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Food and Drug Administration  
New Orleans District Compliance

DEPARTMENT OF HEALTH AND HUMAN SERVICES

D1249B

4298 Elysian Fields Avenue  
New Orleans, LA 70122

March 11, 1997

WARNING LETTER NO. 97-NOL-29

***CERTIFIED MAIL  
RETURN RECEIPT REQUESTED***

Myron A. Caton/Major Shareholder  
Lumen Food Corporation  
17200 Devonshire  
Northridge, California 91325

Dear Mr. Caton:

During an inspection of your facility, Lumen Food Corporation, 409 Scott Street, Lake Charles, Louisiana, on 1/29-30 and 2/6/97, our investigator documented discrepancies in your label for Smoked Ham Style Cajun Jerky. The product is considered misbranded in that the label fails to meet all nutrition labeling requirements under Section 403(q)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) and Title 21 Code of Federal Regulation (CFR), Part 101.9, and are not exempt under Section 403(q)(5) of the FFDCA from this requirement, and have been labeled on or after May 8, 1994.

Also, the label statement "Smoked Ham Style" is false and misleading under Section 403(a)(1) of the FFDCA, in that it implies that the product contains smoke flavoring and ham. However, based on the ingredient statement, the product contains no ham or smoke flavoring.

The product is also misbranded under Section 403(r)(1)(A) of the FFDCA, in that the label bears the nutrient content claims "low in calories," "low in fat," "high in protein," "high in calcium," and "high in iron" - but fails to qualify for making each of these claims.

The product is also misbranded under Section 403(r)(2)(B) of the FFDCA, in that the label bears the nutrient content claim "No Cholesterol" but fails to bear the referral statement "See \_\_\_\_\_ panel for nutrition information" with the blank filled in with the identity of the panel on which nutrition labeling is located [21 CFR 101.13(g)].

Additionally, the serving size declaration for this product is not in compliance with the new requirements that base serving size on established reference amounts customarily consumed. Jerky is listed as an example within the product category "Fish, Shellfish, Game Meats, and Meat

or Poultry Substitutes": Dried, e.g., jerky, which has a referenced amount of 30 grams. However, we note that the serving size for this product is declared as 1/2 oz. Because the labeled serving size is only one-half of the required amount, the nutrient levels declared in nutrition information are only one-half the amount they should be and significantly misrepresent the nutrient profile for this product. Therefore, the nutrient profile must be recalculated to reflect the correct serving size [21 CFR 101.12(b)].

In addition to the violations previously noted, the following deficiencies should also be brought to your attention.

The statement of identity "A Vegetable Protein Product" should more appropriately be declared as "A Soy Protein Product," and should appear in the same type size as the words Cajun Jerky.

If the ingredient declared as "potassium sorbate" is used as a preservative, then it should be declared as such "potassium sorbate (preservative)" [21 CFR 101.22(j)].

The ingredient declared as "soy protein" fails to appear by its common or usual name (e.g., soy protein isolate) (21 CFR 101.3(b)(2)).

The law requires that the net contents be declared in metric units as well as inch-pound units. However, FDA has not published final regulations on how the declaration is to be made. The agency recommends that if you wish to avoid having to change labels again when the regulations on the metric declaration become effective, you should add the metric contents statements now, using the guidance provided in the proposed regulations published in the Federal Register of December 21, 1993. We expect that any differences will be minor and will not by themselves require a label change.

The above violations concern new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

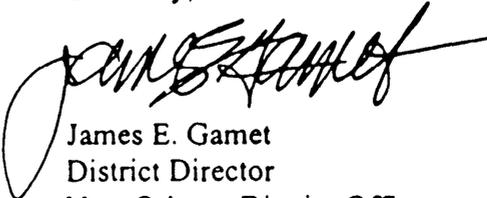
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Page 3 - Lumen Food Corporation/Lake Charles, LA - W/L 97-NOL-29 3-11-97

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

Sincerely,



James E. Gamet  
District Director  
New Orleans District Office

Enclosure: Labeling information package  
Federal Register 12/21/93

cc: Greg J. Canton, President  
Lumen Food Corporation  
409 Scott Street  
Lake Charles, Louisiana 70601