DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
College Park, Maryland 20740

MAR 27 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Roy O. Day, Jr.
R. Day Enterprises, Inc.
284 Industry Way
Upland, California 91784

Ref. No. CL-06-HFS-810-211

Dear Mr. Day:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.rday.com and has determined that the products "Slim' R Days 120" and "Complete Breast Enhancing 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:

Slim' R Days 120
"To test the Hoodia, morbidly obese people from Leicester, England were kept in a place as close to prison as it gets. All the volunteers could do was read papers and watch television -- and eat. Half the group was given Hoodia gordonii and half was given a placebo. At the end of 15 days, the group taking Hoodia had reduced their food intake by 1000 calories per day!"
"Hoodia also … counteracts depression."

Complete Breast Enhancing Formula
"**Fenugreek Extract** [an ingredient in the product]: Trigonelline, a chemical found in Fenugreek, has been in testing as a potential treatment for cancer as well."
"**Mexican Wild Yam** [an ingredient in the product]**:** Commonly used as a treatment for osteoporosis …."
"**Kelp** [an ingredient in the product]: Cultural studies relating to the result of diet including kelp have determined a link to a lower breast cancer rate …."

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, 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.

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.

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. 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)). The manufacturer of a dietary supplement containing a structure/function claim in the product's labeling must have substantiation that the claim is truthful and not misleading [21 U.S.C. § 343(r)(6)(B)].

The Internet labeling of "Complete Breast Enhancing Formula" bears structure/function claims, including the following:

> "RDAY'S Complete Breast Enhancing Formula contains phytoestrogens (naturally occurring non-hormonal plant estrogens). These phytoestrogens stimulate your body to produce new breast tissue growth. Your body responds to RDAY'S Complete Breast Enhancing Formula the way it responds to puberty or pregnancy- with renewed glandular tissue growth in the breast receptor sites."
>
> "Women using RDAY'S Complete Breast Enhancing Formula experience … increases of one, two and sometimes even three cup sizes."

We have reviewed these claims and have concluded that they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded under sections 403(a)(1) and 403(r)(6)(B) of the Act [21 U.S.C. § 343(a)(1), (r)(6)(B)]. It is a violation of section 301(a)

of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded [21 U.S.C. § 331(a)].

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