DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 14 2003

2107 '03 APR 18 P1:59

Ms. Joanne Roberts
Quality Control Manager
Oregon's Wild Harvest
43464 S. E. Phelps Road
Sandy, Oregon 97055

Dear Ms. Roberts:

This is in response to your letter of April 2, 2003 to the Food and Drug Administration (FDA). Your letter responded to our letter of March 10, 2003 in which we described concerns about certain claims being made for your products pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

In our previous letter, we stated that the claim "Supports Sugar Balance" appeared to be a disease claim because it did not clearly establish that the claim is about blood sugar that is already within normal limits. In your current letter, you proposed to revise the claim to be "Supports Maintenance of Healthy Sugar Levels." We do not believe that the revised claim completely addresses the objection raised in our previous letter because it does not explicitly establish that the claims are about the maintenance of healthy blood glucose levels that are **already within normal limits** (emphasis added). Therefore, we believe that the revised claim continues to imply that the product is intended to treat elevated blood glucose or diabetes, which is a disease. This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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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

OREGON'S WILD HARVEST

Susan J. Walker, M.D,
Acting Director
Division of Dietary Supplement Programs (HFS-810)
Office of Nutritional Products, Labeling and Dietary Supplements
US Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD, 20740

APR 0 8 2003

April 2, 2003

RE: LETTER DATED MARCH 10th 2003 REGARDING CLAIMS MADE TO PRODUCTS: ALLERGY AID AND GYMNEMA

Dear Dr. Walker:

Thank you for bringing this issue of non-compliance to our attention. It is very important to us that we are in full compliance as we do not wish make misleading claims on any of our products.

We intend to market these two products cited above as dietary supplements and not as drugs.

In light of this recommendation we have decided to change the names and claims as follows:

Original Product Name	**New Product Name**	**Original claim**	**New Claim**
Gymnema	**Gymnema**	Supports Sugar Balance	**Supports Maintenance of Healthy Sugar Levels.**
Allergy Aid	**Aller-Aid**	Allergy Symptom Support	**none**

We have documented the label revisions and the changes have been submitted to our printer. The revised versions will be printed when needed.

Please inform us if any further action is necessary on our behalf.

Yours Sincerely

Joanne Roberts

Joanne Roberts, Quality Control Manager

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