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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

May 19, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-30

Leonard G. Horowitz, D.M.D., M.A., M.P.H.
Owner/President/Managing Member
Healthy World Distributing
206 North 4th Avenue, Suite 147
Sandpoint, Idaho 83864

WARNING LETTER

Dear Dr. Horowitz:

This letter refers to your firm's marketing and distribution of the products "Urbani SARS Formula Nasal Spray", "Urbani SARS Formula (Standard)", "Extra Strength Urbani SARS Formula", and "Urbani SARS Formula Homeopathic (6X)" for the prevention, treatment, or cure of Severe Acute Respiratory Syndrome.

Statements made on your Internet websites, healthyworlddistributing.com and cureforsarsnet, demonstrate that these products are being marketed with drug claims. Examples of these claims include: "Scientifically formulated as a natural defense and effective treatment for coronavirus infections." Under section 201 (g) of the Federal Food, Drug, and Cosmetic Act (Act), products marketed with such claims are drugs.

The products "Urbani SARS Formula Nasal Spray", "Urbani SARS Formula (Standard)", and "Extra Strength Urbani SARS Formula" are "new drugs" under section 201 (p) of the Act because they are not generally recognized by qualified experts as safe and effective for their intended uses. Since these products are new drugs, section 505(a) of the Act prohibits their marketing in the United States without approved new-drug applications.

Because the "Urbani SARS Formula Homeopathic (6X)" is intended to prevent, treat, or cure a serious disease that requires diagnosis and treatment by a physician, it is a drug that is not safe for use except under the supervision of a practitioner licensed by law to administer it. Accordingly, this product is misbranded within the meaning of Section 503(b) (1) of the Act. The product is further misbranded within the meaning of Section 503(b)(4) of the Act in that its label fails to bear the statement "Rx only".

In addition, these products are misbranded under section 502(f)(1) of the Act because their labeling fails to bear adequate directions for use for the conditions that they are intended to treat.

This letter is not intended to be an all-inclusive review of your Internet web sites and the products marketed by your firm. It is your responsibility to ensure that all of your firm's products comply with the Act and its implementing regulations.

We request that you take prompt action to correct the noted violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunctions against the manufacturer and/or distributor of those products.

Please notify this office in writing within fifteen working days of receipt of this letter regarding the steps that you have taken to correct the noted violations. You should also include an explanation of each step being taken to ensure that similar violations do not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

By copy of this letter, Mr. Mark Gustafson, Administrative Contact for the domain name www.healthyworlddistributing, will be notified of this action.

Sincerely,
/s/

Charles M. Breen
District Director

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