



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

June 10, 2004

VIA FEDERAL EXPRESS

WARNING LETTER
(04-ATL-13)

M. Dennis Burroughs
President
B & G Seed Company
591 Beck Road
Hull, Georgia 30646

Dear Mr. Burroughs:

An inspection of your feed mill was conducted by a Food and Drug Administration (FDA) investigator on March 30, 2004. Our investigator determined that you manufacture various products, including ruminant feeds, which are animal feeds within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed significant deviations from the requirements set forth in Title 21, Code of Federal Regulations (21 CFR), Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). The deviations cause the feed being manufactured and distributed by your facility to be misbranded within the meaning of sections 403(a)(1) of the Act.

The inspection revealed that not all of your feeds that contain protein derived from mammalian tissues and that are intended for use in animal feed (prohibited material) were labeled with the statement "Do not feed to cattle or other ruminants," as required by 21 CFR 589.2000(d)(1) and (c)(1)(i). An example is your B & G Pig Grower. In addition, you have routinely provided scrap or salvage dog food containing prohibited material to be used as pig feed that was not labeled with the required statement. In the case of bulk feed ingredients, the statement could appear on the placard and invoice that accompany the shipment. The lack of the required statement causes these feeds to be misbranded as defined in section 403(a)(1) of the Act.

Our investigator also noted that you had failed to provide for adequate measures to avoid commingling or cross-contamination of products that contain or may contain prohibited material into feeds that may be used for ruminants, as required under 21 CFR 589.2000(e)(1)(iii). You also failed to establish written procedures for separating products which may contain prohibited material from all other protein products from the time of receipt until the time of shipment, as required under 21 CFR 589.2000(e)(1)(iv).

The above is not intended as an all-inclusive list of violations at your firm. As a manufacturer of animal feeds, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have included a copy of the FDA Guidance for Industry 68 - Small Entities Compliance Guide - Protein Blenders, Feed Manufacturers, and Distributors.

You should take prompt action to correct the above violations, and you should establish procedures 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 fifteen (15) working days of the 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. We do note that you initiated some corrective actions during the inspection, including a feed recall and printing new labels. If corrective action cannot be completed within 15 working days, state the reason for the delay and date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made. Your response should be directed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,



Mary Woleske, Director
Atlanta District

Enclosure