



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

94649d
Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

April 15, 2004

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2004-07

David R. Morris, President
Premium Nutritional Products, Inc.
10504 W. 79th Street
Shawnee, KS 66214

Dear Mr. Morris:

An inspection of your own-label animal food distributor operations was conducted by Investigators from our office on January 13, 14, & 16, 2004. During this inspection, a significant deviation from the labeling requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 - Animal Proteins Prohibited in Ruminant Feed was identified. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Under 21 C.F.R. § 589.2000(g)(2), such a deviation causes products being distributed by your facility to be deemed misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), and these products may not be lawfully introduced, or delivered for introduction, into interstate commerce.

Our investigation found a failure to label your ZuPreem Exotic Feline Diet Canned, manufactured for you by [REDACTED] prior to January 13, 2004, with the cautionary statement "Do Not Feed to Cattle or Other Ruminants," as required by 21 C.F.R. § 589.2000(d)(1) and (c)(1)(i). 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 a purchaser.

The above is not intended to be an all-inclusive list of deviations from the regulations. 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.

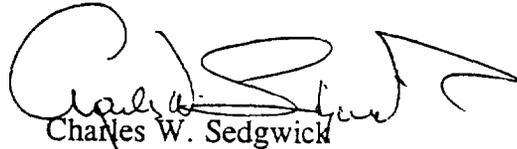
You should take prompt action to correct this violation, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

David R. Morris, President
Premium Nutritional Products, Inc.
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It is necessary for you to take action on this matter now. Please confirm in writing to our office within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. If corrective action cannot be completed within 15 working 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 sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick", written over a faint, illegible typed name.

Charles W. Sedgwick
District Director
Kansas City District