



FARAD™

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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As you can see by the appearance of this newsletter FARAD continues to survive. The program was very fortunate to receive a last minute infusion of funds that will keep the doors open for one year. This however arrived too late to avoid the loss of some of our trained personnel. As you have heard repeatedly, lack of assured multi-year funding has really hurt us in recruiting pharmacologists and pharmacokineticists. Ignoring that problem, we have re-opened the toll-free number for veterinarians to get advice on withdrawal intervals for drugs used extralabelly [ELDU] as permitted under AMDUCA.

The toll-free number – 1(888) US FARAD was turned on last week and we are trying to provide a 72 business hour turn-around on queries. In what we hope is a major advance to help cut the response time, we are beta-testing a new on-line submission for ELDU withdrawal advice called FARMWeb. The FARMWeb data form aims to prompt users to provide all the critical information on their drug use so a reply can be formulated in a single step and not require follow-up calls. The program can be reached through the FARAD web site clicking on the **“Submit a question”** button on the home page of www.farad.org. Remember this is a program in development and we really need your feed-back on how to make it function even better. [email comments to usfarad@gmail.com]

When using any of these methods please allow up to 3 working days for a reply. In the unlikely event that the system is down and you don't hear from us, please send an email to USFARAD@gmail.com giving us your submission number or date of phone call.

FARAD functions at three institutions who all have differing IT requirements. To make communication with FARAD easier we have established this common e-mail address. Messages will be distributed to the appropriate person.

Here is a picture of the FARAD web site's home page to help orientate you >>



A National Food Safety Project administered through the U.S. Department of Agriculture
Cooperative State Research, Education, and Extension Service
FARAD is Authorized by the Agricultural Research, Education and
Extension Reform Act of 1998 (Public Law 105-185, Title 6, Subtitle A, Section 604)

Food Animal Residue Avoidance Databank

Homepage

North Carolina State University
University of California-Davis
University of Florida

toll-free

NEW! The FARAD Residue Hotline Telephone [1-888-USFARAD](tel:1-888-USFARAD) is again Operational.

NEW! Questions to the FARAD Hotline can be submitted online now.

[Submit a question](#)

on-line access

NEW! Please note that FARAD is having a new email address usfarad@gmail.com. Or better yet, use the above link to submit a question online.

[FARAD on CD is available now.](#)

order 2008

ELDU FARAD CONTACT INFORMATION

TOLL-FREE >> **1(888) USFARAD [888 873 2723]**

When you call, be prepared with details of the drug [trade or generic name, strength, dose & route of administration] and the animal(s) treated [species, breed, age, lactating or not and number of doses administered]. [Editor's Note: Y'all find it a whole lot easier to use the internet program <FARMWeb> described below]

INTERNET - **FARMWeb**

>> Just go to www.farad.org and click on button shown above. It will help if you have the drug bottle with you when you log-in. Attached to this newsletter is a copy of Dummies Guide to FARMWeb that we hope will make your first visit to FARMWeb an enjoyable and productive one.

E-Mail .. USFARAD@gmail.com

Unfortunately because extra-label use of drugs is limited to situations where there is a valid-veterinarian –client-patient relationship FARAD can only provide this service to veterinarians. Also, as funding for FARAD has been provided by the US Government to maintain food safety for the US public, we cannot provide assistance to callers from outside the USA. Canadians now have their own Canadian gFARAD program and can reach it at 1-866-CGFARAD or 1-866-246-2723. Those seeking help from other countries should seek help through Global FARAD [gFARAD] if their country is a member.

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INDEXING OF LEGALLY MARKETED UNAPPROVED ANIMAL DRUGS FOR MINOR SPECIES

In 2004 the Federal Food, Drug, and Cosmetic Act (the act) was amended by the Minor Use and Minor Species Animal Health Act (MUMS act) to establish new regulatory procedures that would provide incentives to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species. As a reminder to our readers, a minor species is defined as not being a major species [dogs, cats, horses, swine, cattle, chicken & turkeys] this would be a list that includes small ruminants, gamebirds, fish, rabbits and a host of laboratory and exotic zoo animals. One definition that is still pending is that of “minor use in a major species”. Fortune tellers see FDA facing red tape delays but expectations that these will be overcome and actual number limits of animals affected for each species will be used to define a minor use. This strategy mirrors how orphan drugs are classified in the human side of FDA [Editor’s note – this would be humane as well]

The major incentives of the MUMS act include the following:

- Waiving fees that sponsors normally pay to FDA for processing their applications for drug approval [Animal Drug User Fees]
- Designation provides for eligibility for a 7-year period of exclusive marketing rights to enable sponsors to recover costs of drug development without competition. FDA published the final regulations for this in July 2007.
- Conditional approval will provide for MUMS drugs to be able to be marketed after all safety and manufacturing component requirements have been met. This would allow sponsors up to 5 years to complete the demonstration of effectiveness. Regulations to implement the conditional approval provision are still under development and will be proposed in the future.
- Indexing provides for the legal marketing of unapproved new animal drugs intended for use in a minor species through an integrated process of agency and expert panel review. FDA has just published the regulations that implement the indexing provisions of the MUMS act. These regulations establish procedures and criteria for index listing a new animal drug for use in a minor species. They describe a process whereby the agency makes a determination regarding the following: (a) The eligibility of a new animal drug, (b) the selection of a qualified expert panel, and (c) the findings of the qualified expert panel. There will be about 20 additions of 20 animal drug index listings each year.

There are efforts underway by the MUMS Coalition to get some form of tax relief for sponsors of drugs developed for minor uses or minor species. Readers will appreciate that Congress has to pass FDA's own budget.

Readers who want more information on this or any other matters affecting drug approvals under the MUMS Act should contact Dr. Bernadette Dunham, Director of the Office of MUMS at FDA. Her phone number is (240) 276 9000 and the e-mail address is Bernadette.Dunham@fda.hhs.gov.

PENDING SHORTAGE OF INJECTABLE IRON DEXTRAN

It appears that there is a likelihood of a shortage of the injectable drug, iron dextran, for the prevention and treatment of iron deficiency in baby pigs. Because CVM considers iron dextran a medically necessary drug and recognized that a shortage could result in undue animal suffering and disruption in the swine industry, it is temporarily allowing Bimeda Inc. of Iowa to import and distribute in the USA an injectable 200 mg/ml iron dextran product produced by its Canadian sister company. This approval is through the end of May 2008 or until an adequate U.S. domestically manufactured supply becomes available.

GENTIAN VIOLET PROHIBITED FROM USE IN ANIMAL FEED

FDA has determined that there is not adequate scientific data showing the use of gentian violet in animal feed to be safe. Therefore its use in feed will cause the feed to be adulterated and illegal under the FD&C Act. Deviations from this will require a notice of claimed investigational exemption for a food additive or be part of a new approved animal drug.

GLOBAL RESIDUE ISSUES

Many of you may have seen the article by David Barboza in the New York Times recently concerning the conditions under which fish are raised in China. In the article he reports how in the Chinese town of Fuqing the fish raising ponds are grossly contaminated by sewage, industrial waste and agricultural runoff that includes pesticides. These fish farms raise eels, shrimp and tilapia, much of it destined for markets in Japan and the West. In fact the author cites China as being the fastest-growing supplier of seafood to the United States. The contamination comes from limited water supplies being outstripped by demand with discharges further polluting the water downstream. Farmers are cited as using illegal drugs to combat the toxic waters.

<http://www.nytimes.com/2007/12/15/world/asia/15fish.html?>

This illustrates why FARAD is working internationally as Global FARAD [gFARAD] to spread the importance of residue avoidance or mitigation. The gFARAD partners receive and share technical information to enable production of safe food of animal origin in both their own

countries and when they export it. FARAD and its supporters are concerned that all food the public consumes is safe – whether it be of domestic or foreign origin.

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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 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.

The first issue of the 2008 subscription is ready to go to press so now is a good time to renew your subscription or start a new one. 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 newsletter@farad.us or use the reply to option on the email that brought you this issue. 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.

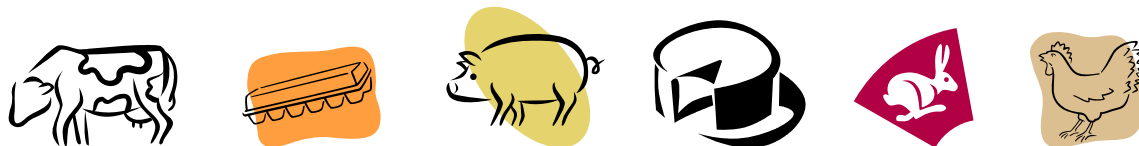
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3rd Edition!



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