



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Los Angeles District  
Pacific Region  
19701 Fairchild  
Irvine, CA 92612-2445

Telephone: 949-608-4415  
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**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

August 25, 2004

W/L 45-04

Gregory F. Victor, President  
La Vencedora Products, Inc.  
3322 Fowler Street  
Los Angeles, CA 90063-2510

Dear Mr. Victor:

On May 12, 2004, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your facility at 3322 Fowler Street, Los Angeles, California. During this inspection, the investigator collected label samples from your firm's "El Rancho" brand Black Bean and Garlic Chips product (7 oz. retail package). Our review reveals that this product is misbranded under Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21 of the Code of Federal Regulations (21 CFR), Part 101- Food Labeling. You can find the Act and FDA's food labeling regulations through links on FDA's Internet homepage at: <http://www.fda.gov>.

The "El Rancho" brand Black Bean and Garlic Chips product (7 oz. retail package) is misbranded under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the label bears the claim "High in Fiber," which is a nutrient content claim because it characterizes the level of fiber in the product, but the claim does not comply with regulations that define the term "high" [see 21 U.S.C. § 343(r)(2)(A)(i)]. When used to describe the level of a nutrient, the term "high" is defined by regulation to mean that the food product contains 20 percent or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) of the referenced nutrient per reference amount customarily consumed (RACC) [21 CFR 101.54(b)(1)]. The DRV for fiber is 25 grams [21 CFR 101.9(c)(9)] and 20 percent of this amount is 5 grams; the RACC for chips is 30 grams [21 CFR 101.12(b), Table 2, Snacks]. Therefore, your "El Rancho" brand Black Bean and Garlic Chips product should contain at least 5 grams of fiber per 30 grams of chips; however, the nutrition labeling for your product declares only 2 g of fiber per 28 grams of chips. Thus, the nutrient content claim "high in fiber" on your product's label misbrands your product under section 403(r)(1)(A) of the Act because this claim is not made in accordance with the definition for the term "high" in 21 CFR 101.54(b)(1).

Letter to Mr. Gregory F. Victor, La Vencedora Products, Inc.

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The above violation is not meant to be an all-inclusive list of deficiencies for your products or their labeling. It is your responsibility to ensure that all of your products comply with the laws and regulations enforced by FDA.

You should take prompt action to correct this violation and to prevent its future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. For example, FDA can take further action to seize your violative product(s) and/or enjoin your firm from shipping or receiving adulterated or misbranded products.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you have taken to correct these deviations. You may wish to include in your response copies of revised labels or other useful information that would assist the agency in evaluating your corrections. If you cannot complete all corrections before you respond, please explain the reason for your delay and state when you will correct any remaining deviations.

Your written reply should be addressed to:

Pamela B. Schweikert, Director  
Compliance Branch  
U. S. Food and Drug Administration  
19701 Fairchild  
Irvine, California 92612-2445

If you should have any specific questions regarding this letter, please contact Mr. Robert B. McNab, Compliance Officer @ (949) 608-4409.

Sincerely,



Alonza E. Cruse  
District Director