



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421
Telephone: 425-486-8788
FAX: 425-483-4996

January 16, 2007

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

IN REPLY REFER TO: SEA 07-07

Truman J. Berst, Founder
Alternative Health & Herbs Remedies
37386 Soap Creek Road
Corvallis, Oregon 97330

WARNING LETTER

Dear Mr. Berst:

The Food and Drug Administration (FDA) has reviewed your website at the internet address www.healthherbs.com, and we have identified serious violations of the Federal Food, Drug and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet web site at <http://www.fda.gov>.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man are drugs as defined in section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(13)]. Based on the claims on your website, we have determined that many of your products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B).

The internet labeling of products on your website includes, but is not limited to, the following claims that cause the products to be drugs:

Gaba:

GABA has been used in the treatment of epilepsy and hypertension GABA is effective in treating attention deficit disorder."

L-Carnitine (250 mg and 500 mg products):

[B]enefits may include: treatment and prevention of some forms of cardiovascular disease; . . . help prevent muscular disease; for protection against liver and kidney disease, for protection against diabetes; ..."

Cleanse & Detoxify Kit, Cleanse & Detoxify Kit Plus, Cleansing Program with Bentonite Clay, Cleansing Program (CAC & Fiber):

- "CAC Colon & Liver Cleanser Liquid : . . . Use of this cleanser liquid ...helps to prevent cancer,. . ."

Truman's Fiber: . . . It helps prevent colon cancer, . . . hemorrhoids, obesity. . . .

[also on your labeling for Cleanse & Detoxify Kit and Cleanse & Detoxify Kit Plus products]

- "Daily Health Tea: Protects the body against bacteria, viruses, other disease-causing germs."

Emergency Home Health Kit (topical and oral administration):

- "Antibiotic: Use for abscesses, acne, arthritis, auto-immune diseases, bladder, breast cancer/tumors, bronchitis ...cancer,.chicken pox... colitis, diphtheria. . . infection, hearing. . . glands -infection, hypoglycemia, impotence, infection, inflammation, kidneys, leukorrhea, lupus, lymphatics, meningitis (spinal meningitis) [,] menstrual problems - profuse flow. . .mumps, nephritis, peritonitis, pleurisy, pneumonia, prostate problems, pyorrhea,. quinsy, scarlet fever, skin disorders. . . stomach-tumors, tonsillitis, tuberculosis, tumors, and venereal disease."

"Fever: ... uses include as an antispasmodic, antibiotic . . ."

- "Sinus & Lung Congestion: . . . Use for allergies, bronchitis. . . lung problems, pleurisy, pneumonia, quinsy, respiratory problems, sinusitis. . . ."
- "Coughs / Sore Throat Syrup: Use for bronchitis, croup..,quinsy, and whooping cough."
- Sleep: To..calm nervous disorders."
- "Strep Throat: Use for strep throat and tonsillitis. This formula contains strong antibiotic herbs. . ."

Immune System Kit; Immune System Plus Kit (topical and oral administration):

- "Colloidal Silver: It may be used both internally and externally, for humans and other animals. Externally, this water maybe applied directly to cuts, rashes, burns, and moles. Internally, it maybe used for viral infections, throat and respiratory infections, diabetes, Candida yeast infections, menstrual difficulties, parasites, diarrhea, allergies, colon spasms. . . .Colloidal Silver may be used as eye drops for retinitis (a disease of the eyes)." .

Colloidal Silver:

[from your pamphlet titled "The End of 650 Diseases," which is available by Internet link titled "Truman's Special Report on Colloidal Silver" on your web site for your product Colloidal Silver Water]

- "Dr. Becker's experiments conclude that silver works on the full spectrum of pathogens And he discovered that all cancer cells can change back to normal cells. All strains of pathogens resistant to other antibiotics are killed by silver. The March 1978 issue of Science Digest, in an article, 'Our Mightiest Germ Fighter,' reported: . . . 'An antibiotic kills perhaps a half-dozen different disease organisms, but silver kills some 650. Resistant strains fail to develop."
- "A researcher at Brigham Young, University sent Colloidal Silver to two different labs including UCLA Medical Center, and reported 'It not only killed the HIV virus but every virus that was tested in the labs."
- "Additional uses include the treatment of AIDS, allergies, anthrax bacilli, arthritis, blood poisoning, boils, wounds of the cornea, chronic fatigue, cerebrospinal meningitis, candida, cholera, colitis, cystitis, diabetes, diptheria, dysentery, enlarged prostate, gonorrhea, herpes, hepatitis, infantile diseases, lesions, leukemia, lupus, lyme disease, parasites . . . rheumatism. ..shingles, skin cancer, staph and strep infections . . .thyroid conditions, tonsillitis, toxemia, stomach ulcers. . .and whooping cough to name a few."

Bilberry Complex:

- "Helpful for many diseases of the, eyes. . . . Also useful for . . . varicose veins, and inhibition of platelet aggregation, possibly preventing blood clots. Also helps control blood sugar levels."
- "Bilberry is widely used as possible preventative treatment for complications of diabetes."
- "Research, done mostly in Italy, has also uncovered billberry's potential for treating retinal problems from poor circulation, diabetes-caused glaucoma, and all day blindness."

Co-Q10 with Hawthorne Berry:

- "Hawthorne berry is one of the most valuable herbs. ..to reduce high blood pressure caused by hardening of the arteries and kidney disease. Has the ability to both lower high

blood, pressure to bring low blood pressure back to normal. Other indications include angina, irregular heartbeat, spasm of the arteries (as with Reynaud's Disease). . . ."

Cat's Claw:

- "It helps to heal numerous stomach/intestinal disorders, including: Asthma, arthritis, ulcers, Chron's disease, diverticulitis, leaky bowel syndrome, colitis, gastritis, hemorrhoids, fistulas, liver disorders, parasites"
- "Other conditions which might be treated with Cat's Claw include: arthritis and painful joints, rheumatism, cancer, bursitis, genital herpes, herpes rooster, allergies, systemic candidiasis, . . . HIV virus, environmental toxin poisoning"

Cleavers (topical and oral administration):

- "Use as a diuretic to treat urinary infections and remove urinary stones and gravel. Beneficial for scalding urine, suppressed or painful urine. . . . A stimulant for the lymphatic system, helping to relieve swollen lymph glands. . . . Useful in treating diseases such as eczema, gall stones, gonorrhea, fevers, scarlet fever, high blood pressure, psoriasis, arthritis, and cancer (especially skin and lymphatic cancers)."

Skin Sores/Antibiotic (topical and oral administration) (Tincture):

- "Traditional and Historical Uses: topically and internally for skin problems or as a general antibiotic. Used for abscesses, appendicitis.. eczema. . . impetigo, infection, measles. . . open sores and ulcers. . . pyorrhea, tonsillitis, and ulcers."

Nerves (Tincture):

- "Can also help with arteriosclerosis/arteriosclerosis, arthritis, auto-immune diseases, birth-prevention of defects . . . burns, . . . convulsions, epilepsy . . . leprosy, lumbago, lumbar pain, Meniere's Syndrome, multiple sclerosis . . . pain, palsy, Parkinson's Disease; peritonitis, psoriasis, schizophrenia, shingles, . . . venereal disease. . . ."

These claims cause your products to be drugs, as defined in Section 201(g)(1)(B) of the Act [21 U.S.C. § 321 (g)(1)(13)]. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in Section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the United States without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drugs are safe and effective. Additionally, the claims on the labeling of many of your products, including but-not limited to all of your products identified above, indicates they are offered for conditions that are not amenable to self-diagnosis-and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended purposes. Such products labeling fails to

bear adequate directions for their intended uses, thus causing them to be misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1).

Furthermore, your Colloidal Silver products, offered on your web site on their own (ie. Colloidal Silver Water) and as part of kits such as the Immune system Kit, to the extent that they are labeled and promoted over the counter (OTC) for the treatment and/or prevention of disease, are subject to 21 CFR § 310.548, which states that there is a lack of adequate data to establish general recognition of the safety and effectiveness of colloidal silver ingredients or silver salts for OTC use in the treatment or prevention of any disease. Under 21 CFR § 310.548(b), any OTC drug product containing colloidal silver ingredients or silver salts that is promoted, labeled, or represented for the treatment or prevention of any disease is regarded as a new drug within the meaning of section 201(p) of the Act, 21 U.S.C. § 321(p), and requires an approved application under section 505(a) of the Act, 21 U.S.C. § 355(a), before marketing. Your firm's colloidal silver products are unapproved new drugs and their delivery into interstate commerce violates section 301(d) of the Act, 21 U.S.C. § 331(d). Absent an approved, new drug application, your colloidal silver products are also misbranded under section 502 of the Act, 21 U.S.C. § 352. See 21 CFR § 310.548(b).

The identification of violations above is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We note you have received two previous letters from the FDA (April 2004 & March 2005) citing products that were promoted for conditions that cause the products to be drugs.

The Act authorizes the seizure of illegal products and injunctions against manufactures and distributors of those products. You should take prompt action to correct all deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be directed to the attention of Lisa M. Brand, Compliance Officer, at the address noted on the letterhead.

Sincerely,

/S/

Charles M. Breeh
District Director