

Attachment 1B

CERTIFIED MAIL

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DRAFT MODEL LETTER

June 4, 2001

Mr. John Smith
Manager, Regulatory Affairs/Nutrition
Bluebird Mills & Pet Care
11111 Bluebird RD
Bluebird, CA 91111

REQUEST FOR COMPLIANCE

Dear Mr. Smith:

On (date), a representative of this agency (your agency) conducted an inspection at (collection point – name & address). The inspection revealed that the following products were offered for sale and distribution at that location: (the products). There is no record of your firm having a current feed license/product registration for these products.

All guarantors of commercial feed and feed ingredients must be licensed and each product must be registered (optional) prior to sale and distribution in (your state). Enclosed are an informational letter, a copy of the Commercial Feed Act & Regulations and an application for a feed license and product registration (optional).

In addition to the licensing and product registration issues, the ingredient(s) (state ingredients) in this/these product(s) are not recognized feed ingredients. All ingredients used in commercial feed must meet one or more of the following criteria:

- Has a common or usual name (salt, sugar, etc.).
- Has a definition accepted by the Association of American Feed Control Officials (AAFCO).
- Is approved by your State agency or Department head.
- Is Generally recognized as Safe (GRAS) by the Food and Drug Administration (FDA).
- Is self-affirmed GRAS (Has all the data required to meet the GRAS standard of safety and general recognition but has not submitted the data for review to a regulatory authority but the data are available upon request.).
- Has a Food Additive Petition approved by FDA.
- Has a New Animal Drug Approval (NADA) from FDA.
- Is an EPA registered pesticide approved for use in feed.

Feed ingredients that are listed as GRAS shall be regarded as GRAS only if, in addition to all the requirements in the applicable regulation, it also meets all of the following requirements:

- It complies with any applicable specifications, or in the absence of such specifications, shall be of a purity suitable for its intended purpose.
- It performs an appropriate function in the feed in which it is used and is GRAS for that function. If the ingredient is GRAS as a flavoring, it cannot be used for another purpose unless it is GRAS for that purpose.
- It is used at a level no higher than necessary to achieve its intended use in the feed. If the ingredient is GRAS as a flavoring, it cannot be used at a level greater than to achieve that function.

The labeling for this/these product(s) also contain drug claims. A drug claim is a claim that states or implies by word or picture that the ingredient or product diagnoses, treats, cures, mitigates, or prevents a disease in man or other animals. The use of the ingredient as specified by claims on the label and in promotional materials is that of a drug, making the product(s) unapproved new animal drug(s). Commercial feeds that contain ingredients that do not meet the criteria listed above or are unapproved new animal drugs are adulterated and/or misbranded under federal and state statutes and are subject to regulatory action. You are hereby notified that you have fifteen (15) days from receipt of this letter to provide written evidence that the ingredient(s) in question meet the criteria stated above for an accepted feed ingredient and that the product(s) is/are FDA approved new animal drug(s). If your firm intends to sell and distribute commercial feed in (state), the proper applications must be submitted to this office. Products not in compliance with the Commercial Feed Act & Regulations are subject to withdrawal from distribution or other regulatory enforcement.

If you have any questions or comments regarding this situation, please contact my office at _____.

Sincerely,

State Feed Control Official
Division of Feed Control

(Initials)

cc: Other Feed Control Officials (AAFCO secure website)
FDA/CVM, Division of Animal Feeds
FDA/CVM, Division of Compliance