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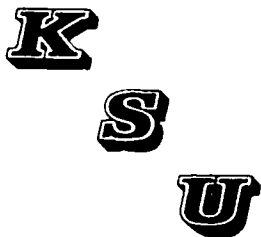
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ANIMAL DRUGS AND THE MILK SUPPLY

Robert W. Wilson¹

The makers of the laws, rules, and regulations governing the production and processing of milk have recognized that milk is the primary diet of the very young and old. This fact mandates that it should be produced and processed in a manner to protect and maintain it in a pure, safe, and unadulterated condition.

To determine adulteration of any milk product, one must first understand the legal definition of that product. In general, milk is defined as "the lacteal secretion of healthy cows that is practically free from colostrum." Anything that alters the product from the intent of this definition constitutes adulteration.

Milk that is further processed also is covered by one of several "Standards of Identity." These are contained in the "Code of Federal Regulations" (CFR's), Title 21; Sections 131, 133, and 135. Any deviation from these standards is considered a violation.

The various regulatory agencies of the country have routinely sampled and tested milk products to assure that they meet these standards. The tests have included those for sediment, added water, pesticides, antibiotics, somatic cells, and bacteria. Now we are entering an era of eliminating sulfamethazine (Sulfas) and other unacceptable drugs from the milk supply. Few, if any, of the drugs administered for the cure or prevention of diseases in animals would be an acceptable residue in the milk supply.

Attention was first focused on the Sulfas by the pork industry, when several foreign countries refused importation of meat because of sulfa residues. At about that time, research was conducted by a manufacturer of laboratory equipment, indicating that the Sulfas were a major contaminate in the milk supplies of this country. So much attention was drawn to this research that it prompted the Food and Drug Administration's (FDA) "Center For Veterinary Medicine" to collect and analyze its own samples.

Forty-nine samples were collected representing different plants. These samples were representative of the product sold in 10 different cities, including Kansas City. Sulfamethazine was the only drug analyzed and was found in 36 of the 49 samples. Many of the concentrations were very low, but were still considered significant because there was no legal use of sulfamethazine in lactating dairy animals.

Sulfamethazine is of special importance, since it is a suspected carcinogen. Congress, in passing the "DeLaney Amendment", has mandated that nothing that can produce cancer in laboratory animals shall be added to food.

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While the upcoming FDA program appears to focus on sulfamethazine, it will attempt to eliminate all unacceptable drug residues from the nation's milk supply. It will do this in the following manner.

- 1) Encourage practicing veterinarians to follow the CFR's and drug labels when prescribing drugs for lactating dairy animals. Dr. G.B. Guest, Director, FDA, Center for Veterinary Medicine, has released a letter noting, among other things, that "veterinarians have a significant role in the production of safe and wholesome animal-derived foods."
- 2) Issue memoranda of interpretation to State regulatory agencies informing them of the necessity for the program. These memos also point out what is considered to be satisfactory compliance in the use and storage of the various drugs found on dairy farms.
- 3) Enlist the aid of American dairy farmers both directly and through their association with the various marketing cooperatives and many national organizations. One of the foremost of these organizations would be the "National Conference on Interstate Milk Shipments."
- 4) State milk sanitation compliance ratings and FDA check-ratings made under the provisions of the "Cooperative State/PHS-FDA Program for the Certification of Interstate Milk Shippers" will stress the proper use and storage of animal drugs.
- 5) States will be encouraged to institute a sampling and testing program that will detect drugs in the milk supply.

Use and Storage of Animal Drugs

Only those drugs that have label indications for use on or in dairy animals will be permitted to be stored in milk houses, milking barns, or adjacent areas. Some judgment may be necessary to identify these drugs. It would be obvious that drugs whose labels only mention dogs, cats, swine, poultry, horses, beef cattle, or other animals should not be stored in any of the three areas stated above.

In the field, we have noted calf bolus products that have been labeled for both "beef and dairy calves" and those just labeled for "calves". Considering the age of the animal being treated, I see no problem with these.

Also noted in the field have been "uterine boluses," which contain Sulfas that are not acceptable for use in dairy animals. I am not aware of a reason to administer a uterine bolus to a non-lactating animal. These types of drugs should not be permitted in the dairy. This is not to say that all "uterine boluses" are unacceptable. Look at the label and see if it gives instructions for use and milk disposal time.

Those drugs labeled "not for use in lactating animals" will probably be acceptable in non-lactating animals. If the label is not clear, check your CFR's. Be sure to be alert when using this type of drug on non-lactating animals to ensure that they are not used too close to freshening. All labels will give a slaughter-withholding time, so the drug should not be administered after that amount of time prior to freshening.

Another similar situation is the drug labeled "not for use in female dairy cattle of breeding age." The drug will give a slaughter-withholding time and should not be used for this length of time prior to breeding age.

Labels of veterinarian-prescribed drugs must meet the "EXTRA LABELING" requirements of the CFR's. This will require the veterinarian's name and address to appear on the label. Also required are the directions for use of the drug and any precautionary restrictions. The veterinarian assumes the responsibility for any drug residue in the milk.

After you are satisfied the drug is one that can legally be on a dairy farm, you must then consider storage. Storage is simpler than determining the status of the drug. All you have to do is determine if the drug is for lactating or non-lactating dairy animals. The two must be segregated from each other during storage. You will have to use judgement in determining what is acceptable segregation. Different shelves in a refrigerator, different shelves in a cabinet, or opposite ends of a long shelf with something stored between could be acceptable; each situation will have to be evaluated.

In general, what we are seeing in the field today is not acceptable for storage of drugs. Everything seems to be thrown on a shelf, in a cabinet or in a refrigerator with labels missing or not readable. There has been no effort to discard out-of-date drugs and we see them with expiration dates up to 5-yr old. In short, we would recommend storing drugs in a neat, orderly condition, so we can evaluate what is available.

Inspections, State Ratings, and FDA Check-Ratings

The State participates in the "COOPERATIVE STATE/PHS-FDA PROGRAM for the CERTIFICATION of INTERSTATE MILK SHIPPERS," which requires substantial compliance with the standards of the program. This means the State must have an inspectional program and enforce the sanitation standards of the program.

In addition, the State is responsible for conducting a sanitation compliance rating of each processing plant and one from each raw-milk source. These ratings are published quarterly and sent to anyone interested in importing milk. A 90% compliance rating is needed for most states to accept imported milk.

The FDA is responsible under the program to conduct check-ratings periodically to determine if the local state inspectors are enforcing the regulations. If it is determined that the exporting state is not meeting the criteria of compliance, the importing state may refuse to accept the milk.

Each item of sanitation on the inspection sheet is given a numerical value so an arithmetic-weighted average can be given the milk plant or raw-milk source. Ten points have been assigned the presence or use of an unacceptable drug (not labeled for use on dairy animals). Two points are deducted if a drug is not properly labeled. A raw-milk source could not tolerate many such violations and still continue to ship milk interstate or to a plant that is on a interstate list.