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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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