The <http://www.farad.org/>FARAD Newsletter
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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## FDA Approves Rumensin® for Increased Milk Production Efficiency in Dairy Cows

The U.S. Food and Drug Administration has approved Rumensin® (monensin sodium) for increased milk production efficiency in dairy cows.

Rumensin®, a product of Elanco Animal Health, a division of Eli Lilly and Company, Greenfield, Indiana, is already approved in feed for therapeutic and production uses in feedlot cattle, pasture cattle (beef and dairy heifers, and slaughter, stocker feeder cattle), beef cows, and calves excluding veal calves.

Rumensin® is the first, approved new animal drug feed ingredient for dairy cows that increases milk-production efficiency. FDA reviewed extensive data to ensure the product met all necessary efficacy, animal health, human food safety, and environmental standards. FDA has concluded that the meat and milk derived from dairy animals fed monensin sodium are safe when the animals are fed according to the approved labeling.

Previous caution statements on the label will remain including the caution not to feed to horses or other equines as ingestion of monensin sodium by horses has been fatal.

FDA's approval of Rumensin® for use in feed for lactating dairy cattle

constitutes a safe use of monensin sodium when used according to the approved label. As a feed additive, extra-label or off label use of monensin sodium is illegal and is not permitted under the Animal Medicinal Drug Use Clarification Act.

FDA/CVM Update, November 3, 2004

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Ractopamine Approved in Cattle

This oral growth promoter was used in pigs ("Paylean") for a number of years. It was approved for cattle late last year. It is particularly important because it is a beta-adrenergic agent (like clenbuterol) and would likely be of high regulatory concern if the drug was used in an extra-label manner. It is also a feed additive and extra-label use in the feed is specifically precluded in AMDUCA. Both Paylean and the new cattle formulation Optaflexx can ONLY be used according to label.

REF: Federal Register 09/18/03
Technical Information
http://www.fda.gov/cvm/efoi/section2/141-221.pdf

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Use of Two Animal Antibiotics Determined Safe, Experts Say

Scientific research shows that use of two macrolide animal antibiotics, tylosin and tilmicosin, does not adversely affect the safety of the food supply. The findings were reported in the peer-reviewed publication, the Journal of Food Protection.

The study assessed two bacteria, which are known to have resistance to certain antibiotics, and developed a mathematical equation to determine if using these two macrolide antibiotics could lead to food-borne infections in humans that are difficult to treat. The results of the study show that the risk of acquiring a resistant Campylobacter infection from beef, pork, or poultry that results in a difficult-to-treat food-borne illness is less than one in 10 million. For resistant Enterococci faecium, the chances are even lower -- less than one in three billion.

The two macrolide antibiotics included in the study, tylosin and tilmicosin, are used in beef cattle to treat respiratory diseases and to prevent liver abscesses. They are used in poultry and swine to treat, prevent, and control diseases and for health maintenance.

The study was conducted using U.S. Food and Drug Administration (FDA) risk assessment guidelines. The study authors analyzed the potential for a person to either acquire macrolide-resistant Campylobacter, a food-borne bacterium, or macrolide-resistant E. faecium, which is thought to carry antibiotic resistance genes, resulting in illness that does not respond to treatment by human antibiotics. Treatment failure was defined as additional duration of illness, progression to a more serious case of illness, or in the worst-case scenario, mortality.

The results were:
Beef: The probability of a resistant infection from beef resulting in treatment failure is less than one case in 236 million per year for resistant Campylobacter and less than one case in 29 billion per year for resistant E. faecium.
Poultry: The probability of a resistant infection from poultry resulting in treatment failure is less than one case out of 14 million people per year for Campylobacter, and less than one in 3 billion people per year for E. faecium.
Pork: The probability of acquiring a resistant infection from pork resulting in treatment failure is less than one out of 53 million people per year for resistant Campylobacter, and less than one out of 21 billion

people per year for E. faecium.

REF: FSnet Release, May 3, 2004

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FDA Withdraws Guidance on Use of Unapproved Hormone Implants in Veal Calves

The Food and Drug Administration (FDA) is withdrawing a Guidance For Industry (GFI #172) entitled "Use of Unapproved Hormone Implants in Veal Calves." This guidance, which was issued April 2, 2004, is being withdrawn because the policy contained within it only applied to veal calves presented for slaughter prior to June 6, 2004.

Additional information about the withdrawal of this guidance document is contained in the July 15, 2004 <http://www.fda.gov/OHRMS/DOCKETS/98fr/04-16036.htm>Federal Register. Questions may be directed to Gloria J. Dunnavan, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Place., Rockville, MD 20855, 301-827-1168, e-mail: gloria.dunnavan@fda.gov.

GFI #172 outlined special measures to ensure the safety of veal in response to the identified illegal use of unapproved hormone implants in veal calves. The policy outlined in this guidance only applied to veal calves presented for slaughter prior to June 6, 2004. Therefore, the guidance is no longer relevant and is being withdrawn.

Growth-promoting hormones are approved for use in ruminating cattle, but 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.

REF: FDA/CVM Update, July 15, 2004

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Reminder – Doramectin Not Permitted for Use in Dairy Cattle

FDA has become aware of recent incidents involving the misuse of Doramectin (Dectomax®) to treat dairy cattle. Doramectin is not approved for use in female dairy cattle 20 months of age or older. If a lactating cow is exposed to Doramectin, milk from the cow may have detectable residues of the drug for as long as 60 days. Any detectable level of Doramectin in milk is considered by FDA to be illegal.

Doramectin (NADA 141-095) is approved for topical use to treat and control various worms (roundworms, lungworms, and eyeworms), grubs, lice, horn flies, and mange mites. It is also approved to control infections and to protect from reinfection with Cooperia oncophora and Dictyocaulus viviparus for 21 days, Ostertagia ostertagi, C. punctata, and Oesophagostomum radiatum for 28 days, and Haemonchus placei for 35 days after treatment.

Under the<http://www.fda.gov/cvm/index/updates/../amducca/amducatoc.htm> Animal Medicinal Drug Use Clarification Act of 1994 amendments to the Federal Food, Drug, and Cosmetic Act, licensed veterinarians are permitted to prescribe extra-label uses of approved animal drugs and human drugs in animals under certain conditions specified in <http://www.fda.gov/cvm/index/updates/../amducca/530.pdf>Title 21, Code of

Federal Regulations, Part 530 . However, non-veterinarians are not permitted to use drugs in an extra-label manner.

As mentioned in the compliance policy guide entitled, " <http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg615-200.html>Proper Drug Use and Residue Avoidance by Non-Veterinarians," "Extra-label use of drugs by non-veterinarians in food-producing animals is a significant public health concern and a contributing factor in illegal residues in edible animal tissue. Such use of drugs is illegal under the Federal Food, Drug, and Cosmetic Act (the Act)."

REF: FDA/CVM Update, June 21, 2004

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Animal Drugs for Use in Animal Feeds; Oxytetracycline

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 Phibro Animal Health, Inc. The supplemental NADAs provide for a 0-day preslaughter withdrawal time for use of oxytetracycline in cattle feed.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 710 Rt. 46 East, suite 401, Fairfield, NJ 07004, filed supplements to NADA 8-804 for TM-50, TM-50D, TM-100, and TM-100D (oxytetracycline) Type A medicated articles and NADA 95-143 for TERRAMYCIN 50, TERRAMYCIN 100, and TERRAMYCIN 200 (oxytetracycline) Type A medicated articles used for making medicated feeds for the treatment of various bacterial diseases of livestock. The supplemental NADAs provide for a 0-day withdrawal time prior to slaughter when Type C medicated feeds containing oxytetracycline are fed continuously to calves, beef cattle, and nonlactating dairy cattle at a dosage of 10 milligrams per pound of body weight for up to 14 days. The supplemental NADAs are approved as of March 12, 2004, and the regulations are amended in 21 CFR 558.450 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

REF: Federal Register, May 19, 2004 (Volume 69, Number 97)

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REMINDER – Medicated Milk Replacers Can Cause Antibiotic Residues in Bob Veal Calves

FDA has seen a dramatic increase in the number of residue violations in bob veal calves due to the drug neomycin. The USDA Food Safety Inspection Service (FSIS) defines bob veal as calves a few days to three weeks of age, weighing up to 150 pounds that are on milk or milk-based diets. The majority of these calves are bull calves from dairy farms. Bob veal make up one third of the total veal slaughtered according to 2002 USDA slaughter statistics.

In 2003, FSIS reported a total of over 1,800 residue violations in the various classes of cattle to FDA for investigation and possible enforcement action. Neomycin residues in bob-veal alone accounted for 44% of these violations. Five states accounted for over 90% of the neomycin residues in bob veal -- Pennsylvania, New York, Maryland, Ohio, and Virginia.

One known source of these neomycin residues is medicated commercial calf milk replacers. Medicated commercial calf milk replacers often contain neomycin (400 grams per ton) and oxytetracycline (200 grams per ton). Their labels carry the warning statement " Warning: A withdrawal period has not been established for use in pre-ruminating calves. Do not use in calves to be processed for veal."

Failure to observe label withdrawal periods before slaughter is the

principal cause of illegal drug residues. Dairy and veal producers using medicated calf milk replacers should observe the labeled withdrawal periods of all products given to young calves that may leave the farm, including medicated milk replacers.

Non-medicated calf milk replacers that do not have a withdrawal period are commercially available. These products have the same nutritional value and differ only by the absence of medication. Use of non-medicated calf milk replacers is recommended for all calves that will be sold off the farm at an early age, and for bob veal calves being held for sale by veal producers.

FDA's Center for Veterinary Medicine urges all food animal producers to remember to read veterinary drug and animal feed labels carefully. They should always follow label directions to help avoid causing illegal residues in the food products they produce.

FDA/CVM Update, July 29, 2004

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Flunixin Approved for Use in Dairy Cattle

New Animal Drugs; Flunixin (Banamine)

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection in lactating dairy cattle for control of pyrexia associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. It also provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection for control of pyrexia associated with acute bovine mastitis and for the establishment of a tolerance for residues of flunixin in milk.

Cattle--(i) Amount. 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day, as a single dose or divided into two doses administered at 12-hour intervals, intravenously, for up to 3 days. 2.2 mg/kg (1.0 mg/lb) of body weight given once by intravenous administration.

Do not slaughter for food use within 4 days of last treatment. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal.

Do not use in dry dairy cows. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. For Nos. 055529, 057561, and 059130: Not for use in lactating or dry dairy cows.

Tolerances--(1) Cattle. The tolerance for flunixin free acid (the marker residue) is:

(i) Liver (the target tissue). 125 parts per billion (ppb).
(ii) Muscle. 25 ppb.
(iii) Milk. 2 ppb.

Ref: Federal Register: October 8, 2004 (Volume 69, Number 159)

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National Milk Drug Residue Data Base

Fiscal Year 2003 Annual Report
Summary

This report presents summary data on samples and tests conducted during the Fiscal Year 2003, October 1, 2002 to September 30, 2003. Fifty States and Puerto Rico submitted data for this report.

The Pasteurized Milk Ordinance (PMO), the rules which State agencies use to implement their milk program, requires that all bulk milk tankers be sampled and analyzed for animal drug residues before the milk is processed. Any tanker found positive is rejected for human consumption.

During this period 4,382,974 samples were analyzed for animal drug residues. Of these samples 2,945 were positive for a residue. A total of 4,456,141 tests were reported on the samples for 11 different groups of families or individual drugs. Thirty-four testing methods were used to analyze the samples for residues. Details are presented in the tables in this report.

For more information link to: http://vm.cfsan.fda.gov/~ear/milkrp03.html

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USDA-FSIS Harmonizes Residue Testing Procedures with FDA

The Department of Agriculture's Food Safety and Inspection Service is modifying its approach to testing meat carcasses for illegal new animal drug residues, and to disposing of carcasses containing residues. The change will make the FSIS' testing procedures consistent with those used by the FDA.

The FSIS announced its intention to make the change in the Federal Register, August 6, 2001, and after reviewing comments from stakeholders, implemented the change June 7, 2004. The change will primarily affect the testing of carcasses of animals treated with new animal drugs for which the FDA has established a residue tolerance for a specific target tissue without also established a residue tolerance for muscle tissue. There are only seven veterinary drugs commonly used in swine and cattle that fall into this category; they are apramycin, carbadox, fenbendazole, melengestrol acetate, morantel tartrate, oxfendazole, and tiamulin.

When the FSIS tests carcasses for residues from those drugs, they will test only the target tissue. If the target tissue contains residues that exceed the FDA's established tolerance, the FSIS will consider the entire carcass adulterated and condemn it. If the FDA has established tolerances for both target and muscle tissue, the FSIS will test the muscle tissue, and allow muscle tissue that contains residues at or below acceptable concentrations to be distributed for human consumption.

Complete information on the change and the FSIS responses to comments on the change is printed in the May 7 issue of the Federal Register.

REF: AVMA, June 15, 2004.
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