



FARADTM

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.

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The members of the Food Animal Residue Avoidance Databank [FARAD] program reluctantly announce the suspension of all interactive activities as of the end of business on Tuesday, May 15th, 2007, due to lack of continued funding.

Click on the item to read the full article:

- **Statement on FARAD's Current & Future Status**
- **Correct Use Of Flunixin Meglumine**
- **Clarification On Extra-Label Use Of Medicated Feed In Minor Species**
- **Hydrogen Peroxide Removed From FDA's List Of Low Regulatory Priority Aquaculture Drugs**
- **FARAD on CD**

We regret having had to suspend FARAD's interactive activities, but with no fiscal support beyond May 2007, we have to conserve remaining resources in hopes that funding will be restored in next year's budget. This turn of events [stripping of all Congressional budget earmarks whether of national or regional importance] has loomed large for FARAD as it has been funded on a year-by-year basis since 1982. You and our other friends and clients have been very busy trying to get the United States Department of Agriculture (USDA) to incorporate FARAD into its budget so multi-year contracts could be negotiated or competed for, but all to no avail. The final outcome may be that FARAD will lose its trained and experienced personnel (some of which have been with the program since its inception) and may never recover. You will all appreciate that dedicated staff cannot survive on a year-by-year basis, and once we shut-down again, they will be reluctant to leave new secure jobs for a yearly gamble no matter how much they love the work and its importance to maintaining a safe national food supply. We managed over the past 8 years to come back, after a historical shut down in 1998-99, to nearly full function despite a flat-line budget, but lightning doesn't strike twice in the same place.

Even though we are in survival mode, we will try to keep faith with those whose efforts brought about the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994 and Minor Use and Minor Species (MUMS) Animal Health Act of 2004, by shutting down in a controlled manner so database integrity is preserved and crucial staff maintained. We will maintain communication via the FARAD Newsletter advising of important residue avoidance events that impact us all, continue our academic work developing our predictive models and algorithms and publish digests in the Journal of American Veterinary Medical Association (JAVMA) to share our experiences in handling extralabel drug use.

We hope this dimming of the FARAD program's lights is not a prelude to a good-bye. We all need to make sure USDA, FDA and our congress men and women are aware of FARAD's fate and with it a real risk of a major residue or contamination crisis.

As readers will appreciate, members of FARAD cannot lobby anyone on behalf of the program. However we know those that value and rely on the services that FARAD provides will make this known to agencies affected like AVMA, FDA and USDA as well as their members of Congress. We have been very heartened by the messages of support we have received and the news of people making the powers that be aware of their opinions.

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THE CORRECT USE OF FLUNIXIN MEGLUMINE

Last month the Food and Drug Administration issued a reminder to veterinarians about the appropriate use of the drug, flunixin meglumine, for use in cattle. FDA's Center for Veterinary Medicine (CVM) had received reports indicating that flunixin meglumine was being prescribed and/or administered by means of an intramuscular route (IM) in cattle. Flunixin

meglumine's only currently approved route of administration is by intravenous (IV) injection in cattle.

It is important for veterinarians to prescribe and use flunixin meglumine and other drugs for food animals according to directions on the FDA approved label so that adulterating residues are avoided. The intramuscular administration of flunixin meglumine has the potential to cause violative drug residues since it requires a longer withdrawal period to deplete the drug-related residue in the animal than does the approved intravenous route of administration. It is considered extra-label use to use an FDA approved product through a route of administration other than as it is approved. Extra-label use is not permitted for reasons such as convenience, yet CVM has learned that flunixin meglumine is being administered via the unapproved intramuscular route for convenience purposes

CVM has investigated a number of violative drug residues in meat that resulted from extra-label use of flunixin and wants to clarify that the Animal Medicinal Drug Use Clarification Act (AMDUCA) (<http://www.fda.gov/cvm/amducatoc.htm>) limits extra-label drug use to treatment when the health of an animal is threatened or suffering or death may result from failure to treat.

Only a veterinarian can prescribe a drug in an extra-label manner. In such cases, the veterinarian must establish a substantially extended withdrawal period supported by appropriate scientific information prior to the marketing of milk, meat, eggs, or other edible products to assure that violative drug residues do not occur.

The withdrawal time is the interval between the time of the last administration of a drug and the time when the animal can be safely slaughtered for food or the milk can be safely consumed. If the labeled withdrawal period is followed along with all other label directions, including route of administration, there is a high degree of assurance that treated animals or milk will be in compliance with applicable regulations, and that the edible products from such treated animals will be safe. There are established withdrawal times for approved products, such as flunixin meglumine. However, there are no approved withdrawal times for unapproved products or FDA approved products which are used in an extra-label manner.

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CLARIFICATION ON EXTRA-LABEL USE OF MEDICATED FEED IN MINOR SPECIES

[Compliance Policy Guide (CPG) section 615.115]

FDA's Center for Veterinary Medicine (CVM) has clarified its Compliance Policy Guide (CPG) section 615.115 entitled, "Extra-Label Use Of Medicated Feed In Minor Species" in order to ensure proper use of medicated feed in minor species. CVM has received a number of inquiries relative to the proper use of the CPG. The inquiries have revealed some common points of confusion regarding the appropriate interpretation of the principles specified in the CPG.

The following conditions, in addition to all other stipulations in the CPG, have to be satisfied in order to ensure proper use of medicated feed in minor species:

- **Veterinarian involvement.** Any extra-label use of medicated feed in minor species per this CPG requires involvement of a licensed veterinarian within the confines of a valid veterinarian-client-patient relationship. The veterinarian is expected to make a written recommendation for the extra-label use of medicated feed based on a recent diagnosis of an active disease for which no other drug treatment is approved.
- **Treatment only use.** Medicated feed may be considered for treatment only when the health of animals is threatened and suffering or death would result from failure to treat the affected animals.
- **No production use.** Extra-label use of medicated feed for production purposes is not allowed.
- **No feed reformulation or relabeling.** Once manufactured and labeled as approved for use in a major species, the feed cannot be either reformulated to meet nutritional needs of the intended minor species or relabeled as such.

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HYDROGEN PEROXIDE REMOVED FROM FDA'S LIST OF LOW REGULATORY PRIORITY AQUACULTURE DRUGS

The Food and Drug Administration (FDA) has announced the removal of hydrogen peroxide from the list of Low Regulatory Priority Aquaculture Drugs identified in the Program Policy and Procedures Manual Guide 1240.4200
<http://www.fda.gov/cvm/Documents/LRPDrugs.pdf>.

FDA, under enforcement discretion, had previously not objected to the use of hydrogen peroxide to control fungi on all species and life stages of fish, including eggs; however, hydrogen peroxide is now the subject of an FDA-approved new animal drug application with the trade name 35% PEROX-AID http://www.fda.gov/cvm/CVM_Updates/perox-aid.htm. Therefore, the only approved hydrogen peroxide product that can be used in fish production is 35% PEROX-AID. There is no longer any enforcement discretion for the use of hydrogen peroxide to control fungi on all species and life stages of fish, including eggs, or for its use to treat any other fish disease.

Aquaculture producers raising fish for human food consumption should not use drug compounds other than the approved product because it can be unsafe for your fish. In addition, the effectiveness of unapproved drug compounds is questionable.

The FDA also reminded food animal producers to read veterinary drug labels carefully and follow label directions to help avoid causing illegal residues in their products.

Questions concerning the use of hydrogen peroxide in aquaculture may be directed to Fran Pell, Consumer Safety Officer, FDA/Center for Veterinary Medicine, Division of Compliance, 240-276-9211, frances.pell@fda.hhs.gov.

The above items were extracted from the FDA/CVM website, June 8, 2007

FARAD ON CD

FARAD on CD has proved to be a successful innovation of the FARAD program. The CD subscription that works in both PC and Macintosh computers replaced the mass printed compendium of the past that had new editions printed every 2-3 years. Instead the subscription includes four quarterly updates mailed out to subscribers. The CD has several compendia including ones for different species. The compendia are in PDF format files which can be annotated and searched by word or phrase. Besides being able to use the CD in your portable laptop computer, the files can be printed for those of us who like the hard copy to work with.

As was stated in the opening article on FARAD's fiscal woes, we are maintaining our databases and will keep VetGRAM up and accessible to the public on the FARAD website [www.farad.org]. This will facilitate us continuing with the "FARAD on CD" subscription series as well. The link to DHIA Services who produces and markets the CDs is on the FARAD website. For ordering details, see the poster on the next page.

Please help FARAD maintain an accurate mailing list

If the e-mail address we used to contact you is not one that is your first choice or is out of date, please let us know at farad@vetmed.ufl.edu. Similarly, if a colleague or somebody you know has not received this issue tell them to write to us at the same e-mail address with their name, address, phone number as well as the e-mail address they want the newsletter sent to.

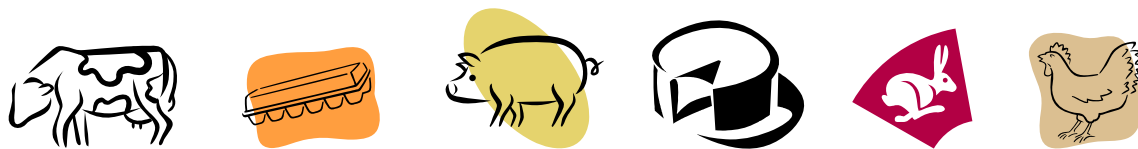
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2nd Edition!



A Searchable Compilation of FDA Approved Food Animal Drugs



CD INCLUDES:

- ❖ Complete Compendium of all FDA Approved Animal Drugs
- ❖ Species Specific Compendia of currently marketed animal drugs
- ❖ Searchable PDF files, printable reports, species specific abstracts, and regulatory information
- ❖ Quarterly Updates (disks will be sent in January, April, July, and October). Subscriptions will be pro-rated so renewal will be solicited in December for the coming year.
- ❖ The CD contains no extra-label information because, while .FARAD provides withdrawal intervals for specific clinical situations, it is not permitted to promote extra-label use of drugs.
- ❖ Annual Subscription is \$75 (January through December). The subscription, which will be prorated, is being handled by DHIA Services. Readers can order on-line .FARAD web site at www.farad.org