DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

Warning Letter

Certified Mail
Return Receipt Requested

July 22, 2003

Green Shack Direct
www.iherb.com
1435 South Shamrock Avenue
Monrovia, California 91016

W/L Number: 46 - 03

Ref: # 03-HFD-310-15

and

Ms. Sandie Smith-Fuller
Manager
iHerb Ltd.
600 East Fig Ave
Monrovia, California 91016

Dear Sir/Madam:

This letter concerns the marketing of "No-Rad, Body Gold" (potassium iodide) on your firm's website, www.iherb.com. Your Internet website, from which the product may be ordered, promotes No-Rad, Body Gold tablets as a product that can protect the consumer against radioactive iodine after a nuclear emergency. Based on the intended uses, the product is a "drug" as defined in Section 201(g) of the Federal Food, Drug, & Cosmetics Act (henceforth "Act") because it is intended to cure, mitigate, treat or prevent disease.

No-Rad, Body Gold's intended uses are documented on your firm's website, as follows:

"Protect your family against the ansorption [sic] of radioactive iodine after a nuclear emergency! WARNING: **Use only in the event of a nuclear emergency! Be Prepared!** ... During a nuclear disaster radioactive particles can become airborne or enter water

supplies affecting areas as far as 200 miles away, putting more than 75% of the US population at risk. The greatest threat comes from exposure to radioactive iodine. ... No-Rad offers your family the same protection provided by the government to the military and emergency workers. No-Rad contains Potassium Iodide (KI) which protects your thyroid gland from the radioactive iodine which can be released during a nuclear accident or attack. When you take Potassium Iodide, your thyroid gland absorbs as much normal iodine as it can hold. This blocks the uptake of radioactive iodine, protecting you form [sic] its harmful effects. ... Take immediately if exposure to radiation is likely, such as the fallout from a nuclear reactor accident or a nuclear explosion. ... Do not use unless exposure to radiation is imminent."

"**SUGGESTED USE:** During a nuclear emergency, adults take two tablets once a day. Children take just once a day. Children under three years old take 1/2 tablet. Stop use promptly when the threat of exposure to radiation has passed."

We are unaware of any evidence that establishes that this drug is generally recognized as safe and effective for the intended uses. Therefore, your product is a "new drug" as defined by section 201(p) of the Act. Under Section 505(a) of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. The continued distribution of No-Rad, Body Gold for these intended uses without an approved NDA is a prohibited act as set forth in Section 301(d) of the Act.

This letter is not intended to be an all-inclusive review of your Internet web site or all of your firm's labeling and products, and it is not intended to be an all-inclusive list of violations concerning your firm and its products. You are responsible for ensuring that all products marketed by your firm are in compliance with applicable United States laws.

With copies of this letter, we are advising the regulatory drug officials in the State of California of these violations.

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

You are instructed to cease these practices, and you must notify this office, in writing, within fifteen (15) working days of your receipt of this letter as to the specific actions you have taken to correct the stated violations. You should also include an explanation of each step you have taken to assure that similar violations will 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 made. Further, if your firm does not manufacture the product, your reply should also include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturing firm.

Address your reply to:

Director of Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Blvd.; Suite # 300
Irvine, California 92612-2445

re: www.iherb.com and iHerb Ltd.
re: Warning Letter Number 46 - 03

Sincerely,

Alonza E. Cruse, ADD for

Alonza E. Cruse
Director
Los Angeles District

cc:

Ms. Diana M. Bonta, Director
State Department of Health Services
714 "P" Street, Office Bldg. #8/1253
Sacramento, California 95814

Ms. Patricia F. Harris
Executive Officer
State Board of Pharmacy
400 R Street
Suite 4070
Sacramento, California 95814

Mr. Jim Waddell
Acting Chief
State Department of Health Services
Food and Drug Branch
P.O. Box 942732
Sacramento, California 94234-7320