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## Inspections, Compliance, Enforcement, and Criminal Investigations

### Diamond Food Inc. 2/22/10



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
College Park, MD 20740

FEB 22 2010

#### WARNING LETTER

#### VIA OVERNIGHT MAIL

Michael J Mendes, President and Chief Executive  
Diamond Food, Inc.  
1050 S. Diamond St.  
Stockton, California 95201

Re: CFSAN-OC-10-11

Dear Mr. Mendes:

The Food and Drug Administration (FDA) has reviewed the label for your "Diamond of California Shelled Walnuts" products and your website at [www.diamondnuts.com](http://www.diamondnuts.com). Based on our review, we have concluded that your walnut products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations (21 CFR). You can find copies of the Act and these regulations through links in FDA's home page at <http://www.fda.gov>.

#### Website

Based on claims made on your firm's website, we have determined that your walnut products are promoted for conditions that cause them to be drugs because these products are intended for use in the prevention, mitigation, and treatment of disease. The following are examples of the claims made on your firm's website under the heading of a web page stating "OMEGA-3s ... Every time you munch a few walnuts, you're doing your body a big favor.":

- "Studies indicate that the omega-3 fatty acids found in walnuts may help lower cholesterol; protect against heart disease, stroke and some cancers; ease arthritis and other inflammatory diseases; and even fight depression and other mental illnesses."
- "[O]mega-3 fatty acids inhibit the tumor growth that is promoted by the acids found in other fats ... "

- "[I]n treating major depression, for example, omega-3s seem to work by making it easier for brain cell receptors to process mood-related signals from neighboring neurons."
- "The omega-3s found in fish oil are thought to be responsible for the significantly lower incidence of breast cancer in Japanese women as compared to women in the United States."

Because of these intended uses, your walnut products are drugs within the meaning of section 201 (g)(1)(B) of the Act [21 U.S.C. § 321(g)(B)]. Your walnut products are also new drugs under section 201(p) of the Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for the above referenced conditions. Therefore, under section 505(a) of the Act [21 U.S.C. § 355(a)], they may not be legally marketed with the above claims in the United States without an approved new drug application. Additionally, your walnut products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your walnut products are also misbranded under section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

Your walnut products are also misbranded under section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because your firm's website also contains several additional unauthorized health claims. The following are examples of the claims made on your firm's website:

- "Studies have also shown that omega-3s may lower the risk of stroke ..."
- "[T]here's good evidence that omega-3s can increase HDL (good cholesterol), further reducing the risk of stroke and heart disease."

### **Product Label**

Further, your "Diamond of California Shelled Walnut" product is misbranded under section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] in that your product bears health claims that are not authorized by the FDA. The front and back of your product label bears the phrase "OMEGA 3 2.5 g per serving." Within the context of this label, the heart symbols adjacent to information about the amount of omega-3 in the product, constitute implied health claims about consumption of omega-3 and a reduced risk of coronary heart disease [21 CFR 101.14(a)].

The back of your product label also bears the following statement: "The omega-3 in walnuts can help you get the proper balance of fatty acids your body needs for promoting and maintaining heart health. In fact, according to the Food and Drug Administration, supportive but not conclusive research shows that eating 1.5 oz of walnuts per day, as part of a low saturated fat and low cholesterol diet, and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. Please refer to nutrition information for fat content and other details about the nutritional profile of walnuts." Although FDA exercises enforcement discretion over the last two sentences of this statement, which meet the criteria for a qualified health claim for walnuts and coronary heart disease, the last two sentences read in conjunction with the first sentence makes the entire statement an unauthorized health claim.

The statement suggests that the evidence supporting a relationship between walnuts and coronary heart disease is related to the omega-3 fatty acid content of walnuts. There is not sufficient evidence to identify a biologically active substance in walnuts that reduces the risk of CHD. Therefore, the above statement is an unauthorized health claim. This letter is not intended to be an inclusive review of your products and their labeling. It is your responsibility to ensure that all of your products comply with the Act and its implementing regulations.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. Such action may include, but is not limited to, seizure or injunction.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations. You should

include in your response documentation such as revised labels or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Your response should be directed to Latasha Robinson, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, you may contact Ms. Robinson at 301-436-1890.

Sincerely,

/S/

Roberta Wagner  
Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition

cc: San Francisco District Office

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**Links on this page:**