



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER CIN-WL-6466-01

March 5, 2001

John T. Dunbar
President
Champaign Landmark, Inc.
304 Bloomfield Avenue
Urbana, OH 43078

Dear Mr. Dunbar:

An inspection of your feed mill was conducted by a Food and Drug Administration (FDA) investigator on February 13-15, 2001. This inspection 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). Such deviations cause products being manufactured and distributed by your facility to be misbranded within the meaning of Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator examined 30 Mixing and Delivery Tickets for products containing prohibited materials. 15 of those tickets lacked the required cautionary statement "**Do not feed to Cattle or Other Ruminants**". We suggest that you find a more reliable method than simply handwriting the statement on the back of the ticket. We also suggest the statement be distinguished by different type size, color, or other means of highlighting so it is easily noticed by the purchaser.

Other issues in addition to the deficiency noted above:

- We question whether flushing with of crushed corn is adequate to clean your mixer, especially for products containing dried molasses. If you haven't already done so, you should establish that the flush method you use cleans out the remainder of preceding batches containing prohibited materials.
- During the inspection, our investigator verbally advised that your batch records should clearly document that the mixing system was cleaned or flushed in accordance with your approved procedures. It was not clear that writing "yes" on the mixing record meant the system should be flushed or that it had been done. The person conducting the clean-out or flush should document the procedure by initialing and dating the batch record immediately after the step is completed.

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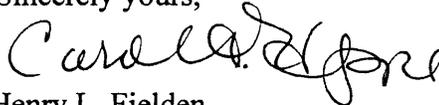
This letter is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in 15 days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Deborah Grelle, Director of Compliance, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Oh 45237, telephone (513) 679-2700 extension 160.

Sincerely yours,


for Henry L. Fielden
District Director

Enclosure: Small Entity Compliance Guide