



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94335d

September 30, 2003

Food and Drug Administration
Center for Biologics Evaluation
and Research
1401 Rockville Pike
Rockville MD 20852-1448

CBER-03-014

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Gordon Josephs
Chelationcare Centers USA LLC (CCUSA)
7315 E. Evans Road
Scottsdale, AZ 85260

Dear Dr. Josephs:

The Food and Drug Administration (FDA) has reviewed your websites at Internet addresses: <http://www.anti-thrax.com> and <http://homeovax.com> and has determined that your Anti-THRAX anthrax vaccine alternative and your Viral Immune alternative immunizations and vaccinations are being promoted for conditions that cause the products to be drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [21 USC 321(g)] and biologics, as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 USC 262]. Anti-THRAX anthrax vaccine alternative and Viral Immune alternative immunizations and vaccinations are considered drugs because the therapeutic claims as shown on your websites establish their intended use as drugs and because the components of these products are recognized in the Homeopathic Pharmacopeia of the United States (HPUS). These products are marketed in violation of sections 301(a) and 301(p) of the Act [21 U.S.C. 331(a) and (p)]. Please be aware that a product's compliance with requirements of the HPUS does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use.

Background

Anti-THRAX and Viral Immune are both drugs under section 201(g) of the Act. According to your website, Anti-THRAX contains Bacillus anthracis, Reudbeckia Agustifolia, Anatherum, Alium Sativa, and Taurine. Each of these components is listed in the HPUS.

Examples of the claims observed on your Anti-THRAX website include: "...a way to stimulate the immune system to resist anthrax (like a vaccine does);" "...rapidly cause the body to stimulate its immune system to resist anthrax;" "...stimulate your immune system to resist anthrax with advanced bio-energetics;" and "We've added some homeopathic ingredients to Anti-THRAX to help boost the immune system and provide for cutaneous anthrax."

Likewise, your Viral Immune website makes therapeutic claims. Examples of the claims observed on your homeovax website include: "Viral Immune No-Shot Flu Shots!" "Our Alternative Immunization Kit contains nosodes which cover viral, bacterial, and even fungal childhood diseases;" "...stimulate the virus-fighting side of the immune system;" "...specificly stimulate the body to overcome several adult viral illnesses;" "At the same time as you defend yourself from the flu, you are also stimulating yourself with nosodes against morbillia (measles), variolinum (smallpox), Bacille Calmette-Guerine, cytomegalovirus and encephalitis viruses;" and "We hope you noticed that SMALLPOX is one of the homeopathic nosodes included in the Viral Immune No-Shot preparation. For those patients worried about bio-terrorism, this product addresses a great concern, especially since regular smallpox vaccine is not generally available, and most people haven't had a smallpox vaccination in decades."

Your Anti-THRAX website states that the product is "Available only to our patients (Ask how you can become a patient)" with a link provided including a registration form and a short medical history form. The link states: "AFTER REGISTERING AS A PATIENT, If you desire any preventive, homeopathic products that we offer to our patients, you are able to request them. We ship anywhere within the USA." This statement also indicates that your products are for sale to citizens of the United States. Prices listed on your website are "\$69.50 plus \$7.50 p+h" for your Alternative Immunization Kit, "\$29.95 plus \$7.50 p+h" for your Viral Immune product, and "\$34.95 plus \$7.50 p+h" for your Anti-THRAX product. It also appears that your products are delivered by the U.S. mail as indicated by the statement "Our orders are encased in aluminum foil to protect homeopathics from radiation now used by the postal service."

Misbranding Your Products

The information on your websites is false or misleading. For example, both of your websites make numerous effectiveness claims, but they lack descriptions of the risks, warnings, and contraindications with respect to Anti-THRAX and Viral Immune alternative immunizations. Consequently, your products are misbranded under sections 301(a), 502(a), and 201(n) of the Act.

Failure to Register Your Products

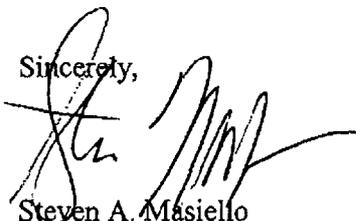
You have failed to register your drug establishment pursuant to section 510 of the Act. Consequently, your products are marketed in violation of sections 502(o) and 301(p) of the Act.

For the reasons above, you should immediately discontinue your website offers to sell your Anti-THRAX anthrax vaccine alternative and your Viral Immune alternative immunizations and vaccinations, and remove from your websites all other promotional materials for products that contain the same or similar violative presentations.

This letter is not intended to be an all-inclusive review of your websites and products your firm may be marketing. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Acts and their implementing regulations. You should take prompt action to correct the violations noted above. Failure to promptly correct these violations may result in regulatory action such as seizure and/or injunction without further notice.

Please notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. If the corrective action(s) cannot be completed within 15 working days, state the reason for the delay and the time within which the correction(s) will be completed. Your response should be sent to the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, HFM-610, 1401 Rockville Pike, Suite 100 N, Rockville, MD 20852-1448, Attention Mr. Steven Masiello, Director, Office of Compliance and Biologics Quality.

Sincerely,



Steven A. Masiello

Director

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

Enclosure:

Internet website pages from <http://www.anti-thrax.com> and <http://www.homeovax.com>