



MAR 10 2003

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Kim Weisner  
Oregon's Wild Harvest  
43464 S.E. Phelps Road  
Sandy, Oregon 97055

Dear Mr. Weisner:

This is in response to your letter of January 17, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual nor does it certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit a notification in accordance with the requirements in 21 CFR 101.93(a).

Nonetheless, in resubmitting your notification, you should be aware that some products bear claims that do not appear to be claims subject to 21 U.S.C. 343(r)(6).

The product **Gymnema** uses the claim "Supports Sugar Balance." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to your claim about sugar balance; that is, a claim that does not establish that the claim is about blood sugar that is already within normal limits implies that the products are intended to treat elevated blood sugar or diabetes, which is a disease.

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You also make a claim of "Allergy Symptom Support" for the product **Allergy Aid**.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products (including the use of the word "allergy" in the name of the product Allergy Aid) suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.

Director (Acting)

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340



Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street  
Washington, D.C. 20204

January 17, 2003

Notification of Statements  
Of Nutritional Support

This notification is filed pursuant to section 403 ( r ) (6) of the federal Food, Drug and Cosmetic ACT (FDC Act), 21 U.S.C. ss 343 ( r ) (6) . Please see attachment for a listing of dietary supplements and corresponding statements of nutritional support.

These statements are being accompanied by the required disclaimer pursuant to Section 403 ( r )(6)(C) ) of the act.

Statements of nutritional support are based on data that render these statements substantiated, truthful and non-misleading.

Two copies of this letter and it's attachments are enclosed.

Sincerely,

Kim Weisner  
Oregon's Wild Harvest

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<b>Dietary Supplement</b>	<b>Brand Name</b>	<b>Statement of Nutritional Support</b>
	<b><i>Oregon's Wild Harvest</i></b>	
Quercetin, N-Acetyl Cysteine	Allergy Aid	Allergy Symptom Support
Maitake mycelia	Maitake	Immune Support
Saw Palmetto berry, Pygeum, Lycopene	Prostate Health*	Prostate Health
Cordyceps mycelia and fruiting body	Cordyceps	Vitality Support
Chaste Tree Berry	Vitex	PMS Support
Gymnema leaf and leaf extract	Gymnema	Supports Sugar Balance
Billberry fruit, Eyebright, Lutein, Zeaxanthin	Eye Health*	Eye Health