

GENERAL REVIEW AND ENFORCEMENT POLICIES

---

REGULATING ANIMAL FOODS WITH DRUG CLAIMS

Purpose:

The purpose of this policy guide is to present, in matrix form, guidance for the regulation of animal feeds/foods which may also have intended uses that permit the products to be regulated as drugs under Section 201(g) of the FD&C Act (the Act.)

Discussion:

"Animal feeds/foods" refers to feed for livestock, poultry, or other animals, and pet food. These articles may ordinarily be thought of as foods as defined in Section 201(f) of the Act, and also, in some cases, as food additives under Section 201(s). However, based upon the claims made for these articles, their intended uses may bring them within the definition of a drug under Section 201(g). In such instances, the articles may, as a matter of law, be both a food and a drug simultaneously. The policy guidance herein will assist in the uniform regulation of marketed products falling in these dual categories.

An article's intended use may be shown, for example, by labeling claims, advertising matter, historical use, and by oral or written statements. It may also be shown by the circumstances under which the article is offered and used, regardless of labeling or advertising. (See 21 CFR 201.128.)

The "Legal Status" column in the matrix shows how the articles are legally classified, taking into account their intended uses. Based upon their intended uses most of the articles carry the Legal Status of both a food and a drug. The "Regulate As" column designates how FDA will usually regulate the articles. There are two important points to be made regarding guidance. First, while the guidance is intended to assist in consistent or uniform regulation, it is not intended to be inflexible but is to be regarded as guidance to be followed in most instances for uniformity. Each product should be evaluated against the matrix. Products may not clearly fall under any of the listed line items, so decisions will have to be made within the context of other CVM and FDA policies and priorities. Also, there may be good reason to deviate from the matrix in specific instances, but this should be supported by written justification. The guidance does not indicate priorities for regulatory attention by the Agency. That is a separate judgment.

Second, the matrix applies to both premarketing approval evaluation and to the regulation of marketed products. The Center should be consistent in its regulation of such products. To assure uniformity there should be close consultation between the Office of New Animal Drug Evaluation and the Office of Surveillance and Compliance.

Finally, it has been a long-standing agency policy that nutrients administered parenterally are regulated as drugs. This category is not included in the animal feed/food matrix.

## POLICY MATRIX

<u>Article</u>	<u>Intended Use</u>	<u>Legal Status</u>	<u>Regulate As</u>
1. Animal Feed or Food <u>1/</u>	Disease prevention or therapy excluding prevention of specific nutritional deficiencies (g)(1)(b) <u>2/</u>	Drug - 201(g) Food - 201(f)	Drug
2. Animal Feed or Food	Production claims, see footnote 3 for examples	Drug - 201(g) Food - 201(f)	Drug
3. Animal Feed or Food	Structure or function - (g)(1)(C), excluding production claims <u>3/</u>	Drug - 201(g) <u>4/</u> Food - 201(f) <u>4/</u>	Food
4. Nutritional Ingredient <u>5/</u>	Disease therapy including treatment of nutritional deficiencies; disease prevention excluding specific substance nutritional deficiencies	Drug - 201(g) <u>6/</u> Food - 201(f)(1) &(3) - 201(s)	Drug
5. Nutritional Ingredient	Production claims, see footnote 3 for examples	Drug - 201(g) Food - 201(f)(1) &(3) - 201(s) substance <u>7/</u>	Drug
6. Nutritional Ingredient	Prevention of nutritional deficiencies - (g)(1)(b) excluding diagnosis, cure mitigation, treatment	Drug - 201(g) Food - 201(f)(1) &(3) - 201(s) substance <u>7/</u>	Food
7. Nutritional Ingredient	Structure or function - (g)(1)(C), excluding production claims <u>3/</u>	Drug - 201(g) <u>4/</u> Food - 201(f)(1) &(3) - 201(s) substance <u>7/</u>	Food

8. Non-nutritive Ingredient <u>8</u> /	Disease prevention or therapy (g)(1)(B)	Drug - 201(g) Drug Food - 201(f)
9. Non-nutritive Ingredient	Structure or function - (g)(1)(C)	Drug - 201(g) Drug Food - 201(f)
10. Non-nutritive Ingredient	No disease prevention or therapy or structure/claims - 201(g)	201(s) substance Food Food - 201(f)

FOOTNOTES

- 1/ For the purpose of this Guide, an article which is a mixture of nutritional ingredients intended for use as a substantial source of nutrients in the diet of the animal, which may or may not be limited to the sole ration of the animal.
- 2/ Nutritional deficiency is defined as a well documented condition directly resulting from deficiency of a single essential nutrient.
- 3/ The Center has traditionally reserved claims for improving animal production, such as increased milk production, increased leanness, and improved growth and efficiency of gain, to drugs. These claims will not be permitted for animal feed and nutritional ingredients.
- 4/ In the starch blockers cases the government argued that the intended use of the product dictated whether FDA may regulate the article as a food or a drug; and that the section 201(g)(1)(C) parenthetical "other than food" does not prevent this approach. Both cases resulted in findings that starch blockers are drugs. FDA's legal argument was implicitly accepted by the Seventh Circuit, but explicitly rejected by a district court in New York. The agency continues to look to intended uses in determining whether a product is a food or a drug.
- 5/ A nutritional ingredient is an article intended for use as food which provides nutrition.
- 6/ If the substance is a drug, but not a new animal drug, it may also be regulated as a food additive under section 201(s) (unless it is GRAS or prior-sanctioned). If it is a new animal drug, it is excluded from 201(s) (See 201(s)(5)).
- 7/ Under 201(s) the substance is a food additive, unless it is GRAS or prior sanctioned.
- 8/ The term "non-nutritive ingredient" refers to articles which do not provide nutrition, e.g., mold inhibitors and emulsifiers.