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 Digest: Antidotes in Food Animal Practice

The March 15 issue of the Journal of the American Veterinary Association [*JAVMA]* contains the most recent FARAD digest on antidotes, including withdrawal interval recommendations and information about compounding certain antidotes from bulk drug (*JAVMA*, 226(6), 2005).

This Digest was the result of over one year's work collecting and analyzing data on the pharmacokinetics and residues of antidotes. Interestingly, in many cases the best pharmacokinetic data were available in humans, especially for the antidotes used to treat organophosphate poisoning. A complete list of the references used to write this digest is available at the farad website: www.farad.org.

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Intramammary dosage forms -- Ceftiofur

Summary: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The NADA provides for the veterinary prescription use of ceftiofur hydrochloride suspension, by intramammary infusion, for the treatment of clinical mastitis in lactating dairy cattle.

Conditions of use in cattle: Lactating cows -- Amount: 125 mg per affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days. Indications for use: For the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, Streptococcus dysgalactiae, and Escherichia coli.

Limitations: **Milk taken from cows during treatment (a maximum of eight daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, no preslaughter withdrawal period is required.** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

REF: *Federal Register* 70(38) February 28, 2005.

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Implantation or injectable dosage form new animal drugs -- Zeranol

Summary: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADAs) filed by Schering-Plough Animal Health Corp. The supplemental NADAs provide for the addition of statements to labeling of subcutaneous implants containing zeranol warning against the use of these products in calves to be processed for veal.

Limitations: Implant subcutaneously in ear only. Do not use in bulls intended for reproduction or in dairy animals. Do not use before 1 month of age or after weaning in heifers intended for reproduction. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. **Do not use in calves to be processed for veal.**

Limitations: Implant subcutaneously in ear only. Do not use in breeding animals. **Do not implant animals within 40 days of slaughter.** Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

REF: *Federal Register* 70(26) February 9, 2005

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CVM Update: Labels Changed on Hormone Implants to Indicate that they are not Permitted for use in Veal Calves

A new warning statement has been added to the labels of all growth-promoting hormones reminding producers and veterinarians that their use in veal calves is illegal. While growth-

promoting hormones are approved for use in ruminating cattle, they have never been approved for use in non-ruminating veal calves. FDA's Center for Veterinary Medicine believes that there are differences in the way ruminating and non-ruminating cattle process and eliminate such hormones.

Because there is no approved animal drug application providing for the use of these implants in veal calves, such use is illegal. Under section 512 of the Federal Food, Drug, and Cosmetic Act (the Act), use of an unapproved new animal drug results in the drug being unsafe, and, therefore, the drugs are adulterated. In addition, food that bears or contains these drugs is adulterated under the Act, and a person or firm that uses these implants illegally is also subject to regulatory action.

Sponsors of 16 New Animal Drug Applications (NADAs) and Abbreviated New Animal Drug Applications (ANADAs) for growth-promoting hormones have voluntarily filed supplemental NADAs or ANADAs with the FDA to update the labels on their approved products to indicate that effectiveness, animal safety, and human food safety have not been demonstrated in veal calves. The labels include the following statements: Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established. These statements appear in the Indications section and are in addition to the following statements that are also included in the Warning Section: A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.

January 19, 2005 http://www.fda.gov/cvm
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Implantation or Injectable Dosage Form New Animal Drugs; Estradiol Benzoate and Testosterone Propionate

Summary: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of supplemental new animal drug applications (NADAs) filed by Fort Dodge Animal Health, Division of Wyeth, and Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental NADAs provide for the addition of statements to labeling of subcutaneous implants containing estradiol benzoate and testosterone propionate warning against the use of these products in calves to be processed for veal.

Supplementary Information: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 011427 for SYNOVEX H (estradiol benzoate and testosterone propionate). Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to NADA 135-906 for COMPONENT E-H (estradiol benzoate and testosterone propionate) and COMPONENT E-H with TYLAN (estradiol benzoate and testosterone propionate with tylosin tartrate). The supplemental NADAs provide for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental applications are approved as of October 18, 2004, and the regulations are amended in 21 CFR 522.842 to reflect the approvals and a current format. The basis of approval is discussed in the freedom of information summaries.

Conditions of use. For implantation in heifers as follows:
(1) Amount: 20 milligrams (mg) estradiol benzoate and 200 mg testosterone propionate (one

implant consisting of 8 pellets, each pellet containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate) per implant dose.

20 mg estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 9 pellets, each of 8 pellets containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.
Indications for use. For increased rate of weight gain and improved feed efficiency.

Limitations: For heifers weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal; **not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.**

REF: *Federal Register*, 69(226) November 24, 2004
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New Animal Drugs for Use in Animal Feeds -- Chlortetracycline

Summary: The Food and Drug Administration (FDA) is amending the animal drug regulations to add the approved withdrawal time to the limitations to conditions of use for chlortetracycline Type C medicated feeds for chickens when fed at the 500 gram per ton level. This change is being made to improve the accuracy of the regulations.

Supplementary Information: FDA has found that the April 1, 2004, edition of Title 21, Parts 500 to 599 of the Code of Federal Regulations (CFR) does not reflect the approved withdrawal time for chlortetracycline in Type C medicated feeds for chickens when fed at the 500 gram per ton level. The approved 24-hour withdrawal time at this dose level was inadvertently removed for all sponsors at the time of a supplemental approval of a zero-day withdrawal time for AUREOMYCIN Type C medicated chicken feeds under NADA 48-761 (63 FR 57245 at 57247, October 27, 1998). At this time, FDA is amending the regulations to correct this error in 21 CFR 558.128. This action is being taken to improve the accuracy of the regulations.

Limitations: 500 g/ton: Feed for 5 d; **0-day withdrawal time when formulated from AUREOMYCIN Type A medicated articles or Type B medicated feeds** under NADA 48-761.

Feed for 5 d; **withdraw 24 h prior to slaughter; do not feed to chickens producing eggs for human consumption.**

REF: *Federal Register* 69(250) December 30, 2004
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New Animal Drugs For Use in Animal Feeds -- Decoquinate

Summary: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADAs) filed by Alpharma Inc. The supplemental NADAs provide for the use of single-ingredient decoquinate and chlortetracycline Type A medicated articles to make two-way Type B and Type C medicated

feeds for cattle at a broader range of concentrations.
Supplementary Information: Alpharma Inc. filed a supplement to NADA 141-147 for use of DECCOX (decoquinate) and CHLORMAX (chlortetracycline) Type A medicated articles to make two-way Type B and Type C medicated feeds for cattle at the broader range of concentrations. Alpharma Inc. also filed a supplement to NADA 141-185 for use of DECCOX and AUREOMYCIN (chlortetracycline) Type A medicated articles for the same revised conditions of use. The supplemental applications are approved as of December 16, 2004, and the regulations are amended in 21 CFR 558.195 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

Decoquinate/Cattle: **Withdraw 24 hours prior to slaughter** when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141-147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141- 185. **A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food.**

REF: *Federal Register* 70(10) January 14, 2005
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