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.

Issue #13 December 2009

ANOTHER YEAR AND WE ARE STILL HERE

Right at the end of the Federal FY 08-09, the FARAD components finally received funding for that year. Even better news is that Congress passed the FY 09-10 budget last month and it includes funding for FARAD. FARAD and the general public who consume food of animal origin need to be very grateful to all who supported us monetarily, politically and morally. We now start to rebuild and repair the program.

ACCESSING FARAD

FARAD has three portals of access depending what upon information is being sought.

APPROVED DRUG DATABASE >>

FARAD maintains an independent database of USA approved veterinary drugs. This is accessible via **VetGRAM** at www.farad.org. The database contains data derived from Federal Register notices and FOI packets. These are kept current including information on a drug's marketing status. An alternative format is **FARAD-ON-CD** which is an annual subscription with quarterly updates. It consists of total and species specific

compendiums with the same information as VetGRAM. These compendia are in PDF format, can be loaded on laptops and are searchable. Details of the CD subscription are attached to this newsletter and your order can be entered through a link at the FARAD web site.

ELDU WITHDRAWAL HELP >>

Veterinarians seeking advice on withdrawal intervals for their client's animals when extralabel drug use [ELDU] is involved can contact FARAD using either the FARAD HOTLINE on-line access at www.farad.org or the toll-free phone line [1 (888) US FARAD]. Most veterinarians find the on-line system easier as it prompts for all information needed for the quickest response. Using the phone system usually entails one or more follow-up calls. Either way, it is helpful to have the drug bottle or label in hand when contacting FARAD.

Please remember that ELDU is regulated by AMDUCA and that FARAD can only provide veterinarians with actual withdrawal intervals when the ELDU was within a valid veterinarian-client-patient relationship and the health of an animal is threatened or suffering or death may result from failure to treat. While FARAD wants to provide help as much as possible, it is bound not to encourage or promote ELDU.

MUMS PROGRAM FINALLY COMING TOGETHER

The efforts of the Minor Use Minor Species [MUMS] Coalition have now just about come to full fruition -

- The Office of MUMS [OMUMS] is a thriving group in FDA/CVM with Dr. Meg Oeller as its Director. FDA advises concerns be addressed to (240) 278-9090
- The *Designation* process is in place. This is where the sponsor of a potential veterinary drug for a minor use or minor species can apply for the drug to be "designated". When a designated drug becomes approved, the sponsor receives seven years of exclusive marketing rights for the drug in the approved dosage form for the same intended use. There are currently 84 drugs listed [11 are already approved and 2 have been terminated at their sponsor's request]
- *Conditional* Approvals are now possible. These are where a sponsor of a veterinary drug for a minor use or minor species can apply for "conditional

approval". This allows the sponsor, after providing FDA information that the drug is safe (in the target species and in food for human consumption) as well as showing a reasonable expectation of effectiveness, to market the drug while collecting the necessary effectiveness data. The drug sponsor can market the drug for up to five years while collecting the effectiveness data. At this time only one product has been given conditional approval - Aquaflor-CA1 [141-259]

- There are now two *Indexed* products available in ornamental fish - Aquacalm [900-002] and Ovaprim [900-001]. Indexing occurs when a minor species drug is intended for use in species that are too rare or too varied to be the subject of adequate and well-controlled studies in support of a drug approval. In such cases, FDA may add the intended use to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index). ELDU is prohibited for indexed products and the provision is limited to minor species that are not used as food for humans or other animals.
- Sponsors of minor use and minor species drug development projects are eligible to apply for *Fee Waivers* such as user fees. Sponsors need to contact OMUMS for details of eligibility and application procedures.
- The numbers in the major species that meet criteria for "*minor use*" have been defined. They are equal to or less than: 50,000 horses; 70,000 dogs; 120,000 cats; 310,000 cattle; 1,450,000 pigs; 14,000,000 turkeys; and 72,000,000 chickens.
- The second round of MUMS *Grants* RFPs have been called.

One aim of the MUMS Coalition that has yet to be realized is obtaining taxation concessions for pharmaceutical sponsors for efforts in developing drugs for use in MUMS. This would be similar to the existing program for Orphan Drugs in human drug approvals. This feature requires changes in tax laws and a totally different legislative approach.

www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm125445.htm

FLUNIXIN - PROBLEMS

FDA recently took action against a dealer and hauler of calves for allegedly selling veal calves for human consumption that contained illegal drug residues in edible tissues. The action is for a permanent injunction against the dealer who has had a

long history of violations with both FDA and USDA. In this "final straw" flunixin residues were found and the drug is not approved in veal calves and a withdrawal time in that group has not been established for flunixin.

Readers are reminded that flunixin meglumine, a non-steroidal anti-inflammatory drug or NSAID, is approved by FDA for only IV injection into cattle to control abnormal rise in body temperature associated with bovine respiratory disease, acute mastitis and endotoxemia.

This comes only two years after FDA cautioned veterinarians about the correct use of flunixin in cattle. Flunixin's label limits the route of administration in cattle to intravenous [IV] injection. Administration by any other route is considered to be extralabel and governed by provisions of the Animal Medicinal Drug Use Clarification Act [AMDUCA] which included a valid-veterinarian-client-patient relationship, and in food producing animals, appropriate record keeping, valid justification, and a substantially extended withdrawal period supported by appropriate scientific information.

The problems with flunixin being administered by a non-approved route are:

(a) extralabel drug use [ELDU] cannot be justified by convenience and

(b) in the case of flunixin, intramuscular [IM] administration produces much slower depletion of the drug potentially resulting in violative drug residues

Flunixin is also approved for use in horses [not for meat production] and swine (Banamine®-S). In the horse the approved route is either IV or IM but in swine the only approved route of administration is IM which might account for some of the confusions in cattle where the only approved route of administration is IV. The significance of the different routes of administration is illustrated by comparison of the withdrawal times for the approved doses and routes – cattle IV 4 days for meat and 12 days for swine [milk withdrawal for cattle 36 hours].

OTHER FDA COMPLIANCE ACTIVITIES

The editors of this newsletter hope readers have better things to do other than stalk news items at the FDA/CVM website [www.fda.gov/AnimalVeterinary/default.htm]. However readers would have seen that FDA/CVM has been active in restraining veterinarians, pharmaceutical manufacturers and producers for non-compliance with drug regulations and standards. Several major pharmaceutical firms have been found to have made incorrect advertizing claims that FDA has made them

withdraw. The message here is that veterinarians need to be aware of drug label information as following unapproved advertizing would lead to unintended extralabel drug use.

CONTROLLED DRUG INFORMATION

Veterinarians in food animal practice have limited use of controlled drugs but that is changing. Although not part of FARAD's role, we are including this note here as a service to our readers. Controlled drug laws are administered through the Federal Drug Enforcement Administration [DEA] and they have a very helpful site [www.deadiversion.usdoj.gov]. Veterinarians can register with DEA on line and get a lot of their questions answered through the site's Q&A section. There is currently a 2006 version of the DEA Practitioner's Manual available for downloading.
http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

NOTES TO READERS

Before ending the newsletter , three housekeeping items remain:

Canadian Readers are reminded that the Canadian gFARAD program is alive and thriving. It has its own website - http://www.cgfarad.usask.ca/ providing data peculiar to Canadian drug requirements. All readers are reminded that there are differences in drug approvals between the two countries and extrapolation may be dangerous. Drug formulations, doses and species approved may vary – but most important is that the laws vary and what is legal or not between countries is not minimized by how close we are geographically.

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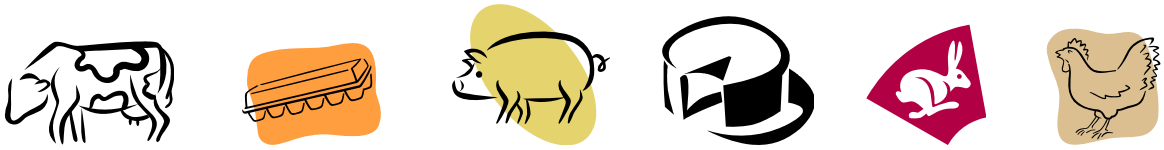
4th Edition!

.FARAD™ on CD

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