

FDA Prohibits Extra-label Use of “Bute” in Certain Dairy Cattle

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The FDA has issued an order prohibiting the extra-label use of phenylbutazone, “Bute”, animal and human drugs in female dairy cattle 20 months of age or older. The FDA issued the order based on evidence that extra-label use of “Bute” in these dairy cattle will likely cause an adverse human event. Currently the drug is approved for oral and injectable use in dogs and horses. The use in horses is limited to use in horses not intended for food. No uses are currently approved for food-producing animals.

Recent investigations by FDA and similar state agencies have found “Bute” on dairy farms and identified tissue residues in marketed dairy cattle. The USDA Food Safety Inspection Service has reported residues in marketed dairy cattle present for slaughter for human food. They feel that this is evidence of the extra-label use of “Bute” in female dairy cows 20 months of age or older. They also think this use will result in residues in human food at toxic levels.

AMDUCA allows veterinarians to prescribe extra-label use of approved animal drugs and human drugs in animals. However, the FDA can specifically prohibit the use of certain drugs in animals when such use presents a risk to public health. Phenylbutazone became available for human use in 1949. However, it was removed from use when it became apparent that patients using the drug were experiencing severe toxic reactions and other less toxic drugs became available for treatment. Phenylbutazone is known to cause blood problems that may lead to death, hypersensitivity reactions, and cancer.

The FDA order will become effective on May 29, 2003 unless the FDA revokes or modifies the order or extends the comment period.

Other drug currently prohibited from extra-label use in food-producing animals are:

Chloramphenicol

Clenbuterol

Diethylstilbestrol (DES)

Dimetridazole

Ipronidazole and other nitroimidazoles

Furazolidone, nitrofurazone and other nitrofurans

Sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxine, Sulfabromomethazine, and sulfaethoxyridazine)

Fluoroquinolones

Glycopeptides