

From: "Art Craigmill" <alcraigmill@ucdavis.edu>, on 1/18/98 10:56 AM:  
To: Stephen Sundlof@OD@FDACVM, Margaret Oeller@ONADE@FDACVM

The following are comments on the information put on the CVM WEB page with questions about several of the proposals.

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**IS THE PROPOSED PROCESS APPROPRIATELY RESTRICTED TO MINOR USES INVOLVING NON-FOOD ANIMALS?**

Under the proposal, drugs which are "conditionally approved" for use in non-food animals would not be available for use under AMDUCA. This is a fairly inconsistent regulatory state of affairs since non-food (companion) animal drugs are already allowed and extensively used under AMDUCA. This would seem to be inconsistent with the spirit of AMDUCA. Such a restriction would be justified for "new chemical entity" drugs, which have no approval for use in any other species.

Leaving food animals out of this does nothing to alleviate the need for minor-use food animal drugs. Why not come up with a systematic approach to collect the data needed with a conditional approval process for food animals? Perhaps such a program would be like the INAD program for aquaculture, in which data MUST be collected and utilized. This collection of residue data could be coordinated with the FARAD program to mark each animal treated, and actually monitor residues at slaughter for those animals known to have been treated. Such residue studies could also be coordinated with the NRSP-7 program.

This "population" approach to residue monitoring and to establishing real-life WDTs (in field situations and in sick animals) would be far superior to the procedure currently used, and which is a statistically based hypothetical WDT, since it is always done in healthy animals under closely regulated condition.

How much better it would be to get these data from the field!

For a new drug entity, not approved at all in any species, then initial residue studies would of course have to be done for comparison with known toxicology data and a suitable method would have to be available to detect residues in tissue and environmental samples.

**EXPERT REVIEW PANELS: IS THE PROPOSED PROCESS APPROPRIATELY RESTRICTED TO MINOR USES INVOLVING NON-FOOD ANIMALS?**

No. Again, the ERP could serve as invaluable resources for helping with the collection and interpretation of the data above. This would be particularly true for a new entity for which all of the toxicology studies

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necessary for tolerance setting had not been done. An ERP of toxicologists could review know toxicology data to establish provisional safe levels. As with other chemicals, the more that is known, the lower the safety factors needed.

**IDENTIFICATION OF EXISTING FOREIGN NEW ANIMAL DRUG APPROVALS AND/OR DATA ARE THERE SUFFICIENT NUMBERS OF FOREIGN APPROVALS TO JUSTIFY ESTABLISHING THIS PROGRAM?**

The FARAD will be working to compile an international compendium of drugs, focussing on those approved for use in food animals. The answer to this questions should be available within 2 years or less at no additional cost or effort on the part of FDA/CVM.

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