

For Release: June 19, 2003

# No Silver Lining for Marketers of Bogus Supplement; Federal Agencies Crack Down on Health Fraud

## FTC Charges Marketers of Seasilver with Making False and Deceptive Claims; FDA Seizes Seasilver Inventories

The Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) announced coordinated actions against two companies - both charged with promoting the dietary supplement "Seasilver" with unsubstantiated medical claims. The agencies' actions against Seasilver USA, Inc. and Americaloe, Inc. are designed to halt the fraudulent marketing of Seasilver and to seize the available inventory of the product. Today's actions are the latest part of Operation Cure.All, an on-going coordinated effort among the FTC, the FDA, Health Canada, Canada's Competition Bureau, and state Attorneys General to crack down on unscrupulous marketers who prey on consumers with serious illnesses.

The FTC has charged the two companies, their owners, the principal distributor, and a purported "expert" with making false and unsubstantiated claims about the health benefits and safety of a product they market called "Seasilver"- a purported cure-all liquid supplement. The FTC alleges that the defendants promoted Seasilver as safe and effective to treat or cure 650 diseases, including AIDS and cancers, and to cause substantial and permanent weight loss. The FDA has seized inventories of the product.

"The FTC and the FDA are committed to aggressive action against fraudulent claims in the dietary supplement market," said Timothy J. Muris, Chairman of the FTC. "Like the snake oil salesman of old, Seasilver claimed to cure 650 different health problems, including such serious diseases as cancer, AIDS, and diabetes. These claims may keep consumers from seeking appropriate treatment. They certainly empty consumers' pockets."

"This is the sort of intolerable health fraud I had in mind when I announced six months ago that the FDA will take vigorous actions against firms that prey on consumers and patients by selling worthless dietary supplements as cures for serious and chronic diseases and conditions," said Mark B. McClellan, M.D., PhD, the FDA Commissioner. "Using these ineffective products is worse than wasting money - it may cause irreparable harm by delaying or replacing approved treatments that can bring actual health benefits."

In a complaint filed in federal district court in Nevada on June 12, 2003, the FTC alleges that two Carlsbad, California-based companies, Seasilver USA. Inc. and Americaloe, Inc., their principals, Bela and Jason Berkes; Brett Rademacher, doing business as Netmark International and NetmarkPro; and David R. Friedman, D.C., violated the FTC Act by making false and unsubstantiated claims for Seasilver. Seasilver is a liquid multi-vitamin/mineral/amino acid dietary supplement that purports to contain, among other ingredients, aloe vera, phyto-silver (purportedly a plant-based silver), sea vegetables, the herb Pau D'Arco, and cranberry concentrate. A 32-oz. bottle of Seasilver costs \$39.95.

According to the FTC, the defendants promote Seasilver through national television and radio infomercials, Web sites at www.seasilver.com and www.myseasilver.com/main, spam emails, and a glossy 28-page consumer brochure. The defendants publicly claimed that Seasilver USA earns \$180 million annually from selling Seasilver. The FTC alleges that the defendants' ads and promotional materials represented that Seasilver: (1) treats or cures cancer; (2) enables nine out of ten diabetes patients to stop their insulin medication; and (3) causes rapid, substantial, and permanent weight loss without dieting. The FTC charges that these and other claims go beyond existing scientific evidence on any of the ingredients contained in the product, and therefore, are false and unsubstantiated.

In addition, the complaint alleges that the defendants represented, without scientific support, that Seasilver treats or cures AIDS, diabetes, lyme disease, and various cancers; cures chronic obstructive pulmonary disease; enables post-heart attack patients to reduce their heart medication, eliminates high blood pressure; and is 100 percent safe for pregnant and lactating women, senior citizens, children, and infants. Finally, the complaint alleges that defendants provided deceptive advertisements and promotional materials to distributors for use in their marketing and sale of Seasilver.

At the FTC's request, on June 13, 2003, the federal district court issued a temporary restraining order prohibiting the defendants from making the challenged claims and freezing their assets. In addition, the FTC is seeking preliminary and permanent injunctive relief, including restitution to consumers who purchased the product.

On June 16, 2003, acting at the FDA's request, the United States Attorney for the Southern District of California filed a

complaint seeking the seizure of Seasilver USA's Seasilver product. On June 17, 2003, United States Marshals seized 132,480 bottles of Seasilver, worth nearly \$5.3 million from Seasilver USA's San Diego headquarters. The Government's complaint alleges that, although Seasilver USA markets Seasilver as a dietary supplement, it promotes it on the Internet and in marketing materials sent with the product as a treatment for serious diseases including cancer, diabetes, hypoglycemia, psoriasis, hepatitis, and arthritis. These claims cause Seasilver to be an unapproved new drug under the Federal Food, Drug, and Cosmetic Act (the Act). Such claims also cause Seasilver to be misbranded under the Act because it lacks adequate directions for use. Seasilver's labeling also contains claims such as "cleanses your vital organs" and "oxygenates your body's cells." According to the complaint, these claims show that Seasilver is intended to affect the structure or function of the body. Because the claims are unsubstantiated, Seasilver is misbranded under the Act.

In addition to the violations caused by its product claims, Seasilver USA has had obgoing sanitation problems at its manufacturing facility. As recently as December of last year, FDA cited the company for using equipment that cannot be properly cleaned and for permitting its employees to work the production line in street clothes. Employees in facilities like Seasilver USA's must wear garments that protect against contamination of food and food containers.

#### **Operation Cure.all**

The multi-jurisdictional nature of these deceptive marketing practices, particularly with the growth of the Internet, requires law enforcement organizations, domestically and internationally, to work in full cooperation to combat the problem effectively. In its continuous efforts through Operation Cure.All, the FTC, FDA, Health Canada, Canada's Competition Bureau, the Federal Commission for the Protection from Sanitary Risks (COFEPRIS) of Mexico, and state Attorneys General, the FTC, FDA, Health Canada, Canada's Competition Bureau, and state Attorneys General are working cooperatively to detect and deter fraudulent marketing of health-related products. For additional information on Operation Cure.All. see the FTC's Cure.All Web site at http://www.ftc.gov/bcp/conline/edcams/cureall/index.html.

#### **Tips for Consumers**

The FTC, the FDA, and other sister agencies have compiled a list of valuable and reliable sources of health information for consumers. The FTC Web site at <a href="https://www.ftc.gov/cureall">www.ftc.gov/cureall</a>, and the FDA Web site at <a href="https://www.ftda.gov">www.ftda.gov</a>, provides direct links to these sources of information. Consumers are encouraged to visit these Web sites when searching for health information and ask the following questions before deciding whether to purchase a health-related product:

- What is the product?
- What is the evidence that this product will do whatever the product purports to do (e.g., counteract the disease or medical condition being relieved; lead to better results than conventional treatment?)
- Have results from studies of this product been published in any peer-reviewed medical journals? Can I have copies of the publications or references to these publications?
- What are the training and credentials of the provider?
- Is the provider willing to communicate with my primary care physician and/or my health insurance company?

The FTC vote to authorize staff to file the complaint in this matter was 5-0. The case was filed in the U.S. District Court of Nevada, on June 12, 2003.

**NOTE**: The Commission authorizes the filing of a complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. The complaint is not a finding or ruling that the defendant actually has violated the law. The case will be decided by the court.

The FTC has established a telephone hotline recording that it will kept update with the latest developments. Distributors are urged to use this number: 1-877-862-0886 (option #5).

Copies of the complaint and related documents in both actions are available from the FTC's Web site at <a href="http://www.ftc.gov">http://www.ftc.gov</a> and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint, or to get free information on any of 150 consumer topics, call toll-free, 1-877-FTC-HELP ( 1 877-382-4357 ), or use the complaint form at <a href="http://www.ftc.gov">http://www.ftc.gov</a>. The FTC enters Internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure, online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

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### **Related Documents:**

Federal Trade Commission v. Seasilver USA, Inc.; Americaloe, Inc.; Bela Berkes; Jason Berkes; Brett Rademacher, individually and doing business as Netmark International and NetmarkPro; and David R. Friedman, D.C., CV-S-03-0676-RLH(LRL) (District of Nevada).

Operation Cure.All Web site