UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
WASHINGTON, D.C. 20580

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20740

April 28, 2011

WARNING LETTER

Dr. Aundrea Adams
International Institute of Holistic Healing, Inc.
1730 Cordova Drive
Mesquite, TX 75150-6825

P.O. Box 944
Lancaster, TX 75146

2331 Gus Thomasson
Suite 115
Dallas, TX 75228

Dear Dr. Adams:

This letter is to advise you that the United States Food and Drug Administration (FDA) and the United States Federal Trade Commission (FTC) have reviewed your web site at the internet address, http://www.DoctorAJAdams.com. The FDA has determined that your firm's marketing of the products Colloidal Silver 500 ppm (Liquid), Essaic Tonic Liquid Drops, and Oil of Oregano P73 Physician's Strength, which are offered for sale on your website, violates the Federal Food, Drug, and Cosmetic Act (the Act). As described in more detail below, Colloidal Silver 500 ppm (Liquid), Essaic Tonic Liquid Drops, and Oil of Oregano P73 Physician's Strength are unapproved new drugs in violation of sections 301(d) and 505(a) of the Act [21 U.S.C. Â§Â§ 331(d) and 355(a)] and are misbranded under sections 502 and 502(t)(1) of the Act [21 U.S.C Â§Â§ 352 and 352(f)(1)]. These products are further misbranded under section 502(j) of the Act in that they are dangerous to health when used in the manner recommended or suggested in their labeling.

UNAPPROVED AND MISBRANDED NEW DRUGS

Labeling statements on your website and in sample labeling include, but are not limited to, the following:

Colloidal Silver 500 ppm (Liquid):

- "Colloidal Silver Uses ... AIDS ... Cold Sores ... Genital Herpes ... Genital Warts ... HIV ..."

- "Research States That Colloidal Silver Has Been Used For:
Acid Reflux [Caused by Intestinal Candida], Acne, Allergies, Athletes Foot, Bad Breath, Bladder Infections [Cystitis], Bleeding Gums, Severe Bums, Blood Parasites, Boils, Colitis, Canker Sores, Chronic Fatigue, Colds, Conjunctivitis, Cornea Injury, Dandruff, Dermatitis, Diarrhea, Digestive Aid, Dysentery, Ear Infections, Eczema, Enlarged Spleen, Entamoeba, Enteritis, Fibrositis, Flu, Gastritis, Gingivitis, Gonorrhea, Gum Recession, H Pylori [Helicobacter Pylori], Halitosis, Hay Fever, Hemorrhoids, Impetigo, Keratitis, Lymphagitis, Meniere's Disease, Moles, Natural Decongestant, Ophthalmology, Pruritis, Psoriasis, Rheumatoid Arthritis, Ringworm, Skin Rashes, Rhinitis, Rosacea, Seborrhea, Sinusitis, Sore Throat, Tonsillitis, Tooth Decay, Trench Foot, Ulcers, Vincents Angina, Warts, Whooping Cough, Yeast Infections, Other Infections [Bacterial, Viral, Fungal, Parasitic]"

- "For Children's Immune System Health and Infections: Viruses, Bacteria, Fungi, Candida, Parasites, Allergies ..."

- "The Colloidal Silver really helped my daughter recover from Mononucleosis."

- "My bladder infection is almost gone! Colloidal Silver worked wonders."

- "I want to let you know that your brand of colloidal silver along with the P73 Orgeno [sic] Oil are 2 very potent remedies for microbes, and they have nearly cleared up a very, very strong infection - certainly one of the worst infections I've ever had in my life."

Essaic Tonic Liquid Drops:

- "Other Suggested Uses for Essiac: ... AIDS and HIV infections Blood Sugar Problems Type II Diabetes ... Genital herpes viral infections Hepatitis liver disease Virus Infections; Recurrent viral, bacterial or parasitic infections"

- "Protect, Repair, and Detox Liver and All Other Major Organs With This Miraculous Herbal Formula Used for Cancer, Diabetes, Thyroid Disorders, Tumors, Cysts, Growths, Immune Disorders, AIDS, HIV, Kidney Disorders, All Chronic Illnesses ... "

- "In addition to its reputation for reversing cancer, it has since proven itself to be an effective remedy for many infections, inflammatory conditions, immune disorders [sic] other ailments as well."

Oil of Oregano P73 Physician's Strength:

- "Natural Support for Immune Health, Lungs, Cancer, Growths, Bacteria, Viruses, Fungi, Parasites, All Infections and Inflammations, With Oil of Oregano P73 Physician's Strength!"

- "Oil of Oregano Uses ... AIDS ... Anthrax ... Anti-Viral ... Cancer Cold Sores ... Genital Herpes ... Genital Warts ... Gonorrhea ... Heart Disease Herpes ... HIV ... Kidney Infection ... Meningitis ... SARS ... Skin Cancer ... Syphilis ... Tuberculosis West Nile Virus ..."

- "For Herpes: the oil completely destroyed herpes viruses...."

- "Oregano oil has been tested against a variety of microorganisms [infections] and is found to exert a high degree of anti-fungal, anti-parasitic, anti-viral and antibacterial actions."

- "Oregano is such a potent anti-fungal agent that it is capable of destroying even resistant fungal forms, such as the mutated fungi which result from antibiotic therapy."

- "[o]ne of the testimonials given in the book states that a woman's genital herpes completely disappeared after only 1 month, after having it for several years."

- "The oil of oregano is helping my shingles."

Based on these claims, your Colloidal Silver 500 ppm (Liquid), Essaic Tonic Liquid Drops, and Oil of Oregano P73 Physician's Strength products are drugs as defined by sections 201(g)(1)(B) and (C) of the Act [21 U.S.C. Â§Â§ 321(g)(1)(B) and 321(g)(1)(C)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body of man. Furthermore, these products are "new drugs," as defined by section 201(p) of the Act [21 U.S.C. Â§ 321(p)], because they are not generally recognized as safe and effective for their labeled uses. Under sections 301(d) and 505(a) of the Act, a new drug may not be introduced into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Your sale of these products without approved NDAs violates these provisions of the Act.

Your Colloidal Silver 500 ppm (Liquid) is also a new drug under FDA's regulations because, to the extent that it is labeled and promoted for OTC use, it is subject to 21 CFR Â§ 310.548. That regulation 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 Â§ 310.548(b), any OTC drug product containing these ingredients that is labeled, represented, or promoted for the treatment and/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. Â§ 321(p)] and requires an approved application under section 505 in order to be legally marketed. Additionally, per 21 CFR Â§ 310.548(b), any product containing colloidal silver ingredients or silver salts that is labeled, represented, or promoted for the treatment and/or prevention of any disease, and is not the subject of an FDA-approved application, is misbranded under section 502 of the Act [21 U.S.C. Â§ 352].

Moreover, many of the indications for which you market these product (for example, genital herpes, HIV, AIDS, cancer, and SARS) are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners. "Adequate directions for use" is defined in 21 CFR Â§ 201.5 as "directions under which the layman can use a drug safely and for the purposes for which it is intended." Because these conditions require the supervision of a practitioner licensed to prescribe drugs, adequate directions cannot be written for them so that a layperson can use your products safely for these uses. Thus, your products' labeling fails to bear adequate directions for use for these indications, which causes the products to be misbranded under section 502(t)(1) of the Act [21 U.S.C. Â§ 352(t)(1)]. Because your products lack required approved applications, they are not exempt under 21 CFR Â§Â§ 201.100(c)(2) and 201.115 from the requirements of section 502(t)(1) of the Act. The introduction or delivery for introduction into interstate commerce of these products therefore violates sections 301(a) and (d) of the Act [21 U.S.C. Â§Â§ 331(a) and (d)].

The labeling for Colloidal Silver 500 ppm (Liquid), Essaic Tonic Liquid Drops, and Oil of Oregano P73 Physician's Strength, includes claims for the prevention, treatment, and cure of genital herpes, HIV, and AIDS, as noted above. A consumer who uses these products as labeled may forgo or delay appropriate treatment, which can be dangerous not only to the consumer but also to the consumer's

sexual partners. These products are therefore dangerous to health and misbranded under section 502(j) of the Act [21 U.S.C. Â§ 352(j)].

Genital Herpes and Cold Sores

Claims Regarding Treatment of Genital Herpes

We note that your Colloidal Silver 500 ppm (Liquid), Oil of Oregano P73 Physician's Strength, and Essaic Tonic Liquid Drops products are offered over-the-counter (OTC) for the treatment of genital herpes. This indication is not covered by any monograph or ongoing rulemaking under the OTC Drug Review. In addition, we are not aware of any evidence that similarly formulated and labeled products were marketed on or before the inception of the OTC Drug Review, nor has FDA ever proposed that such products be included in the OTC Drug Review. Your products are therefore not covered by the OTC Drug Review.

Claims Regarding Treatment of Cold Sores

OTC drug products intended for the topical treatment of fever blisters and cold sores are being evaluated under the ongoing OTC Drug Review. The Tentative Final Monograph (TFM) for this category of products was published in 1990 [External Analgesic Drug Products for Over-The-Counter Human Use; Proposed Rulemaking for Fever Blister and Cold Sore Treatment Drug Products, 55 Fed. Reg. 3370 (Jan. 31, 1990)]. However, FDA considers the use of the term "herpes" alone misleading for products marketed under the OTC Drug Review for treatment of fever blisters and cold sores, because a consumer may associate it with the genital form of herpes. 55 Fed. Reg. at 3373. As stated above, genital herpes is neither covered by any OTC monograph or ongoing rulemaking, nor is it an appropriate OTC indication.

To the extent your Colloidal Silver 500 ppm and Oil of Oregano P73 Physician's Strength products are intended for indications covered by the TFM for products for topical treatment of fever blisters and cold sores, they are also inconsistent with the OTC Drug Review for such products in other respects. For example, according to your website, their active ingredients are "Colloidal Silver" and "Oil of Oregano," respectively. These active ingredients have not been evaluated under the OTC Drug Review for products for topical treatment of fever blisters and cold sores.

Furthermore, FDA has determined that there is a lack of adequate data to establish general recognition of the safety and effectiveness of any orally administered ingredients for OTC use to treat or relieve the symptoms or discomfort of cold sores. 21 CFR Â§ 310.537(a). Any OTC drug product for oral administration, including your Colloidal Silver 500 ppm (Liquid) and Oil of Oregano P73 Physician's Strength products, that is labeled, represented, or promoted to treat or relieve the symptoms or discomfort of cold sores is regarded as a new drug under section 201(p) of the Act and requires an approved NDA in order to be legally marketed. 21 CFR Â§ 310.537(b). Additionally, per 21 CFR Â§ 310.537(b), any product that is labeled, represented, or promoted to treat or remove cold sores, and is not the subject of an FDA-approved application, is misbranded under section 502 of the Act [21 U.S.C. Â§ 352].

Treatment of Warts

In addition, FDA has issued a final monograph for OTC drug products intended for the topical treatment of common and plantar warts. 21 CFR part 358 Subpart B. In order to be lawfully marketed under the final common and plantar wart remover monograph, a product must meet the

requirements of the final monograph. We note that the active ingredients in Colloidal Silver 500 ppm (Liquid) and Oil of Oregano P73 Physician's Strength are not included in that final monograph. Indeed, the final monograph lists salicylic acid as the only acceptable active ingredient for the topical treatment of common and plantar warts, and your products do not appear to contain salicylic acid.

Additionally, we note that the final common and plantar wart remover monograph requires that the labeling for OTC wart remover drugs contain the warning: "Do not use on ... genital warts[.]" 21 CFR Â§ 358.150(c)(1)(iv). Colloidal Silver 500 ppm (Liquid) and Oil of Oregano P73 Physician's Strength are not labeled with this warning; rather, as noted above, they are labeled for the treatment of genital warts.

To the extent your products are offered for oral use in the treatment of genital warts, this indication is not covered by any monograph or ongoing rulemaking under the OTC Drug Review. In addition, we are not aware of any evidence that similarly formulated and labeled products were marketed on or before the inception of the OTC Drug Review, nor has FDA ever proposed that such products be included in the OTC Drug Review. Your products are therefore not covered by the OTC Drug Review.

* * *

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law, the Act and its implementing regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify the FDA in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Furthermore, please advise the FDA of what actions you will take to address product that you have already distributed.

Address your reply to the U.S. Food and Drug Administration; Attn: Shari Shambaugh, Director, Compliance Branch, 4040 North Central Expressway, Suite 300, Dallas, TX 75204. You may reach Ms. Shambaugh at (214) 253-5215 if you have any questions about this matter.

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. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10001 New Hampshire Avenue, Silver Spring, MD 20993.

In addition, you are also marketing on your website the Vaginosis Profile Vaginal Swab Test In-Home Lab Test Kit and the Metabolic Analysis Profile (Organic Acids) Urine Test In-Home Lab Test Kit. These are devices within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) because they are intended for use in the diagnosis of disease or other

conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. It appears that you are offering these tests directly to consumers without the order of a physician or other authorized person in violation of federal law. Please provide information in your response to this letter explaining and documenting how the in vitro diagnostic tests that you market comply with applicable FDA regulations.

In addition, it is unlawful under the FTC Act, 15 U.S.C. Â§ 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. See FTC v. Direct Mktg. Concepts, 569 F. Supp. 2d 285,300,303 (D. Mass. 2008), aff'd, 624 F.3d 1 (1 st Cir. 2010); FTC v. Nat'l Urological Group, Inc., 645 F. Supp. 2d 1167, 1190, 1202 (N.D. Ga. 2008), aff'd, 356 Fed. Appx. 358 (11th Cir. 2009); FTC v. Natural Solution, Inc., No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75,866, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7,2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See In re Daniel Chapter One, No. 9239, slip op. 18-20,2009 WL 516000 (F.T.C.), 17-19 (Dec. 24, 2009) (http://www.ftc.gov/os/adjpro/d9329/091224cornmissionopinion.pdf), pet. for review den., 2010 WL 5108600 (D.C. Cir. Dec. 10, 2010).

FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers. Please notify FTC via electronic mail at healthproducts@ftc.gov, within fifteen working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Richard Cleland at 202-326-3088.

Sincerely,
/S/
Reynaldo Rodriguez
District Director
Dallas District Office
U.S. Food and Drug Administration

/S/
Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

/S/
Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission

This page was posted on June 5, 2011.

Make a Donation | Search All of Our Affiliated Sites | Home

Links to Recommended Companies

- Natural Medicines Comprehensive Database. Trustworthy information on dietary supplements and herbs.
- PharmacyChecker.com: Compare drug prices and save money at verified online pharmacies.
- ConsumerLab.com: Evaluates the quality of dietary supplement and herbal products.
- Law Offices of Bukh & Associates: Free phone consultation for health fraud victims.
- OnlyMyEmail: Award-winning anti-spam services.
- Herbal Medicine, 3rd edition. Excellent reference book, discount-priced.
- 10 Types: Website design, development, and hosting with superb technical support.