LABELING

THERAPEUTIC USE DIRECTIONS FOR MEDICATED FEED AND DRINKING WATER

1. Purpose:

This guide establishes the Center's policy on therapeutic use directions for medicated feed and drinking water.

2. Policy:

CVM representatives and the drug sponsor should reach agreement at the protocol stage concerning the method of data collection since this will govern the method of dosage declaration. The key factors of this agreement are that the directions for use must be consistent with the manner in which the studies were conducted and that they reasonably assure effective doses are received.

3. Acceptable Methods for Data Collection:

There are two acceptable options for studying and declaring doses: unit drug/unit of feed or water, or unit drug/unit of body weight. While there is no best way in all circumstances for declaring dosages, it is recognized that the unit drug/unit feed or water is the simplest method, particularly with OTC products. This method, however, may result in a wide-variation in the dose of drug each animal receives due to numerous factors associated with conditions of use.

a. If a mg/gal or gm/ton declaration is desired, the protocol should be developed to measure the inherent variation in feed or water consumption under different environmental conditions. Multi-location titration experiments should be requested utilizing similar protocol in each experiment to document the ranges in consumption under expected use conditions (e.g., various temperature extremes, humidity, and various rations). In this way, efficacy at a particular concentration can be reasonably assured over the range of actual amounts of drug each animal receives and the product can be labeled on a unit drug/unit of body weight dosage.

b. A mg/unit of body weight designation may be desirable for particular diseases in

which a more precise titration is necessary or in cases in which a narrow safety margin exists. In these instances, a single location titration experiment is acceptable where consumption is measured to calculate actual unit drug/unit body weight. Subsequent field confirmation studies also should be conducted to define the actual mg/kg or mg/lb doses received. Directions for use detailing when to vary drug concentrations depending on consumption would be required. Included in this labeling should be a conversion table for mg drug/unit feed or water which incorporates directions for factoring in temperature ranges and/or other criteria that need to be considered. Of particular importance with water preparations is the use of water proportioners and the ability of the user to make proper conversions.