



July 20, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2001-028

Mr. Eric N. Blomkuist, CEO
Farnam Companies, Inc.
301 W. Osborn
P.O. Box 34820
Phoenix, AZ 85013

Dear Mr. Blomkuist:

An inspection of your Council Bluffs, Iowa facility that serves as a manufacturing/repackaging site for animal feed and as a distribution operation for animal drugs and feeds conducted on June 13-20, 2001 by an Investigator representing this office found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 - Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE) within the borders of the United States. Such deviations cause products being manufactured and/or distributed by your facility to be adulterated within the meaning of Section 402(a)(4) and misbranded within the meaning of Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed the following:

- There are no written procedures demonstrating the clean-out process used to prevent the cross- contamination of product. Your firm uses common equipment for product manufactured with prohibited material and for feed and/or drugs that are not.
- Your firm distributes products that may contain prohibited material, specifically Flex Free, Equinyl, Generation and Max Flex, that are not labeled with the required cautionary statement "*Do Not Feed to Cattle or Other Ruminants*".

The above is not intended to be an all-inclusive list of violations. As a manufacturer of products intended for animal feed use you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. At the conclusion of the inspection Form FDA483, List of Inspectional Observations was issued to

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Ronald G. Adler, Plant Manager identifying these and other deviations. A copy is enclosed for your information.

Our Investigator reported a telephone discussion with Mr. Barry G. Harrison who identified himself as the Corporate Counsel of the Farnam Companies, Inc. During this discussion Mr. Harrison, reportedly, claimed the products in question are exempt from the cautionary statement requirement. This claimed exemption is based on the fact the products are intended only for the equine market and your firm defines horses as pets. We cannot accept this claimed exemption because while some horses may be held as pets, horses are also working animals and in some parts of North America, food animals.

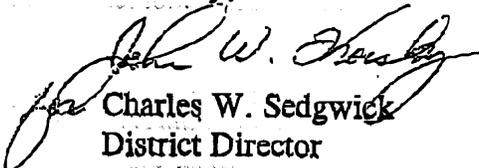
Based on our knowledge of working ranches, horse feed is often stored in the same general area as ruminant feed making a conspicuous cautionary statement vital on feeds and supplements containing prohibited materials.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to make immediate and lasting corrections may result in regulatory actions without further notice including but not limited to product seizure and/or injunction.

You should respond, in writing, within 15 working days of the steps you have taken to bring your firm into compliance with the law. Please include all the steps you plan to take, the timeframe for completing these actions and any documentation demonstrating the action's completion.

Your response should be directed to Ralph J. Gray, Compliance Officer at the above address.

Sincerely,


Charles W. Sedgwick
District Director
Kansas City District Office

Enclosure

Cc: Mr. John C. Williams
CEO, Manufacturing and Distribution
Farnam Companies, Inc.
1302 Lew Ross Road
Council Bluffs, IA 51501