FDA Accepts AVMA Recommendations on Extra-Label Drug Use

On January 13, 1984, the Food and Drug Administration's Bureau of Veterinary Medicine (BVM) accepted recommendations from the American Veterinary Medical Association (AVMA) that allow veterinarians to use FDA-approved drugs for extra-label purposes under specific conditions.

The AVMA's recommendations were written on December 15, 1983, by the ad hoc Committee on Extra-Label Use of Drugs. They were adopted by the AVMA's Board of Governors on January 5, 1984, and immediately sent to the BVM.

The recommendations specify that when a veterinarian-client-patient relationship exists, veterinarians may prescribe or use FDA-approved products in food-producing animals, but only when the veterinarian has taken appropriate steps to assure adequate identification of treated animals and has provided for extended withdrawal times when necessary.

The AVMA believes that the BVM's acceptance of the recommendations will quell the controversy that resulted from the BVM's announcement last July of a more restrictive drug use policy. Once again, veterinarians will have the freedom to treat animals in a professional manner.

A Brief History and Analysis of the Extra-Label Drug Use Controversy

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On January 13, 1984, Dr. Lester M. Crawford, Director of FDA's Bureau of Veterinary Medicine (BVM), notified the AVMA that the agency agrees with AVMA's recommendations for an enforcement policy regarding the use of drugs in food-producing animals. BVM responded quickly to recommendations that had been adopted by AVMA's Board of Governors on January 5. The AVMA recommendation was accepted without modification.

In July, 1983, Dr. Crawford announced a new enforcement policy intended to crack down on a few "flagrant violators" who were improperly providing drugs for use in food-producing animals. Although BVM consistently maintained that the new policy was aimed solely at a few individuals and companies, the wording of the policy was such as to threaten some generally accepted drug-use practices by legitimate practicing veterinarians.

FDA's policy declared that no use of a drug in a food animal will be tolerated if that use is not specified in the product's labeling. The policy applied to labeling limitations regarding species, indications, and dosages, and it declared that FDA would refrain from regulatory action only in the most limited circumstances.

A conference of veterinarians representing a number of practice groups and spokesmen for several livestock groups met under AVMA auspices in late September to address the issue (see *ISU Veterinarian,* 45:2, p.124). The purpose was to seek a solution to the problem that BVM had identified—but a solution that did not interfere with the legitimate practice of veterinary medicine. The group proposed that FDA modify the policy to declare that extra-label use of drugs in food-producing animals is only appropriate if the drug is used in the context of a bona fide veterinarian-client-patient relationship. It was understood that the veterinarian and client must assume responsibility for any residues that enter the human food supply.

Despite a prompt rejection of the proposal by BVM, the leadership of AVMA adopted the policy in October, 1983, and appointed an ad hoc committee to try again for a solution that

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would be acceptable to BVM and practitioners. The issue continued to be a focus of debate throughout the fall, and the ad hoc committee developed a revised policy statement at a meeting on December 15, 1983. This is the statement that has now been accepted by AVMA and FDA as an appropriate enforcement policy.

The key language of the policy statement, identifying the problem and setting the standard of extra-label drug use, is as follows:

> The Bureau of Veterinary Medicine has found instances in which prescription veterinary drugs have been distributed to non-veterinarians "by or on the order of a licensed veterinarian," but this has taken place under circumstances that the Bureau believes are beyond the intended scope of "the course of the (veterinarian's) professional practice." In other instances, the Bureau has become aware of distribution of other drug substances not approved for food animal use and the use of these drugs in the absence of a veterinarian-client-patient relationship.
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> The agency does not intend to interfere with responsible veterinary practice where diagnosis and treatment dictate drug therapy for a condition for which there is no approved drug or for which approved drugs or dosages have been found to be clinically ineffective. However, scrupulous precautions shall be taken to maintain adequate identity of the treated animals and to assure that appropriate, extended time periods elapse before meat, milk, and eggs are marketed for human food. The agency acknowledges, therefore, that the prudent use of FDA-approved drugs for extra-label purposes is necessary in the course of veterinary practice within the framework of a bona fide veterinarian-client-patient relationship. Furthermore, the agency will take necessary action to prevent, stay, or curb the distribution and use of drugs not approved for use in food animals in the absence of a veterinarian-client-patient relationship.

The policy statement recognizes that a drug should be used in food-producing animals only under the supervision of a veterinarian if FDA has not determined that it can be used safely. This supervision requires the existence of a bona fide veterinarian-client-patient relationship, and that relationship, for the purposes of federal food and drug law, is defined in the policy statement.

Some of the implications of this policy statement deserve to be highlighted:

- AVMA supports the principle of the Food, Drug, and Cosmetic Act that no drug should be used unless it has FDA approval for some purpose, although that approval may not be for the use decided upon by the veterinarian.
- Veterinarians and livestock producers should remember that any extra-label use of a drug has the potential for greater liability than a within-label use. An indication for use on a label of an approved drug assures the user that the drug sponsor and FDA have found, on the basis of scientific evidence, that the use is safe and effective, with side effects or adverse reactions noted. In contrast, with an extra-label use, the veterinarian is on his own to some extent, and he is really on his own if there is little support for his use of the drug within the veterinary medical community.
- Nothing in the policy statement diminishes the veterinarian's or producer's potential liability under federal laws for causing illegal residues of drugs in human food.
- Good judgment must be applied in the interpretation of the sentence that states, "However, scrupulous precautions shall be taken to maintain adequate identity of the treated animals and to assure that appropriate, extended time periods elapse before meat, milk, and eggs are marketed for human food." Reasonable, effective means must be adopted to keep track of any food animal or group of food animals that receives drug therapy that has not been approved by FDA. The "appropriate, extended time period" prior to marketing requires a medical judgment based on the nature of the drug therapy and the condition of the animals.

All the discussions of drug use within the veterinary profession and the livestock industry have heightened the awareness of all parties of the need for proper drug use in food-producing animals. This has, in effect, been an educational activity, and Dr. Crawford urged AVMA to continue to help its members use drugs wisely. In a similar vein, USDA's Food Safety and Inspection Service has been working with the Extension Service to develop informational materials for producers as a part of the Residue Avoidance Program (RAP). There is widespread feeling that it will be much more effective to provide producers and veterinarians with good information on avoiding drug and chemical residues than to implement a stringent (but necessarily selective) enforcement effort by FDA and USDA.