Veterinary Pharmaceuticals

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The Bureau of Veterinary Medicine is one of the six Bureaus of the Food and Drug Administration. We in the Bureau of Veterinary Medicine are responsible for regulating the use of animal drugs and feed additives by livestock producers to ensure their safe and effective use in treating, preventing and controlling disease in food producing animals, pet animals, and birds. Our responsibility is not only to ensure the safety of drugs for the animal but also for the user and the consumer who buys food derived from treated animals. This latter responsibility is currently our number one priority because it is safe to say that sometime during their lifetime, food producing animals receive one or more drugs before they reach market size or weight. The majority of confined animals, swine, beef cattle, lambs or poultry are fed one or more drugs continuously in their rations for disease prevention or to improve their pound of feed to pound of gain conversion rates in order for them to be raised and marketed more efficiently. In 1973 more than 400 million dollars worth of drugs were sold for use in feed alone. And if these same animals get sick, they are administered a variety of drugs by parenteral injection and by mouth. Unlike drugs used in human medicine, 68 percent of therapeutic drugs used in animals are labeled for over the counter use as opposed to prescription use. That is, the livestock producer can buy most of the drugs he needs to treat his own animals without seeking the aid of a veterinarian.

The intent of Congress when considering the prescription section of the Food and Drug Law has always been to enable a livestock owner to treat his own animals. Therefore if adequate directions for use of a drug by a livestock producer can be written, the Bureau of Veterinary Medicine must permit its sale directly to the user. However, these adequate directions for use must include not only directions for administration of the drug to the animal

but also adequate instructions to enable the farm worker to use the drug safely. Directions for use include, where applicable, cautions to wear gloves, to avoid inhalation, how to dispose of empty containers, emergency antidotes and how to handle and clean equipment. They are based upon information concerning the pharmacology of the chemical, the dosage form of the product, the conditions under which the drug is expected to be used and the results of studies conducted under field conditions which have been designed to demonstrate, among other things, the directions for use can reasonably be expected to be followed in practice.

In addition, today, the label of all drugs given to food producing animals must include a Warning statement telling the user how long after the administration of the last dose of a drug the animal must be withheld from slaughter or its milk or eggs discarded following treatment if metabolism studies have demonstrated that residues of the drug are likely to be found in food following its use.

Although we are not aware of any documented evidence that harm has resulted to man from eating meat containing drug residues, the potential does exist and the literature contains one reported incident from England in which a woman, hypersensitive to penicillin, developed an allergic dermatitis from milk containing as little as 0.018 ppm of penicillin.

Therefore the possibility of harm is present and a major concern of the Food and Drug Administration is not only to educate and prevent the livestock producer from marketing animals and their products too soon after a drug has been withdrawn but also that he doesn't slaughter an injured animal for his own and his family's use without observing drug label warning statements. From the results of an FDA contract recently completed in Missouri, we know there is a positive correlation between the numbers of antibiotic resistant fecal organisms found in farm families and their animals. The same study also demonstrated a positive correlation between the fecal flora of non-farm families that consumed meat from the farms in the study. The

study did not tell us the significance of these data, however. We do not know, and there is no indication that these families have a higher incidence of gastro-intestinal disease than the normal urban family or when ill that these families respond differently to treatment.

Our drug experience reporting system which requires the manufacturer of a drug to report adverse reactions and complaints to us at least once a year of within 10 days if a report is serious, contains only two reports of adverse effect to a drug user. One concerned a veterinarian who swallowed horse worm medicine while stomach tubing horses and had symptoms of nausea and incoordination for 10 days. The other concerned an employee of a small animal hospital who developed a sensitivity to a flea dip for dogs. This does not imply that because we have received so few reports of drug accidents that none occur. On the contrary, it seems strange that we do not have more. We have no reports, for example, of hypersensitivities developing among agricultural workers handling medicated feeds either at feed mills or on farms. Both environments can be extremely dusty and one would think some feed handlers exposed to dust, which in all likelihood contains antibiotics and other medicaments, would show some adverse effects. We know that allergic reactions have occurred among workers exposed to dust in drug manufacturing plants. Perhaps, like a lot of other things, such incidents have not been looked for and therefore not reported rather than not occurring.

At the present time the Bureau of Veterinary Medicine is initiating an audio-visual educational program for use by farm radio and television stations of which there are about 7000, which is designed to tell producers where they can obtain information about proper usage and repeating over and over again the importance of observing the label direction, warning, and caution statements.

We hope by this means, in conjunction with our scientific review of field use data before new animal drugs are approved, to prevent accidental misuse and injuries from occurring during or following the use of animal

drugs. When we do receive reports of adverse effects that either result in harm to an animal, drug user or to people consuming food derived from animals, however we are prepared to take regulatory action to re-label, restrict distribution or if necessary, remove a drug from the market.

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