



SEP 27 2005

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Robert Held

Wellness Support Network

1449 Marion Drive

Glendale, California 91205

Ref. No. CL-05-HFS-810-193

Dear Mr. Held:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.realfoodnutrients.com> and has determined that the products "WSN® Diabetic Pack" and "WSN® Neuropathy Support Formula" are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

WSN® Diabetic Pack

"Don't be a prisoner of Diabetes! You don't have to go down the path of diabetic oral drugs, insulin, and eventually diabetic complications. ...Now there is a completely natural product that will help lower your blood sugar levels safely and effectively with absolutely no side effects! Guaranteed!"

*"Nobel Prize winning technology validates WSN® Diabetic Pack ingredients! Studies show a **31.9%** drop in blood sugar levels!"*

"The WSN® Diabetic Pack Breakthrough Benefits* Include:

- ✓ Lower Blood Glucose Levels ...
- ✓ Lower Cholesterol Levels ...
- ✓ Less Dependency on Medications"

"Diabetes is a disease that if you don't take effective action against, it simply gets worse. Unfortunately, medications only treat the symptoms and usually do nothing to address the underlying causes. The good news is that cutting-edge science and nutrition have come together to create a truly monumental and natural breakthrough for diabetics. ...The reason Foodform® technology works is because it operates at the cellular level and addresses a key problem that every type 2 diabetic has. All type 2 diabetics have a deficiency of key nutrients the body needs to support healthy blood sugar levels."

*"This study [of an herbal ingredient in WSN® Diabetic Pack] was done on type 2 diabetics (mildly insulin dependent) and reported an **average drop of blood glucose levels of 31.9% and average weight loss of 4.8 pounds in just 30 days!**"*

"The staff of Wellness Support Network have over 12 years of experience working with diabetics and the diabetic condition."

Your web site also contains disease claims in the form of testimonials, including:

“My blood sugar went from 230 to 117 in just 21 days.” - James Marshall, Georgia”

“Barbara Culver, Michigan

"I was taking 50 units of insulin plus pills twice a day and my blood sugar just kept going up. I was tired all of the time and could fall asleep as soon as I sat down. I also kept gaining weight.

Since I've been ... using the Diabetic Pack ... I have all kinds of energy and my sugar is down in the low 100s also I don't take insulin any more!"

“Mike Corcoran, California

"About 60 days ago when I started your program my blood sugar count was at 332. My kidneys were in very poor condition

Just today I was given my results from my last physical and can report that my blood sugar count is 117 and my kidney function[sic] is just slightly elevated above normal (which is a vast improvement [sic] from when I was first diagnosed). ...

By the way, I forgot to mention... when I was first diagnosed, I weighed over 250 pounds and my blood pressure was high. I now weigh 193 pounds and my blood pressure is normal." "

In addition, the name of your product suggests that it is intended for use in the cure, mitigation, treatment, or prevention of diabetes, a disease.

WSN® Neuropathy Support Formula

“Clinical Studies validate WSN® Neuropathy Support Formula Ingredients! Studies show a significant reduction in neuropathy symptoms!”

“It is amazing! The neuropathy in my feet, especially my toes is gone!” - Sandra Peters, Tennessee”

“The WSN® Neuropathy Support Formula Breakthrough Benefits Include:

- ✓ Reduced Tingling or Numbness in the Fingers, Toes or Legs
- ✓ Ability to experience touch without pain
- ✓ Reduced Feeling of Cold, Burning or Pain in the Hands, Feet or Legs
- ✓ Improved Sense of Balance and Coordination
- ✓ Reduced Pain and Cramps
- ✓ Less Dependency on Medications”

“Now, for the first time, you can safely and naturally reduce or entirely eliminate the pain and discomfort caused by neuropathy, without the need of drugs or medications. ...

Unfortunately, drugs and medications only treat the symptoms and usually do nothing to address the underlying causes. The good news is that cutting-edge science and nutrition have come together to create a truly monumental and natural breakthrough for people who are affected by neuropathy.”

“Diabetes and Neuropathy

Up to 60 percent of all diabetics suffer from neuropathy. One form of diabetic neuropathy is a condition where the nerves around the periphery (outer part of the body) are damaged. It is called “Diabetic Peripheral Neuropathy”. ...

The staff of Wellness Support Network have many years of experience working with individuals and diabetics who have been suffering with neuropathy.”

“Order your WSN® Neuropathy Support Formula below and experience the results for yourself.

[Click here to learn about the causes of peripheral neuropathy and information about this amazing breakthrough and what you can do to reverse the condition.](#)

In addition, the name of your product suggests that it is intended for use in the cure, mitigation, treatment, or prevention of neuropathy, a disease.

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Linda J. Webb, Compliance Officer, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Ms. Webb at (301) 436-2375.

Sincerely yours,

/s/

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