GENERAL REVIEW AND ENFORCEMENT POLICIES

NUTRITIONAL INGREDIENTS IN ANIMAL DRUGS AND FEEDS

The Federal Food, Drug, and Cosmetic Act (FFDCA) defines the term "food" as an article used for food or drink for man or other animals including components of such articles. Thus, any nutrient ingredient (e.g., vitamins, minerals, and amino acids) which is added to a food is also a food by definition. The FFDCA also defines the term "drug" as including any article intended for use as a component of a drug. A nutrient ingredient used as a component of a dosage form drug must meet the requirements for a drug. A nutrient ingredient used as a component of all other medicated products must meet the requirements for a food. While a nutrient ingredient of a non-dosage form product is also a drug when it is intended for use as a component of a drug, the nutrient will be primarily regulated as a food and need not be shown to serve an active drug purpose provided no drug claims are made or implied for the nutrient.

The Center has partitioned animal drugs and feeds into two policy categories: (1) Dosage Form Drug Products, and (2) Non-Dosage Form Medicated and Non-Medicated Feed Products.

1. Purpose:

   The purpose of this guide is to describe the policies pertaining to nutritional ingredients in animal drug dosage form products, non-dosage form medicated feed products, and non-medicated feed products. Refer to Policy and Procedures Guide 1240.3150 for specific guidance on oral electrolytes.

2. Dosage Form Drug Products:

   New animal drug applications (FD 356V) for any animal drug dosage form containing a nutrient ingredient, regardless of route of administration, will not be approved unless:

   a. Each nutrient qualifies as an active drug ingredient, and the product is labeled with appropriate directions for use.

   b. Labeling includes a statement that the nutrient is included to prevent and/or treat the dietary deficiency associated with the disease:

      (1) When a single claim for the prevention and/or treatment of a disease is made,

the nutrient is demonstrated to contribute in an additive manner to the overall efficacy of label claim.

(2) When a separate claim (such as prevention and/or treatment of a dietary deficiency) is made for a nutrient ingredient other than that made for the drug component, data (published or unpublished) are provided to show that a dietary deficiency occurs concurrently with the disease in question in a significant portion of the target animal population, and that the drug alone does not alleviate the deficiency.

c. Data establishes non-interference among the active ingredients in the product.

d. Data demonstrates that the nutrient ingredient is present in a stable, biological active form.

e. The article is not otherwise adulterated or misbranded.

f. When soluble dosage form new animal drugs intended for medication of drinking water contain one or more nutrient ingredients intended only for nutritional purposes, new animal drug applications (FD 356V) for such products will not be approved unless the following conditions are met:

(1) Nutrient components must be clearly indicated to be for nutritional purposes only. When so labeled, the nutrients in drinking water medications will not be subject to 2a.-2e. of this policy and will be considered therapeutically inactive drug components and not active drug ingredients subject to the combination drug policy.

(2) Data establish that the nutrient ingredients do not interfere with the claimed activity of the active drug ingredients.

(3) Information (usually literature references would suffice) supports a need for the included nutrients and establishes that the nutrients will not present a hazard to the target species.

(4) The article is not otherwise adulterated or misbranded.

3. Non-Dosage form Medicated and Non-Medicated Feed Products and Medicated Feeds

a. This section applies to all non-medicated feed products and to all non-dosage form drugs and medicated feeds whether the product is subject to Form FD 356V or Form FD 1900, or waived from the requirements of section 512(m) of the FFDCA.

b. The following medicated products are included in this category:

(1) Type A Medicated Article;

(2) Type B Medicated Feed;

(3) Type C Medicated Feeds;

(4) Free Choice Feeds (Covers only those NADAs submitted as per 21 CFR 510.455(c) (2) and all medicated feed applications which rely on approvals based on this regulation.)

c. The above products containing nutrient ingredients may be considered adulterated and/or misbranded unless they are formulated and labeled so that:

(1) They are not hazardous to animals or humans;

(2) The labeling does not contain any statement which represents or suggests a therapeutic purpose for the nutrient ingredients;

(3) The labeling is not otherwise false or misleading in any particular.

(4) Nutrient ingredients included in free choice feeds which are submitted for approval as per 21 CFR 510.455(c)(1) will not be considered active drug components; rather, they will be regulated primarily as food provided no therapeutic intent is shown.

d. In the absence of any therapeutic intent for a nutrient, there is no need to establish that the nutrient serves an active drug purpose.

e. Nutrient ingredients which are not generally recognized as safe (e.g., new sources or additional species) may require approval in the form of a regulation which may be proposed in a food additive petition as outlined under Section 409 of the Act or by

determination of GRAS eligibility under 21 CFR 570.30 or GRAS affirmation under 21 CFR 570.35.

f. In the post-approval marketed products, those animal feeds found hazardous to animals or humans because of an unsafe level of a nutrient, or because of the presence of an ingredient which is not GRAS or an approved food additive, or because of misbranding due to false and misleading claims, will be considered for enforcement action on a case-by-case basis under the general provisions of the statute.