



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Los Angeles District  
Pacific Region  
19701 Fairchild  
Irvine, CA 92612-2506  
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## WARNING LETTER

### CERTIFIED MAIL RETURN RECEIPT REQUESTED

September 9, 2011

WL 55-11

Ms. Cynthia Foster  
[www.drfosteressentials.com](http://www.drfosteressentials.com)  
3320 Keystone Ave Apt 4  
Los Angeles, Ca 90034-4634  
  
2461 Santa Monica Blvd. Suite #338  
Santa Monica, Ca 90404

Dear Ms. Foster:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your website at the internet address, [www.drfosteressentials.com](http://www.drfosteressentials.com) and has determined that the products "Adrenal Support", "Blood Detox Formula", "Candida-G", "Diabetes Type I", "Essential Nutrients", "Eyebright Formula", "Flora-G", "Healthy Heart Formula", "Healing (28-Day Program)", "Lobelia Tincture", "Immune Valor", "L/GB Formula", "Peaceful Nerves", "Sweet Essence Oil Blend" and "Vibrant Colon" are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)].

The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of the products with these claims violates the Act.

Selecting the heading "Search by Health Concern" on your home page opens a drop-down menu listing multiple diseases that when selected, open to your product recommendations for that condition. The "See Entire List" link in the drop-down menu opens to your webpage titled "List of Health Concerns" that lists 86 diseases and health conditions.

The "List of Health Concerns" webpage includes instructions to "Click on a health concern below for recommended products and more information." Clicking on a disease or health condition opens to a web page that lists recommended products for that condition.

Examples of diseases and some of the products you recommend for those diseases include, but are not limited to are listed below. Clicking on one of the products will open a web page with claims for the various products.

#### Attention Deficit

- **Flora-G**

- o "[D]ramatic effects on incurable skin diseases, fibromyalgia...as well as arthritis."

- **Immune Valor**

- o "[C]an provide protection in times of infectious epidemics such as colds and flus."

#### Crohn's

- **Adrenal Support**

- o "[I]t is used to heal...diabetes, high blood pressure, rheumatism, arthritis, infertility,...tumors, impotence, frigidity, mononucleosis, allergies, and digestive disorders."

- **Immune Valor**

- o “Cordyceps has a very positive effect on those with severely weak immune systems (as in AIDS and cancer).”
- o “[A]stragaloside ...is an extremely potent immune modulator...suppressing excessive immune activity, such as occurs with autoimmune conditions (i.e. lupus, allergies, rheumatoid arthritis, Crohn’s disease, Hashimoto’s thyroiditis, etc.)”
- o
- o

## **Blood Pressure**

- **Healthy Heart Formula**

- o “[H]elps regulate heart rhythms. Also helpful for heart valve defects as well as anxiety and palpitations due to overactive thyroid.”
- o “[I] also contains cayenne to increase...speed of healing.”

## **Cancer**

- **Blood Detox Formula**

- o “[H]erbs which...reverse degenerative processes in the body, such as cancer and severe incurable disease.”
- o “[T]hins the blood.”
- o “Contains special European herbs known in Europe for their ability to shrink tumors.”

- **Healing (28-Day Program)**

- o **“Lobelia Tincture”**

- “[O]pens up the breathing passages, taking away the struggle of wheezing, coughing and shortness of breath.”
- “Can be used by those with severe and incurable lung conditions such as asbestosis, chronic interstitial lung disease, pneumoconiosis, pleurisy, COPD and emphysema.”

## **Diabetes Type I**

- **Sweet Essence Essential Oil Blend**

- o “Cypress is a specific for weak pancreatic function, and is what I have used to bring diabetics out of hypoglycemic seizures. Whether the blood sugar is too high or too low, this formula helps bring balance.”

## **Hepatitis**

- **L/GB Formula**

- o “[H]elp rid the body of gallstones.”
- o “A cooling formula for...hepatitis and other liver disorders. Helps the body to rid itself of excess cholesterol. May be used in liver failure, cirrhosis or those awaiting liver transplants.”

- **Essential Nutrients**

- o “The #1 product recommended for alkalizing the body pH which can also help bone density...[T]akes many out of depression...[T]hese antioxidant foods can accelerate healing from injuries, wounds and burns. Blood Sugar stabilizing effect is noted and can be helpful for diabetics and hypoglycemics.”

- **“Healing (28-Day Program), Immune Valor”**

## **Colon Cancer**

- **Vibrant Colon**

- o “This formula has been known to kill parasites, and other harmful organisms that breed in the intestines.”

## **Epilepsy**

- **Peaceful Nerves**

- o “A powerful herbal antispasmodic formula which helps to release cramps and spasms of all kinds. This formula contains the same herbs I took to prevent seizures from coming on when I had epilepsy....”

## Eye Disease

### • Eyebright Formula

- o “Natural healers have traditionally used eyebright to heal eye ailments, heal eye infections and other eye disturbances.”

In addition, on each of the web pages that list the products you recommend for specific diseases, you include instructions to “**Click here to see the Ailment reference Guide**” for more details. The words “here to see” are hyperlinked to a webpage titled “**Ailment Reference Guide Copyright 2010 Cynthia Foster, MD,**” which consists of a table listing diseases and conditions, along with your products you recommend to use. Under the heading “How to Use The Reference Guide” you state that “In this reference, each ailment is followed by Dr. Foster’s clinical recommendations of herbal formulae and programs to use...If you start with one and...do not get the desired results, try the second and then the third recommended formula.”

The “**Ailment Reference Guide**” consists of a table that lists 86 diseases and conditions in the first column and the products you “recommended to use for these conditions in the second column. Examples of a few of the diseases and your recommended products include, but are not limited to the following:

**AIDS:** “28-Day Healing + Immune Valor + Adrenal Support...”

**Autism Spectrum Disorder:** “Begin with Flora-G or Flora Chew depending on child’s age...”

**Cancer Chemo Herbal Support Program:** “Vibrant Colon (unless there is diarrhea)... Herbs encourage apoptosis of diseased cancer cells and strengthen healthy cells. They do not interfere with killing of cancer cells-they encourage it.”

**Cervix Infections:** “Blood Detox Formula...”, “Candida-G used as vaginal implant.”

**Conjunctivitis:** “Eyebright Formula”-use as eyewash and take as oral supplement...”

**Diabetes I and II:** “(Sweet Essence Oil Blend + 28 Day Healing)...”

**Drug withdrawal – alcohol & sedatives:** “Peaceful Nerves”, “Essential Nutrients”, “28-Day Healing Program”, Healthy Heart (regulate blood pressure, sedating)...”

**Esophageal Cancer, Kidney Cancer, Lung Cancer, Ovarian Cancer:** “28-Day healing Program...”

**Lupus:** “Immune Valor...”, “28-Day Healing Program”, “Adrenal Support.”

**Lyme’s Disease:** “Blood Detox Formula”, “Sweet Essence...”

**Stroke:** “Healing 28-Day Program...”

Your website also contains disease claims in the form of personal testimonials. The following are excerpted from the tab on the home page titled “**Testimonials**”:

### **Diabetes/Sweet Essence**

- “The Sweet Essence combined with a better diet has allowed me to stop taking my diabetic prescription oral meds. My blood sugar have [sic] been between 91 and 127!”

### **Cholesterol/Heart Problems**

- “My triglycerides went from 286 in October 1999 down to 59 in January of 2004. My total cholesterol went from 239 in 1999 down to 222 in 2001 down to 156 [in the normal healthy range] in January 2004. My doctor said that my problem was probably genetic and that I wouldn’t be able to lower it. He strongly encouraged me to start on Lipitor. I told him that I would get back with him later;)”

### **Female Problems**

- “The doctors diagnosed me with an ovarian cyst the size of an orange....They guessed it was endometriosis, and scheduled surgery to remove it, but they were afraid there would be complications because it was so large. You started me immediately on the Liver Regeneration Program and the Blood Detox Formula. In 2 weeks, I could feel it had shrank. In 4 weeks, it was half the size, and the doctors were able to easily remove it.”

### **T Cell Count Improves Dramatically**

- “My ex-boyfriend with AIDS and cancer, his T cell count went from 58 to 650 in one month while taking the Echinacea[sic] Premium and Immune Valor.”

On your homepage, the entitled “FAQs” links to your webpage titled “Frequently Asked Questions” that includes your answers to questions from consumers that when clicked on Dr. Foster answers questions from consumers. The following is an example of a question and your answer:

Will herbs interact with my medications?

- “I had one client who had high blood pressure due to a kidney stone. She was taking blood pressure medication. On the second day of the Kidney Revitalization Program, the stone dissolved, and her blood pressure suddenly went low....As soon as she realized her blood pressure was low, she stopped taking her blood pressure medication. The symptoms went away the next day. Because the cause of the high blood pressure was released, she no longer needed to take the medication. Her blood pressure has been normal ever since.”
- “I have had clients who underwent chemotherapy and herbs at the same time with terrific results...The Essentials Nutrients Formulas helps to protect against severe anemia which is so common during and after chemotherapy...[T]he clients I’ve had who used herbs with chemotherapy were more likely to survive the chemotherapy and live longer than expected for their type and stage of cancer.”

Your products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are a new drug 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.

Furthermore, your products are misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] because the products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, therefore, adequate directions cannot be written so that a layman can use the product safely for its intended use. Thus, the labeling fails to bear adequate directions for its intended use, causing the product to be misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1). The introduction of a misbranded drug into interstate commerce is a violation of § 301(a) of the Act, 21 U.S.C. § 331(a).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. You promote “Eyebright Formula” to “heal eye infections and other eye disturbances” with intended topical uses for conjunctivitis. “Candida-G” is also promoted for cervix infections to be used as a vaginal implant. For these intended uses, “Eyebright Formula” and “Candida-G” are not a dietary supplement because they are not intended for ingestion. 21 U.S.C. 321(ff)(2)(A)(i) defines the term, “dietary supplement” to mean a product that is intended for ingestion. Consequently, a product that is not intended for ingestion cannot be a “dietary supplement.”

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your product do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

Please notify this office, in writing, within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not recur. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for the delay and the date by which the corrections will be completed.

Your reply should be sent to the following address: Food and Drug Administration, Attention: Blake Bevill, Director Compliance Branch, 19701 Fairchild, Irvine, California 92612-2445.

Sincerely,

/s/

Alonza E. Cruse  
District Director  
Los Angeles District