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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FARAD on CD

.FARAD has not produced a hard copy of its databases for over ten years. Initially it was because of the re-writing of the core approved animal drug database and subsequent validation of its contents. This was further complicated by funding cuts and uncertainties leading to staff changes. However, as the dust settles we have decided to join the digital age and produce a CD subscription that will be updated quarterly and have PDF files that can be both printed for those who need hard copies and can be searched by words or phrases. Details of this new venture can be found on the last page of this newsletter along with how to order it on-line.

The following minimum requirements are required in order to view the files on the disk:

Adobe Acrobat Reader 7.0 (provided on this CD)

Windows

- Intel® Pentium® processor
- Microsoft® Windows 2000 with Service Pack 2, Windows XP Professional or Home Edition, or Windows XP Tablet PC Edition, Windows 2003 Server, Windows NT SP6 or 6a

- 128MB of RAM min, 256 MB or greater recommended
- Up to 90MB of available hard-disk space
- Microsoft Internet Explorer 5.5 or higher or Netscape 7.1 or 8.0, Firefox 1.0 or Mozilla 1.7

Macintosh

- PowerPC® G4, G5 processor
- Mac OS X v.10.2.8 or 10.3 or 10.4
- 128 MB of RAM minimum, 256 MB or greater memory recommended
- Up to 110MB of available hard-disk space
- Safari 1.2.2 browser supported

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MUMS Update

FDA is working at implementing the Minor Uses and Minor Species Animal Health Act (commonly called MUMS Act): first: an Office of Minor Uses and Minor Species Animal Drug Development has been created with Dr. Andrew Beaulieu as its inaugural director, second: its initial rules for **Designation** have been published for general comment and announcement of a final version is imminent. The designation process is meant to act as an incentive to pharmaceutical companies to gain approval for new animal drugs for minor uses or minor species. It does this by granting seven years of marketing exclusivity, which means the sponsor will face no competition in the marketplace for the approved use of the drug for that time. Schering Plough Animal Health was the first sponsor to be given a drug approval under this new provision with Aquaflor® for treatment of enteric septicemia in catfish [http://www.fda.gov/cvm/CVM_Updates/catfishapp.htm]. The FDA has received a number of other applications for drugs under development and those are listed on FDA's website. Each designation that is granted must be unique, i.e., only one sponsor can be designated for a particular drug substance in a particular dosage form for a particular intended use.

Another set of rules that is underdevelopment is that for **Indexing** – this is a marketing method for minor species where the potential market for a minor species drug is just too small to ever support the costs of the drug approval process and the FDA adds the drug to an index of legally marketed unapproved new animal drugs. This provision promises to be especially helpful to veterinarians treating zoo or endangered animals or classes of animals that include numerous different species, such as ornamental fish. A final area for potential rule making is the **Conditional Approval** *where a* sponsor of a veterinary drug can ask CVM for "conditional approval," which allows the sponsor to make the drug available before collecting all necessary effectiveness data, but after proving the drug is safe. The drug sponsor can keep the product on the market for up to five years, through annual renewals, while collecting the required effectiveness data. Readers who are interested in commenting on these implementations should watch the MUMS at CVM's website [http://www.fda.gov/cvm/minortoc.htm].

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FDA Prohibits Use of Antiviral Drugs in Poultry to Keep Drugs Effective for Humans

Earlier this month FDA issued an order that prohibits the extralabel use in poultry of two classes of approved human antiviral drugs in treating influenza. FDA has taken this measure to help preserve the effectiveness of these drugs for treating or preventing influenza A infections in humans. The drugs involved are adamantane (amantadine and rimantadine) and neuraminidase inhibitor (oseltamivir and zanamivir). Although the prohibition is currently limited to poultry (chickens, turkeys and ducks) FDA has indicated that it may add other animal species to the prohibited list as new data becomes available. Readers of this newsletter are reminded that extralabel drug use (ELDU) is where use or intended use of a drug in an animal is not in accordance with the approved labeling. A current listing of drugs with limited or prohibited ELDU in food producing animals can be accessed in the Code of Federal Regulations. [http://a257.g.akamaitech.net/7/257/2422/10apr20061500/edocket.access.gpo.gov/cfr_2006/aprqtr/21cfr530.41.htm]

FDA states that there have been no reported cases of avian influenza H5N1 in the U.S. and that it is unaware if there is ongoing extralabel use of these antiviral drugs in the U.S. by poultry producers. However, concerns have been raised by a number of public health organizations, such as the World Health Organization, Food and Agriculture Organization, and the World Animal Health Organization, that the extralabel use of these drugs in poultry could lead to the emergence of resistant strains of type A influenza. This is of particular concern if the avian influenza H5N1 (commonly known as bird flu) that has been identified in other countries were to emerge in the U.S.

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Website Password Restored

Visitors to the .FARAD website will notice that the visitors' password system has been restored. If readers have forgotten or want to change their passwords, this can be done at *Member Services* (second item on left side list). User name is your registered e-mail address.

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FDA – Center for Veterinary Medicine

Heads-UP! CVM is moving to a new e-mail system with full names & a new server. An example: donald.duck@fda.hhs.gov. To complete the make-over their phone numbers are changing. Currently they are in dual modes but who knows for how long.

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SUBSCRIPTION INFORMATION

If you wish to be removed from the subscription list please reply to this E-mail and put "REMOVE" in the subject area. To have your name added to the mailing list, just E-mail us at farad@mail.vetmed.ufl.edu with your name, address and phone number. The phone number allows us to contact you if there is any problem with your E-mail address and is not shared with any third party.

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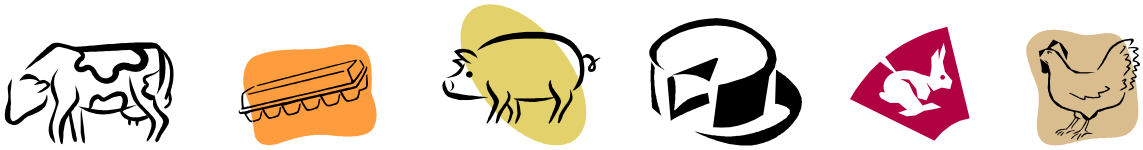
Available NOW!!

.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 renewals 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) but the initial subscription is prorated at $37.50 through December. The subscription is being handled by DHIA Services. Readers can order on-line through the .FARAD web site www.farad.org