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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

WARNING LETTER

FLA-03-32

May 28, 2003

Lois Linville, President
Zephyr Feed Company
4622 Gall Blvd.
Zephyrhills, Florida 33539

Dear Mrs. Linville:

During an inspection of your feed mill located at 4140 Lynbrook Drive, Zephyrhills, Florida, from March 3, 2003 to March 17, 2003, FDA Investigators Nicolas Riveratorres and Dillard H. Woody determined that you manufacture various products which are animal feeds within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations (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). Such deviations cause products being manufactured and 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 Act.

The inspection found that your firm failed to establish or use appropriate written clean-out procedures and/or flushing procedures adequate to prevent cross contamination of ruminant feeds with feeds or feed ingredients containing prohibited animal proteins, as required by 21 CFR 589.2000(e)(1).

You should establish adequate procedures and verify that the flush/clean-out method you use cleans out the remainder of preceding batches containing prohibited materials. This clean-out procedure should include mixers, conveyors, and conveyances (e.g. trucks) used to transport both types of

feed, as well as storage facilities. Note: If you flush with feed ingredients, or sequence with non-ruminant feed, you must label products made with the flushing material with the cautionary statement "Do Not Feed to Cattle or Other Ruminants", as required by 21 CFR 589.2000(c)(1).

The inspection found that feeds containing prohibited material, specifically chicken feed, were not labeled with the cautionary statement, "Do Not Feed to cattle or Other Ruminants," as required by 21 CFR 589.2000(c)(1). In the case of raw or bulk ingredients, labeling may consist of a placard or other labels attached to the invoice or delivery ticket, or manufacturer's invoice that identifies the animal feed or feed ingredient. The FDA suggests the statement be distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by purchaser or consumer.

The inspection also found that your firm failed to maintain appropriate records (receiving, processing and distribution) of animal feeds for a minimum of one year, as required by 21 CFR 589.2000(h).

During the inspection, your firm's management stated that your firm would no longer manufacture cattle and other ruminant feed. Please indicate in your response to this letter if this is a permanent decision and if you have implemented it.

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, it is your responsibility to ensure that your overall operation and the products you manufacture and distribute are in compliance with the Act and regulations. 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 these or similar violations do not recur. Failure to correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice.

These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to the Food and Drug Administration, Florida District Office, 555 Winderley Place, Suite #200, Maitland, Florida, 32751, Attention: Martin E. Katz, Compliance Officer.

Sincerely,

A handwritten signature in cursive script, appearing to read "Emma R. Singleton".

Emma R. Singleton
Director, Florida District

Enclosure: Form FDA 483

cc: Jay B. Linville, Vice President
Zephyr Feed Co.

Terry Linville, Secretary/ Treasurer
Zephyr Feed Co.