

Food and Drug Administration

CYBERLETTER

VIA FEDEX

RETURN RECEIPT REQUESTED

May 21, 2008

Carson Krogh Christensen TriHerba Marketing 2190 Pitt River Road Port Coquitlam, British Columbia V3C 1R4 Canada

Dear Mr. Christensen:

The United States Food and Drug Administration (FDA) has reviewed your website, www.triherba.com, and has determined that you promote and sell Triherba Black Salve, Triherba Black Salve Tonic, Herbal Horizons Heart Drops, and Glucose Balance to mitigate, prevent, treat, or cure disease in humans or to affect the structure or function of the body. Statements on your website that document these intended uses include, but are not limited to, the following:

Triherba Black Salve and Triherba Black Tonic

- "TRIHERBA BLACK SALVE & TONIC MAY HELP:
 - Skin Growths and Tumors
 - Prevent Tumorous Cells from Multiplying
 - Prostate and Colon Tumors
 - Breast Tumors . . .
 - Skin problems such as Tumors, Viral Moles, Cysts & Warts
 - Viral Disorders and Internal Growths

For many years, TriHerba Black Salve products have been used to help tumorous growths, not only in humans but also in animals. The above are but some uses for these products."

• "<u>Testimonial</u>: I've had a tumorous growth in my colon. I know for a fact that TriHerba Tonic has slowed down the growth. X-rays revealed this. I can't praise TriHerba Products enough."

• "Black Salve and Black Tonic contain natural herbs and enzymes known to neutralize carcinogens prior to their stimulating any tumor growth and preventing tumorous cells from multiplying once they have started."

Herbal Horizons Heart Drops

- "Herbal Horizons Heart Drops help: Prevent heart attacks, strokes, aneurysms! Eliminate angina pain within a few days!"Prevent the clogging ofarteries! Shrink swollen enlarged heart!
- "A safe sure way to unclog your arteries with no adverse reactions to prescription drugs or food and no negative side effects!"

Glucose Balance

- "GLUCOSE BALANCE OFFERS HELP FOR THE MORE THAN "20 MILLION AMERICANS" WHO SUFFER FROM DIABETES!"
- "Glucose Balance is said to be the next best thing to a diebetes [sic] cure by many who have consumed this product. Additionally many who have had diabetic symptoms and have taken the product claim that within a short period of time the diabetes symptoms have completely vanished."
- "Glucose Balance will balance your sugar levels, increase insulin activity, increase your circlulation [sic] (contains powerful antioxidants) . . . stimulates regeneration of the liver while offering some protection from further damage, helps to prevent and repair memory loss, helps reduce complications such as hypertension and cardiovascular disease."

Triherba Black Salve, Triherba Black Salve Tonic, Herbal Horizons Heart Drops, and Glucose Balance are drugs, as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans, or to affect the structure or any function of the body of man or other animals. Moreover, Triherba Black Salve, Triherba Black Salve Tonic, Herbal Horizons Heart Drops, and Glucose Balance are new drugs, as defined by section 201(p) of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of these products to consumers in the United States without an approved application violates these provisions of the Act.

Furthermore, because these products are offered for conditions, such as cancer, which are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use these products safely for their intended uses. Thus, your products' labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1).

The above violations are not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure that all of the drug products marketed to individuals in the U.S. by your firm are in compliance with United States laws. We advise you to review your websites, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

With a copy of this letter, we are advising the drug regulatory officials in Canada of these potential violations. In addition, we have advised the U.S. Customs Service through an Import Alert that all shipments of your product offered for importation into the United States as a result of your activities may be detained and subject to refusal of entry.

A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/cder/regulatory/applications/default.htm. If you need additional information or have questions concerning the marketing and distribution of your products within the United States, please contact the FDA. Any correspondence should be directed to the Food and Drug Administration, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 10903 New Hampshire Ave., WO51-2201, Silver Spring, MD 20993.

You may also provide a written response to this letter via fax to John Pace at (301) 847-8748.

Sincerely,

Michael Levy

Cc:

Mike Ward
Health Canada
International Programs Division, Policy Bureau
Holland Cross, Tower B, A.L.# 3102C4
1600 Scott Street
Ottawa Ontario K1A 1B6
Canada