



NEWSLETTER

The [FARAD](#) Newsletter is an electronic publication from the **Food Animal Residue Avoidance Databank (FARAD)** for veterinarians, animal scientists, extension specialists and the regulatory community.

Issue # 6

January 6th 2006

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FARAD Represented at The North American Veterinary Conference

The University of Florida component of FARAD will be attending TNAVC starting Next Sunday [January 8th] through Wednesday the 11th. The booth will be at the foot of the escalators on the ground floor outside the trade exhibit. A feature will be the release of "FARAD on CD" - a new searchable version of FARAD's approved drug database offered as a quarterly issue subscription service marketed by the ADDS Center (do you want to add the price?). Conference attendees will be offered subscriptions at a 10% discount.

Details for non-attendees will be available later this month on the FARAD web site [www.farad.org] and in a special FARAD newsletter to be released at the same time.

Conference attendees are urged to come by and look at the CD and update themselves on FARAD.

Animals Destined for Rendering

FARAD recently received a question about a withdrawal interval for a horse going to slaughter then directly on to rendering. This response is from a senior FDA/CVM official:

“Technically, any drug used in a horse that was destined for rendering would be an extralabel use because the label would carry the statement "Do not use in horses intended for human consumption ". Since the rendered product would likely be used in **animal feed, which falls under the FD&C Act definition of food, the rules of AMDUCA would apply.** From a regulatory point of view, there is not much concern since the amount of drug residue in the rendered product would be small thus presenting little risk of the accumulating in food animals that consume the feed containing the rendered material. There is one exception, however. **Animals that are euthanized by lethal injection should not be rendered.** Pentobarbital has been detected in pet food and other animal feeds made with rendered material. Since there is no possibility of setting a withdrawal time for euthanasia drugs, AMDUCA would not apply in this case.”

REF: FARAD, October 26, 2005

FDA Investigates Illegal Extralabel Use of Sulfonamides (Sulfa Drugs) in Dairy Cows

Some veterinarians have been illegally using sulfonamides (sulfa drugs) in lactating dairy cows, according to information reported to the Center for Veterinary Medicine.

For example, during an inspection of a Wisconsin dairy, a State inspector found containers of unapproved sulfa drugs in the milk barn -- evidence of improper sulfa drug use. The drug had been prescribed by a veterinarian, who later received a warning against prescribing any sulfa drug that was not specifically approved for use in lactating dairy cattle.

CVM's concern is that the use of even a small amount of a sulfa drug in a lactating dairy cow's milk can result in the contamination of milk from several hundred cows when mixed in a bulk tank.

CVM has issued a "CVM UPDATE" warning veterinarians that FDA's rules prohibit the extralabel use of sulfa drugs in lactating cows. It also said, "CVM

has received some information indicating that sulfonamides, some in combination with trimethoprim, are being prescribed for use in treating conditions in lactating dairy cattle for which they are not approved.” The article stated that unapproved use of sulfonamides is a frequent cause of violative residues in food-producing animals.

In some cases the Animal Medicinal Drug Use Clarification Act [AMDUCA] can permit extralabel, or off-label, use of FDA-approved animal and human drugs. However, FDA's extralabel drug use rule specifically prohibits the extralabel use of sulfonamide drugs in lactating dairy cows. (See entire article for this list. <http://www.fda.gov/cvm/FdaVetJulAug2005.htm#5634>)

According to Dr. Mike Talley, CVM's milk safety specialist, the only currently marketed drug approved for use in lactating dairy cows 20 months of age or older is sulfadimethoxine as an injectable or oral bolus. Use of the product also carries with it the responsibility to discard the cow's milk for 60 hours after treatment as prescribed on the labeling.

CVM has also found that veterinarians are misusing the approved injectable product by intramammary infusion to treat mastitis. CVM is concerned about veterinarians increasing the dose or treating conditions in lactating cattle not on the approved labeling. Administering a drug in an unapproved manner or dose is another form of extralabel drug use and is prohibited in the case of sulfonamide drugs in lactating dairy cows.

The drug is approved as a sustained release oral bolus, in **beef** cattle but CVM has received reports that veterinarians have used the sustained release boluses to treat lactating dairy cattle.

REF: FDA Veterinarian Newsletter, July/August 2005.

FDA Approves New Antimicrobial for Catfish

The U.S. Food and Drug Administration has approved Aquaflor® Type A Medicated Article (florfenicol), an antimicrobial for the control of mortality due to enteric septicemia of catfish (New Animal Drug Application 141-246). Enteric septicemia of catfish, a bacterial disease, is one of the most serious diseases of farm-raised catfish. The disease results in significant economic losses to the catfish industry.

Aquaflor®, a product of Schering-Plough Animal Health Corporation, Union, New Jersey, is the first new antimicrobial approved for finfish in over two decades. The product is the second approved [Veterinary Feed Directive](#) (VFD) drug meaning that the medicated feed can only be fed on the order of a licensed veterinarian. Extra-label use of medicated feed containing florfenicol is prohibited under AMDUCA.

Aquaflor® for the approved indication was the first drug designated under the [Minor Use and Minor Species](#) Animal Health Act. This entitles Schering-Plough Animal Health Corporation to seven years of exclusive marketing rights for the approved indication beginning on the date of approval.

REF: CVM Update, October 25, 2005

FDA Approves TYLAN Soluble for the Control of American Foulbrood in Honey Bees

The U.S. Food and Drug Administration (FDA) has approved TYLAN (tylosin tartrate) Soluble for the control of American foulbrood (*Paenibacillus larvae*) in honey bees. This is the first approval for the use of TYLAN Soluble in a minor species (honey bees).

TYLAN Soluble, a product of Elanco Animal Health, a division of Eli Lilly and Company, Greenfield, Indiana, is already approved for therapeutic uses in chickens and swine and production uses in turkeys. (New Animal Drug Application 013-076)

TYLAN Soluble is only the second approved new animal drug approved for honey bees that controls American foulbrood (*Paenibacillus larvae*). The approval of this supplemental new animal drug application relied on safety and effectiveness data contained in Public Master File 5783, which were compiled under the oversight of the National Research Support Project-7 (NSRP-7). Studies were conducted by USDA's Bee Research Laboratories. FDA has concluded that the honey derived from honey bees fed tylosin tartrate is safe when the animals are fed according to the approved labeling, which states that drug treatments should be completed at least 4 weeks prior to main honey flow.

REF: CVM Update, October 20, 2005

FDA Proposes Additional "Mad Cow" Safeguards

FDA announced new measures to help further protect consumers against the agent thought to cause bovine spongiform encephalopathy (BSE, also known as "mad cow disease"). The Agency is proposing to amend its animal feed regulations to **prohibit from use in the food or feed** of all animals certain high risk cattle materials that can potentially carry the BSE-infectious agent. All of the proposed prohibitions, except for those related to tallow, have already applied to cattle feed since 1997.

These high risk cattle materials prohibited in the new proposed rule include:

- the brains and spinal cords from cattle 30 months of age and older,
- the brains and spinal cords from cattle of any age not inspected and passed for human consumption,

- the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed,
- tallow that is derived from the materials prohibited by this proposed rule if the tallow contains more than 0.15 percent insoluble impurities,
- mechanically separated beef that is derived from the materials prohibited by this proposed rule.

REF: FDA News, October 4, 2005

FDA's New Acting Commissioner

FDA's new acting commissioner is Dr. Andrew C. von Eschenbach. He is also director of the National Cancer Institute. Bush appointed Dr. Eschenbach after the resignation of Dr. Lester Crawford.

REF: FDA website

When can a veterinarian import a drug? The FDA's criteria for regulatory discretion

In the August 15, 2005 issues of JAVMA, an article was printed which details all the criteria which must be met if a veterinarian wishes to import a drug. Excerpts from this article follow.

“The Federal Food, Drug and Cosmetic Act, Sec. 801 (a)(3), states that importation of an animal drug that is not the subject of an approval in the United States is forbidden. However, the FDA Center for Veterinary Medicine recognizes that the lack of certain drugs could result in undue animal suffering.”

“The FDA has chosen not to prosecute importers who obtain written authorization for which the following conditions apply:

- The drug does not pose a significant risk to animal or human health
- The drug is used to treat or prevent a serious disease or condition in an animal
- There is no other available source of that drug or alternative drug(s) that is judged by FDA-CVM veterinary staff to be an adequate substitute
- The request for importation is made by a licensed veterinarian within the context of a valid veterinarian-client-patient relationship
- A relatively small amount of drug is requested for import
- There is no active promotion or marketing of the drug in U.S. markets for the intended use of the product “

“Interested veterinarians may contact the CVM and request permission to import a foreign drug. It is the veterinarian's duty to identify a supplier.

Discretion, if granted, is on a single-patient basis. The Personal Import Policy is not a means to import foreign versions of FDA-approved drugs for economic reasons. Moreover, actions can be taken against veterinarians who import illegal drugs for commercial distribution.”

“The FDA needs the following information to fully evaluate the request:

- How the veterinarian learned of the existence of the drug/product
- Veterinarian's name, address and phone number
- Clinic name and address
- Client's name and address
- Patient name and nonfood species
- Name of drug
- Drug family or class
- Name and address of drug supplier
- Legal status of the drug in the foreign country
- Amount of drug to be imported—must be small, noncommercial quantities
- Disease condition to be treated
- Reason why an approved human or animal drug will not treat the disease condition
- Statement that the veterinarian will notify the animal owner that the drug is not approved, that the drug will not be used in any food animal, and that the veterinarian agrees to notify the FDA if there are any adverse reactions. “

“Veterinarians who wish to use the Personal Import Policy for the treatment of a patient may direct their request to Toni Wooten, Division of Compliance, HFV-230, Center for Veterinary Medicine, Food and Drug Administration, Metro Park North IV, 7519 Standish Place, Rockville, MD 20855; phone, (240) 276-9220 or (240) 276-9200; fax, (240) 276-9241; or Toni.Wooten@fda.gov.”

Please see the article in JAVMA for complete information about the process.

REF: JAVMA, August 15, 2005

FDA Announces Final Decision About Baytril

U.S. Food and Drug Administration (FDA) Commissioner Lester Crawford announced the Agency's final decision to no longer allow distribution or use of the antimicrobial drug enrofloxacin for the purpose of treating bacterial infections in poultry effective September 12, 2005. **This ruling does not affect other approved uses of the drug.** This animal drug belongs to a class of drugs known as fluoroquinolones and is marketed under the name Baytril by Bayer Corporation.

U.S. FDA Press Release

<http://www.fda.gov/bbs/topics/news/2005/new01212.html>

Animal Health Institute, American Veterinary Medical Association and American Veterinary Distributors Association Launch New Brochure to Help Veterinarians Provide Legal, Safe Compounded Drugs

A new brochure entitled "Veterinary Compounding" is now available to help veterinarians and pharmacists safely treat animal diseases for which no approved drugs exist. Produced as a joint effort among the Animal Health Institute, the American Veterinary Medical Association and the American Veterinary Distributors Association, the brochure explains the requirements of legal compounding of veterinary drugs and the distinction between compounded drugs and drugs approved by the Food and Drug Administration (FDA).

The cooperative effort was sparked by recent concerns that have been raised about illegal compounding.

Since there are not always FDA-approved, commercially available drugs to meet a patient's needs, FDA has established rules by which pharmacists, working with veterinarians, can compound drugs. Because FDA has not evaluated these compounded drugs, they do not carry the same assurances of FDA approved drugs, including guarantees of safety, effectiveness and safe manufacturing procedures. Strict adherence to drug compounding rules established by FDA is vital so that animal pain and suffering can be relieved safely.

Requirements for compounding include the need for a valid Veterinarian-Client-Patient relationship, the need to compound from an FDA-approved product, and making only enough compounded product to meet the need of the animal identified.

<http://www.ahi.org/resources/documents/Compounding6pg.pdf>

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