

Attachment 1A

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

NOTICE OF WARNING

Dear Mr. Smith:

On (date), a representative of this agency (your agency) obtained a sample of (the product name) at (collection point – name and address). The sample consisted of a portion of the feed and a copy of the label. The sample is referenced by (laboratory sample number and inspector number, if applicable). There is no record of your firm having a current feed license/product registration (optional) for this product. All guarantors of commercial feed and feed ingredients must be licensed and each product must be registered (optional) prior to sale and distribution. Enclosed is 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 registration issues, this product contains the following ingredient(s): (unapproved ingredient(s)). 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.

The ingredients identified above are not recognized for inclusion or use in animal feeds. The labeling for this product contains 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 these ingredients, as specified by claims on the label and in promotional materials, is that of a drug, making the product an unapproved new animal drug. 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.

Because of these licensing, labeling, product and registration deficiencies, you are in violation of Section (?) (Licensing), Section (?) (Registration), Section (?) (Adulteration) and Section (?) (Misbranding) of the Act of (date), (additional codification), "The Commercial Feed Act."

You are hereby notified that you have fifteen (15) days from receipt of this letter to present your written views in response to this notice. Please include in the written response corrective measures that the firm intends to initiate to resolve this issue.

All correspondence and questions should be directed to my attention. If you have any questions or comments regarding this situation, please contact me 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