FDA:
A Case of Drug Abuse

As methods of measuring toxic residues in tissues become more and more sophisticated, "old" drugs will be taken off the market. At the same time, it is becoming more and more time consuming and expensive to get new drug approval from the Food and Drug Administration (FDA). How long will it be before there are virtually no drugs available for use with food-producing animals?

'Hot very long," according to several very qualified sources, who asked not to be identified in fear of potential FDA complications.

People involved with animal health and animal health products were reluctant to talk when asked about the Food and Drug Administration and its effects on the

At the heart of the matter is a piece of legislation that happens to fall under the jurisdiction of the Food and Drug Administration. This piece of legislation deals with drug use approval and is called the Delaney Amendment. The problem in the animal health industry comes from two words in the amendment, "no residue," referring to the amount of any drug allowed in edible portions of food-producing animals.

Sources generally agreed that the Delaney Amendment, at the time it became law, was acceptable. At that time, 1958, scientists were not capable of measuring infinitesimal amounts of residue.

It is the increasing sophistication of methods used to detect residues that is troubling people in the industry. That-and the fact that some agencies seem to have become preoccupied with detecting these minute amounts of residue with no regard to whether they are actually harmful.

To demonstrate the problem, ANGUS JOURNAL sources provided several anecdotes: 'Recently, a hormone implant was developed and then denied approval. The amount of estrogen it introduced into the environment was actually less than the amount a female in heat would normally generate."

same strict requirements as those same products raised here in this country.)

The drug xylazine is awaiting approval. It has been waiting for three years. Xylazine has been used for a number of years as a chemical restraint and analgesia in horses, and it has been proven highly effective and safe for use prior to many surgical procedures in food animals. To quote an article in the JOURNAL OF THE AMERICAN VETERINARY MEDICAL ASSOCIATION:

Short Excretion Time

"1) Xylazine has a relatively short excretion time in cattle. Residues are below 0.1 ppm in all edible tissue except the injection site, liver and kidneys in 10 hours and below 0.1 ppm in all tissue in 72 hours.

"2) Xylazine's specific usage for minor surgical procedures in cattle would preclude its use in animals going to slaughter, and its general use would be in only a small percentage of cattle.

"Xylazine has been used as a therapeutic agent in human medicine. The usual dose of 100 mg. of xylazine in a 1,000-lb. cow would result in less than one-half the safe human dose being consumed if a human ate the entire cow within the first 24


DELANEY
AMENDMENT
"NO RESIDUE"
FDA
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carcinogenic drugs out of the nation's food supply. What they are questioning is the apparent lack of common sense used in dealing with the problem.

They are concerned because risk is not assessed, nor is degree of risk or relationship of risk to benefit considered. In addition, they feel that linking animal studies to human risk is often unrealistic.

Adding to Problem

One source pointed out that certain popular public opinions may be adding to the problem. These opinions hold that additives are evil. Chemical" is a dirty word. Everything must be pure, natural, with little consideration given to the relative risks and benefits involved in the use of certain drugs.

Sources generally agreed that the FDA's representatives are concerned and sincere. However, a common complaint was that the FDA deals too much with theory, not enough with the real world. "Bureaucracy," "red tape," "politics" were words that surfaced frequently in conversations about the FDA, with one unhappy source summing up his opinion, "We're getting a hell of a lot more government than we're paying for."

All cannot be blamed on the FDA, however. According to an article in the JOURNAL OF THE AMERICAN VETERINARY MEDICAL ASSOCIATION, "Congressional committees frequently review, investigate or criticize approval of a new drug. However, we are not aware of any instance of congressional investigation of FDA failure to approve a new drug. It would appear, therefore, that congressional pressure for-negative FDA action on new drug approval is intense."

Cyclic Review

Now there is another regulation facing the food animal health industry, cyclic review, which would require that every drug already on the market would be reviewed every five years using the prevailing methods of detection.

Cyclic review with increasingly sophisticated methods of detection and the literal interpretation of the words "no residue" could add up to zero. Zero drug proval. According to one source, this time will vary with the amount of pressure applied by the drug's sponsor.

So-$5 million and five years are tied up in one drug. What are the implications? What does this mean?

It means that, if a drug does not have a huge potential market, it will not be considered.

It means that, if a compound is even suspected of being carcinogenic, it will not be considered.

It means that drugs for minor species or minor uses will not be considered.

It means that only drugs with a great degree of profitability will be considered-and those are not necessarily the ones most needed.

It means that fewer and fewer drugs will be available.

And it means that available drugs will be

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search-research devoted to keeping existing drugs on the market. And the industry is doing a lot of market research. It is being forced to determine the best market for its products, not the best products for its market.

The American Veterinary Medical Assn. (AVMA) has become so concerned with drug availability that it has formed a committee, the Drug Availability Committee (DAC), to study the problem and offer recommendations to the FDA. In last December's JOURNAL OF THE AMERICAN VETERINARY MEDICAL ASSOCIATION, the DAC addressed FDA Commissioner Kennedy with some of the problems facing the food animal industry.

The DAC could see no reason for new animal drug approval to be divided between two bureaus, the Bureau of Foods and the Bureau of Veterinary Medicine. The committee suggested that the existing too early to tell what effects this may have.

"Old" Versus "New" Drugs

The question of "old" versus "new" drugs was another issue addressed by the DAC. Some drugs have been in use for years, but if a new use is developed for that drug, it is then classified as a new animal drug and can no longer be obtained legally even for its former use. The Bureau of Veterinary Medicine has offered some guidelines here; but/as yet, no real action has been taken.

The AVMA committee has suggested that, for all practical purposes, there are three times in a food animal's life when it should not be considered a food producer. The committee feels that newborn and breeding animals and major surgical cases fall into this category and that these special cases should be exempt from food animal drug restrictions. The FDA has agreed to consider this proposal on a case-by-case basis. At this writing, however, there have been no cases.

Drug Combinations

Livestock management today often involves concentrated confinement breeding, rapid transportation and mixing of animals, all of which contribute to disease outbreaks from multiple causes. Effective treatment often requires combinations of drugs, which is not allowed, so the AVMA has asked the FDA for some freedom from the restrictions governing combinations. In response, the FDA has established guidelines; but, according to one source, these quidelines are so highly technical that they are not satisfactory or realistic. In the meantime, livestock producers are wasting time and money treating animals with two or more drugs sequentially or individually.

The list could go on-and it doesn't get any more encouraging. And the subject of low-level antibiotics in feeds hasn't even been mentioned. That is a story in itself. What does the future hold?

There does seem to be a note of cautious

And unless there are some changes, the