



DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
7520 Standish Place - Room 254
Rockville, MD 20855

December 13, 2000

Ref. No. 01-HFD-310-062

Marcy Weinzimer
Purple Mountain Products
310 East Ridgeland St.
Tucson, AZ 85737

Dear Ms. Weinzimer:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: <http://www.purplemountainproducts.com> and has determined that the products, RENEWED BALANCE Body Cream, Activated Ginkgo, PARA 90, Cellsparc 360, EarthWise, Barleygreen, METABOLITE, PROANCYNOL, and Reassure, being offered on this site are promoted for conditions that may cause them to be drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)]. The products may be considered drugs because the therapeutic claims as shown on your web site establish their intended use as drugs.

Examples of some of the products and claims observed on your web site include, in part:

RENEWED BALANCE: reference to progesterone in product labeling, symptoms of hormonal imbalance, breast swelling and tenderness, fatigue, hot flashes, night sweats, mood swings. Comparison to ERT, HRT, progestin, and Provera. Fluid retention, nausea, insomnia, and depression, breast fibrocysts, and normalize blood clotting and blood sugar levels.

Activated Ginkgo: vascular conditions, cardiovascular disease, arthritis, other health conditions, interfere with platelet activating factor (PAF). PAF has been implicated in asthma, graft rejection, and other immune disorders.

PARA 90: parasites, hookworm, roundworm, pinworm, constipation, diarrhea, irritable bowel syndrome, joint and muscle aches and pains, anemia, allergies, skin conditions, sleep disturbances, chronic fatigue, abdominal pain, allergic reactions, depress[ed] immune system function, malabsorption of nutrients, prevent growth of bacteria, destroys worms, expels worms, muscular spasms, convulsions, and cramps.

Cellsparc 360: heart disease, congestive heart failure, and reduce serum cholesterol.

EarthWise [colloidal silver]: viruses, bacteria, and fungi.

Barleygreen: more than 80 diseases, increases in the percent of nonspecific immune defense {neutrophils and complements}...reflect a more efficient first line of defense, cancer, colds, chronic fatigue, and immune dysfunction syndrome (CFIDS).

METABOLITE: Comparison to illegal or prescription drugs including: amphetamine, methamphetamine, diethylpropion, phenmetrazine, fenfluramine, and the OTC drug phenylpropanolamine (PPA).

PROANCYNOL: cancer, heart disease, other diseases, reducing blood pressure, destroy bacteria, inhibiting some bacteria.

Furthermore, FDA has no information that your products are generally recognized as safe and effective for the above referenced conditions and therefore, they may also be new drugs under section 201 (p) of the Act [21 USC 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 USC 355(a)]. FDA approves new drugs 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 or as cosmetics if certain therapeutic claims 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 (DSHEA), dietary supplements may be legally marketed with claims that they are intended to affect the structure or function of the body (structure/function claims) if certain conditions are met. Claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims) excepting health claims authorized for use by FDA, may not be made as they 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 statements allowed as structure/function claims and those that represent disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html>.

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

Additional information is available in Title 21, Code of Federal Regulations, (21 CFR) Parts 310 and 330-358. These parts include the Final Rules for various OTC ingredients or products that may or may not be legally marketed without prior approval. Renewed Balance Body Cream is subject to the final monograph, "Topically applied hormone-containing drug products for over-the-counter (OTC) use," (21 CFR) Part 310.530. Your product does not appear to conform to this monograph.

Furthermore, your Internet site may be subject to statutes enforced by the Federal Trade Commission (FTC). Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. Sections 45 and 52. You are encouraged to consult the FTC Web site at <http://www.ftc.gov/bcp/online/pubs/dietsupp.htm> for further information. The FTC Web site also provides copies of complaints and orders that have been filed by the FTC against companies making misleading or deceptive advertising claims on the Internet. Some of these complaints and orders can be found at <http://www.ftc.gov/opa/2000/06/lanelabs.htm>, <http://www.ftc.gov/opa/2000/04/cure-all2.htm> and <http://www.ftc.gov/opa/1999/9906/opcureall.htm>. You may want to review your advertisement in light of these standards. Related questions should be directed for the FTC at (202) 326-3090.

This letter is not intended to be an all-inclusive review of your web site and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the statutes administered by both the FDA and FTC.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may reach FDA electronically (e-mail) at DAVISJ@CDER.FDA.GOV, or

you may respond in writing to Jan Davis, Compliance Officer, Food and Drug Administration, HFD-314, 7520 Standish Place, Rockville, MD 20855 or by telephone at (301) 594-0070.

Sincerely yours,

/s/

David J. Horowitz, Esq.

Acting Director

Office of Compliance

Center for Drug Evaluation and Research

Food and Drug Administration

