VET CALL
INDUSTRY UPDATE

Extra-label Use of Veterinary Drugs Explained

Last October, President Clinton signed the Animal Medicinal Drug Use Clarification Act of 1994. Once implementing regulations are adopted, veterinarians will be allowed by the Act to prescribe extra-label use of veterinary drugs for animals under specific circumstances. In addition, the legislation allows licensed veterinarians to prescribe human drugs for use in animals under certain conditions once implementing regulations are adopted.

It is a violation of current law for users of approved new animal drug products not to follow the exact directions that are on the labeling of the drug. This extra-label use restriction precludes use in species or for indications (disease or other conditions) not listed in the labeling, and use at dosage levels higher than those stated on the label. In addition, the Federal Food, Drug, and Cosmetic Act did not provide for the use of human-labeled drugs for treating animals.

Since FDA recognized that a veterinarian, on occasion, would find the need to use or prescribe use of an approved animal drug in a manner that does not appear on the label, the Agency developed a Compliance Policy Guide (CPG) on extra-label use of animal drugs in food-producing animals. This policy (CPG 7125.06) states that regulatory action against a veterinarian would not ordinarily be considered provided that extra-label drug use by a veterinarian met certain criteria and precautions were observed.

FDA also developed a CPG on the distribution and use of human-labeled drugs in veterinary medicine. This policy (CPG 7125.35) states that under usual circumstances, veterinarians may consider the use of human-labeled drug products in non-food-producing animals without the threat of FDA enforcement action. The CPG also states that FDA recognizes that there are legitimate and important veterinary needs for human-labeled drugs in the treatment of disease or to prevent pain in food-producing animals in instances where there are simply no animal drug products available that would prevent animal suffering and death. Because of these needs, CPG 7125.35 provides for enforcement discretion under certain limited circumstances when food-animal veterinarians prescribe human-labeled drugs within the context of a valid veterinarian-client-patient relationship.

Once FDA adopts implementing regulations, the Animal Medicinal Drug Use Clarification Act of 1994 will permit veterinarians, like physicians, to prescribe drugs as they wish for their patients. However, certain restrictions will be placed on veterinarians prescribing animal and human drugs in an extra-label manner. First, use has to be by or on the order of a veterinarian within the context of a veterinarian-client-patient relationship. Second, the use must be in compliance with regulations to be adopted by FDA.

In the case of animal drugs, the new legislation states that if the Secretary of Health and Human Services finds that there is a reasonable probability that a drug use may present a risk to public health, the Secretary may establish a safe level for a residue for such extra-label use, and require the development of analytical methods for the detection of residues. If the Secretary finds that a use presents a risk to public health or if no analytical method is developed, the Secretary may prohibit such use. The Secretary may also provide access to records of veterinarians to ascertain any use or intended use that the Secretary has determined may present a risk to public health.

Also, the legislation states that extra-label drug use of veterinary drugs is permissible only if no other specifically labeled animal drug is marketed or available to treat the disease condition, or if there is, the label dosage is not clinically effective in the animals to be treated. These restrictions do not apply to the use of human-labeled drugs in animals.

FDA has two years to promulgate regulations to implement the Animal Medicinal Drug Use Clarification Act of 1994. Until the final regulations are adopted, extra-label use will continue to be regulated under CPG 7125.06. Also, the use of human-labeled drugs will be regulated under CPG 7125.35.

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