LABELING POLICY FOR ANIMAL DRUGS THAT MAY BE HUMAN CARCINOGENS

1. Purpose:

The purpose of this policy is to assure human safety relative to handling and administration of animal drugs that may be human carcinogens. This policy does not address the issues of human food safety or target animal safety.

There may be animal drugs that are suspect human carcinogens but that nevertheless merit approval. Approval is based in part on a determination that there is virtually no risk of human exposure from handling/ administration when the drug is used in accordance with labeling directions. For example, there is ordinarily no risk of human exposure associated with the administration of injectable and solid oral dosage form animal drugs. The potential for human exposure that otherwise exists with some alternate dosage forms (e.g., inhalants and some topicals - dips, sprays, etc.) may be prevented by appropriate container(s), packaging and labeling Warning statements and Directions For Use.

2. Policy:

This policy provides for a labeling statement disclosing that a drug is a potential carcinogen for dosage forms where the potential for human exposure exists but may be eliminated by packaging and labeling directions. The purpose of the carcinogenicity statement is to encourage adherence to labeling instructions intended to prevent human exposure.

The Center for Veterinary Medicine (CVM) definition for evidence of carcinogenic activity in animals is met by studies that are interpreted as showing a chemically or dose-related increased incidence of malignant neoplasms, benign neoplasms, or combination of malignant and benign neoplasms. CVM considers a drug that causes carcinogenic activity in animals to be a suspect human carcinogen. Thus, this policy may be applied whenever there is evidence that a drug is an animal carcinogen. This CVM definition of carcinogenic activity is consistent with the National Toxicology Program (NTP) definitions for positive results.

Any labeling with the statement disclosing carcinogenicity should also contain a Human Warning section to ensure that no undue human exposure occurs from careless handling.

3. Prototype Labeling statement:

"Carcinogenesis:_____ has been shown to (name of drug)
cause cancer in _____ (See Human Warnings)." (species)

4. Implementation:

This policy, as of Sept. 15, 1988, is to be used by all (date) CVM reviewers as they evaluate currently pending unapproved and future original and supplemental submitted to CVM.