



# 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 #11

July 2008

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This will be a short newsletter as we wanted to make you aware of a couple of major items:

- Pending Prohibition of extra-label drug use [ELDU] involving cephalosporins and food producing animals
  
- Future outlook for FARAD

On July 3<sup>rd</sup> the FDA published an order that will prohibit the extra-label use of cephalosporin antimicrobial drugs in food-producing animals. This prohibition, which would affect species such as cattle, swine, chickens, turkeys, and the small ruminants (sheep, goats and deer), is to take effect October 1<sup>st</sup> 2008. Before that date, the FDA has called for comments that can be submitted until September 2<sup>nd</sup> 2008. Such comments should be identified as Docket No. FDA-2008-N-0326 and can be submitted electronically, by fax or by mail. Details on this are contained in the Federal Register (Volume 73, Number 129, pages 38110-38113).

The FDA has stated that they are issuing the order based on evidence that extra-label use of these drugs in food-producing animals will likely cause an adverse event in humans and, as such, presents a risk to the public health.

Many practitioners, producers and industry groups are concerned at the prospect of this prohibition, so are expected to submit comments. We will have to wait and see whether the order will be delayed or modified. FARAD will issue a newsletter as soon as this becomes known. FARAD is also producing a Digest, to be published in JAVMA, that will outline what is behind the FDA's decision as detailed in the original order as well as listing the current permitted labeled uses in the food producing species.

Related links of possible interest to our readers

AMDUCA: <http://www.fda.gov/cvm/Documents/530.txt>

Cephalosporin July 3<sup>rd</sup> notice: <http://edocket.access.gpo.gov/2008/E8-15052.htm>

Current ELDU prohibited list: <http://edocket.access.gpo.gov/2008/E8-15052.htm>

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Many of our readers are aware that FARAD was included in the recently passed FARM Bill. What they may not be aware of is that the Bill AUTHORIZED the program but did not appropriate any funds – the classic grammar catch we learned in middle school – “you may but you can’t”. Simply put, FARAD’s bridging funding, received last September, was for one year only and only by carefully stretching it, can FARAD keep access centers alive through late this year. Again professional groups like AVMA, producers and pharmaceutical industry members are trying to wrinkle an emergency supplement to keep FARAD alive but time is running out. Members of the FARAD program are not allowed to lobby regulatory agencies or Congress on this so we must rely on those who use or depend on the existence of FARAD for implementation of AMDUCA. Here is a link that you can use to find out who your congressional representatives are, along with numbers and e-mail addresses you can use to make them aware of what you think of FARAD [good thoughts we hope].

Congressional Link: <http://www.congressmerge.com/onlinedb/index.htm>

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Other news includes the staff movements within FDA. Starting at the top: Dr Steve Sundlof was appointed Director of the Center for Food Safety & Applied Nutrition. His former deputy at the Center for Veterinary Medicine, Dr Bernadette Dunham, was appointed to succeed him. We congratulate them both and are pleased that these two vital centers are in good hands.

Not wanting to dwell on the musical chair aspect of FDA, we can also report the appointment of Dr Meg Oeller as the director of the Office of Minor Uses and Minor Species. If you need to contact any of the three, their positions, titles and phone numbers may have all changed but their e-mail addresses remain the same.

Aquaculture folk will be pleased to take note that their colleague, Dr Renate Reimschuessel, is one of 29 “Service to America Medal” finalists for her work on the melamine pet food crisis. If it seems odd that a fish worker helps cats you might want to read how she tested her theories with fish.

FDA’s CVM has posted on its web site [[http://www.fda.gov/cvm/ade\\_cum.htm](http://www.fda.gov/cvm/ade_cum.htm)] the Cumulative Adverse Drug Experiences (ADE) Summaries Report [1987 to July 7 2008]. In addition that veterinarians and animal owners can have easy access to information about signs that have been associated with drugs. Appropriate use of this website information is to search the active ingredient of a drug to see if particular signs associated with adverse reactions have been reported with the drug’s use. These signs are listed in order of frequency from most frequently

observed to least frequently observed. The site also explains how the reports are set out and advises how they should be interpreted.

## **ELDU FARAD CONTACT INFORMATION**

### **INTERNET - FARMWeb**

>> Just go to [www.farad.org](http://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.

### **TOLL-FREE >> 1(888) FARAD [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]

### **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 \$\$\$\$.

Those seeking help from other countries should seek help through Global FARAD [gFARAD] if their country is a member.

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### **FARAD ON CD**

FARAD on CD continues 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.

The third issue of the 2008 subscription has just been released 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.

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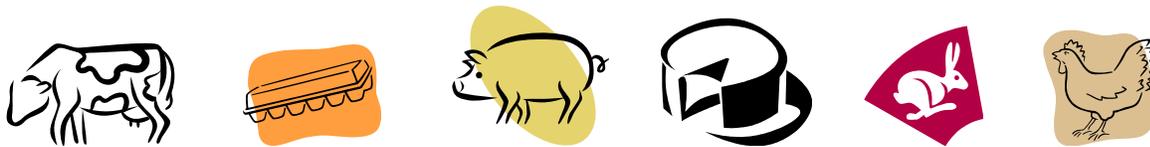
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# 2nd Edition!



## 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](http://www.farad.org)