazole decoquinate and monensin) were approved through NRSP-7. Only three (neomycin, proparacaine and thiabendazole) were approved through the normal regulatory approval process. FARAD has a formal data sharing arrangement with NRSP-7.

The Freedom of Information Summary for the ceftiofur goat label addition can be found at:
http://www.fda.gov/cvm/efoi/section2/140338s051401.html

The Pharmacia Animal Health home page is:
http://www.pharmaciaah.com

The NRSP-7 (the Minor Use Animal Drug Program) home page is:
http://www.nrsp-7.org

3. NEW FLUNIXIN LABEL FOR CATTLE

ProLabs, the prescription division of AgriLabs, recently gained a label addition for its equine flunixin meglumine product Flu-Nix™. The label now allows for treatment of beef and non-lactating dairy cattle with bovine respiratory disease. While several equine flunixin products are currently marketed, until now Banamine® was the only flunixin product with a food animal label. The Animal Medicinal Drug Use Clarification Act (AMDUCA) requires that veterinarians use and prescribe products with food animal labels preferentially over other similar products having companion animal or human labels. Labels for both Banamine® and Flu-Nix™ specify slow IV administration of 1.1-2.2 mg/kg or 1-2 cc/100 lbs body weight. Flunixin is highly irritating when injected into the muscle and should only be administered intravenously. The slaughter withdrawal for both products when used on-label is 4 days. The use of either product in dairy cattle older then 20 months of age (CVM's definition of a "lactating dairy cow") is extra-label and requires that a veterinarian's label be applied to bottles stored on the dairy. By virtue of the fact that Flu-Nix™ and Banamine® share the same New Animal Drug Application number (NADA 101-479) we can assume them to be chemically identical and FARAD's extra-label milk withdrawal recommendation (when used according to the beef label) are the same for the two products, 72 hours. Because Banamine® and Flu-Nix™ are the only two flunixin-containing products approved for a food animal species, veterinarians are required to use one of them over other equine flunixin products when a food animal species is treated.

Summary information for AgriLabs original equine product is available at:
http://www.hiproanimalhealth.com/catalog/usa/1/1386/13861007.htm

The AgriLabs home page is:
http://www.agrilabs.com

4. DRUG TESTING SHOW ANIMALS

In response to incidence reports of violative residue levels in show and fair animals USDA has issued a notice clarifying FSIS's policies regarding the testing of these animals. While the notice covers antibiotic testing it also highlights testing procedures for beta-adrenergic agonists. Beta-adrenergic agonists have

limited approved veterinary applications in the United States: clenbuterol is approved only for horses not intended for use as food and ractopamine is approved for swine only. However, beta-agonists are sometimes administered to show animals to increase muscle mass, giving them a competitive advantage. Illicit use of clenbuterol is reported to have resulted in more than 1000 emergency hospitalizations and several deaths in Europe. The extra label use of beta agonists in food animals represents one of the FDA's highest priorities for regulatory attention. One veterinarian convicted of conspiring to smuggle clenbuterol into the US received fines and a jail term.

The complete text for the FSIS Notice can be found at:
http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/45-01.htm

5. ACCURACY OF "MEATSAFE" BETA-LACTAM URINE ASSAY

FARAD has received several inquiries regarding the accuracy of the "Meatsafe" cow urine beta-lactam assay. The assay requires no incubator or reader making it the only true "cowside" pre-slaughter test for the penicillin class of antibiotics, the most frequent antibiotic class detected in cows at slaughter. Apparently only a single non peer-reviewed study has reviewed the test's accuracy (Proceedings, 1999 AVMA's Annual Convention). In that study, urine test results of 759 slaughter cows were compared with the regulatory screening assay results. Based on this limited data it would appear that if a cow is positive on a FAST test then the Meatsafe urine assay is 100% predictive. Defining the regulatory assay as the gold standard, there was a 6.3% false positive rate when 48 of 759 samples were urine positive but FAST test negative. In 2000 boning utility cows (cull cows) averaged approximately $40/cwt or approximately $600 per 1,500 pound cull dairy cow. The retail price of Meatsafe is $39.95 for a box of 10 tests or about $4 per test. They are available through distributors or directly from Silver Lake Research (toll-free 888-438-1942).

The home page for the product is:
www.meatsafe.com

6. PESTICIDE PRODUCT INFORMATION AVAILABLE ONLINE

Veterinarians and regulatory staff dealing with pesticide exposures to food animals may access product information for free at two sites. The Crop Data Management Systems website contains complete U.S. labels and Material Data Safety Sheets for some 1,300 products from more than 80 manufacturers. The Electronic Pesticide Dictionary contains much the same information as the Farm Chemical Handbook, a standard quick-reference for agricultural professionals for 90 years containing summary information on 10,000 products.

The Crop Data Management Systems home page is:
http://www.cdms.net/pfa/LUpdateMsg.asp

Electronic Pesticide Dictionary can be found at the Meisterpro website:
www.meisterpro.com

7. OXYTETRACYCLINE IN FISH DATA AVAILABLE

The Food and Drug Administration (FDA) announced the availability of human food safety data that sponsors may use in support of a new animal drug application (NADA) or supplemental NADA for the treatment of walleye and northern pike (considered minor species). The U.S. Geological Survey, Upper Midwest Environmental Sciences Center (UMESC) compiled the data. Juvenile fish were fed medicated feed containing up to 94.2 mg/kg body weight oxytetracycline /day for 10 days at a water temperature of between 13.8 and 17.5 deg.C. The tissue residues as measured by HPLC were below the tolerance of 2 parts per million at all time points. The announcement was made in the Federal Register: November 16, 2001, Volume 66, Number 222, Page 57720-57721.

The full text can be obtained using "Browse" at the Federal Register web site:
http://www.access.gpo.gov/su_docs/aces/aces140.html

8. FDA EXTENDS COMMENT PERIOD ON IMPORT TOLERANCES

The Food and Drug Administration (FDA) is extending to March 11, 2002, the comment period on proposed regulation establishing import tolerances. The FDA is authorized by the Animal Drug Availability Act of 1996 (ADAA) to establish drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States. Food products of animal origin that are in compliance with the import tolerance will not be considered adulterated under the Federal Food, Drug, and Cosmetic Act and may be imported into the United States. The notice was published in the Federal Register: December 7, 2001, Volume 66, Number 236, page 63519.

The full text can be obtained using "Browse" at the Federal Register web site:
http://www.access.gpo.gov/su_docs/aces/aces140.html

9. FDA RELEASES INDUSTRY GUIDANCE ON FUMONISIN LEVELS

FDA has announced the availability of a final guidance document entitled “Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds.” The purpose of this guidance is to identify for the industry fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. Based on information obtained from future national and international workshops on the risk from exposure to fumonisins, FDA will consider whether to establish tolerances, regulatory limits, or action levels, as appropriate, for fumonisins in human foods and animal feeds. The announcement was published in the Federal Register: November 9, 2001, Volume 66, Number 218, page 56688-56689]

The text of the industry guidance can be found at:

http://www.fda.gov/cvm/index/other/fumonisin.htm

10. MILK WITHDRAWAL FOLLOWING ANTHRAX VACCINATION

FARAD was contacted regarding milk withdrawal in dairy cattle vaccinated following a natural outbreak or a deliberate exposure. Only one anthrax vaccine is approved for food animals in the US. The label 60-day slaughter withdrawal was awarded with the vaccine's approval in 1957 and appears to have been a standard regulatory vaccine withdrawal period not based on scientific studies. The vaccine manufacturer (Colorado Serum Company) uses the “Sterne Strain, 34F2” live spore non-encapsulated strain which has been studied since the 1930's. A standard computer-assisted literature search was conducted utilizing the FARAD, BIOSIS, CABI, MEDLINE, AGRICOLA and FSTA databases. The pivotal study located was Tanner, WB et al. “Public health aspects of anthrax vaccination of dairy cattle” (JAVMA; 173 (11):1465-1466, 1978). The abstract reads “A study was conducted to determine whether cows shed Bacillus anthracis in their milk following vaccination with the Sterne strain of B. anthracis. The study group consisted of 49 vaccinated and 6 non-vaccinated cows in a single herd. Following vaccination, blood samples were collected daily for 7 days, and milk samples were collected twice daily for 10 days. B. anthracis was not isolated from any of the blood or milk samples.” A literature search continues using usual sources but based on this currently available information FARAD recommends a zero milk withdrawal interval when Colorado Serum's anthrax vaccine is used in lactating dairy cows.

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