OVERFORMULATION IN ANIMAL DRUG PRODUCTS

I. Purpose:

This guide establishes the policy and criteria for permitting overformulation of active drug ingredients in animal drug products.

II. Policy:

All manufacturers of animal drug products should formulate active drug ingredients in new animal drug products and abbreviated new animal drug products at 100% of label claim. Overformulation (addition of an overage) of active ingredients in any drug dosage form (finished pharmaceuticals and Type A medicated articles) may be permitted for extenuating circumstances. Any overage subsequently found unnecessary should be eliminated.

III. Criteria:

A manufacturing overage will be permitted for a new dosage form or an existing approved dosage form under the following criteria:

A. Any proposed overage for a dosage form should be justified with data or information, as follows:

1. A manufacturing overage of not more than 3% of the active ingredient for non-antibiotic dosage forms will be considered acceptable, only if consistent loss of the active ingredient in the manufacturing process is demonstrated.

2. A manufacturing overage of not more than 5% of the active ingredient for antibiotic dosage forms will be considered acceptable, only if consistent loss of the active ingredient in the manufacturing process is demonstrated.

3. A manufacturing overage may be considered for extenuating circumstances other than the consistent loss of the active ingredient in the manufacturing process. Justified overages, in excess to those specified above, may be considered acceptable and will be discussed with the appropriate review personnel in regard to safety to the target species and, where appropriate, any possible effect on tissue residues.

B. Abbreviated new animal drug products will be allowed overages of the active ingredients, as specified above, with appropriate justification. Under most circumstances, abbreviated new animal drug products will not be allowed greater overformulation of the active ingredients than the pioneer new animal drug products.