FDA proposal threatens animal drugs

WASHINGTON, D.C. - The most widely used livestock drugs, including a list of products named just last month as among the safest on the market, would face prolonged and costly new testing under a Food and Drug Administration (FDA) proposal called "SOM."

The "SOM", or Sensitivity of Method, proposal was commented upon officially on September 4, by the Animal Health Institute (AHI), the national trade association for the major manufacturers of the animal health products used by U.S. livestock producers.

"The SOM proposal, in its current form, threatens the continued availability of most, if not all, of the widely used drugs presently approved by FDA for use in protecting the health and promoting the growth of food-producing animals," according to Mr. Fred H. Holt, AHI's President. "If put into effect unchanged, 'SOM' would threaten the very future of animal health product research in this country," Mr. Holt added.

As with a previous proposal offered in July 1973, AHI said it supports the philosophy behind the FDA's effort to interpret the animal drug exception to the Food, Drug and Cosmetic Act's so-called "Delaney anti-cancer Clause."

However, the trade association was critical of the proposal's scope and offered its own alternative proposal.

The "SOM" proposal, in concept, is designed to provide a scientific definition of what the animal drug provison means when it says no residues of a carcinogenic drug are to be found in food from treated animals. AHI endorses the idea that safe levels can and must be established for these residues. Without such a definition, AHI's President said, "government and industry will continue to chase the latest definition of 'zero residues' as defined by the newest residue detection test, without ever telling the public what is or is not safe."

AHI said it continues to believe that a workable "SOM" procedure can be developed. Holt said AHI offers an alternative for each step of the FDA procedure. AHI's alternative, he added, assure the safety for the consumer while protecting the health and production efficiency of food-producing animals.

An essential feature of the "SOM" proposal is its threshold assessment system, according to AHI. This system is used to determine whether an animal drug will undergo further testing, which FDA admits will cost at least $4.3 million per product.

FDA says it has 648 drugs currently approved for food-animal use. AHI estimates that in 1978, the combined annual sales of food animal drugs totalled $691 million, according to a survey of its member firms. "It would be economic foolishness for a manufacturer to spend $4.3 million or more to test a drug whose annual sales may be less than $1 million a year," AHI's President said. "Under these conditions, a drug that fails 'threshold assessment' and faces full testing under 'SOM' would simply be withdrawn from the market by the manufacturer."

How many drugs may face the full brunt of "SOM?" In mid-August, FDA's Bureau of Veterinary Medicine (BVM) categorized animal drugs according to their relative human safety. BVM described its "Category I" drugs as having the highest degree of human safety based on the amount of safety data provided by the manufacturers and available in the scientific literature.

AHI estimates that at least nine, and possibly more, of BVM's "Category I" drugs would have to undergo "SOM"-required testing under FDA's proposed threshold assessment scheme. The nine include: amprolium, chlortetracycline, erythromycin, lincomycin, oleandomycin, oxytetracycline, penicillin, tylosin and virginiamycin. All are among the most widely used animal drugs. It's because of their extensive use that most would likely fall under "SOM"'s testing requirements.

AHI scientists and regulatory experts who prepared the Institute's "SOM" comments found the proposal would have the following impacts:

- All but a few of the food animal drugs currently listed in the **Feed Additive Compendium**, the unofficial guide to feed-use drugs, would be subject to the costly and time-consuming new tests.

- Today's most advanced technology cannot provide some of the answers required by FDA's "SOM" proposal; and the effort needed to do the other research work demanded would strain the nation's scientific capacity severely.

- The testing necessary to find a sensitive enough method for detecting drug residues in food, under "SOM", could be the most costly requirement of all. One AHI member firm reports spending over $2 million on the residue test for one product and expects to spend even more before FDA approves a method. This is more than four times the FDA estimate for the cost of the residue test development under the proposed "SOM" regulations.

- The sensitivity of the tissue residue tests that "SOM" may require could be beyond the capability of even the most modern government laboratory and may be altogether beyond the range of present technology.

- The present proposal would probably increase the cost of food to the consumer by reducing livestock production efficiency and increasing losses due to animal disease because of the loss of drugs under "SOM".

In place of the FDA proposal, AHI suggests an alternative under which only drugs shown to be carcinogenic would be subject to the "SOM" regulation. AHI says the law provides that only cancer-causing compounds can be regulated under the "no residue" requirements of the animal drug provision to the Delaney Clause. Animal drugs that are not carcinogenic would continue to be regulated under the general safety provisions of the FD&C Act, noted AHI. This part of the Act requires that a drug be shown to be safe for animals and man, but does not subject them unnecessarily to the more severe restrictions mandated by the Delaney Clause for carcinogens.

"AHI feels that its alternative proposals will accomplish everything the FDA version attempts to do," Mr. Holt said. "But, AHI uses a much more realistic approach by employing 'state of the art' technology."

AHI's proposal would use:

- An expanded threshold assessment to determine which products would two years of chronic toxicity study in two test animals species;

- The results of these tests - along with data from comparative metabolism studies, which test whether laboratory animals and target animals metabolize the drug in the same way, and so-called short-term tests, which show the effects a compound and its metabolites have on bacterial genes – to decide whether a drug should be subject to further testing under the "SOM" regulations or the FD&C Act's general safety provisions.

- A variety of statistical models to predict the safe level of residues permitted in food under "SOM," thereby allowing use of the statistical model that provides the most protection to the public based on the scientific data available; and

- Both government and independent laboratories to validate the residue detection tests with the process similar to that used by the Association of Official Analytical Chemists to review testing methods.