DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

June 10, 2003

W/L 39-03
Ref #: 03-HFD-310-14

Mr. Joseph Deihl
Chief Executive Officer
www.kispray.com and www.vitamist.com
Regency Medical Research, Ltd.
2401 South 24th Street
Phoenix, Arizona 85034
US

Dear Mr. Dihl:

This letter concerns the marketing of "KI-Spray™" (potassium iodide) on your firm's websites, www.kispray.com and www.vitamist.com. Your Internet websites, from which the product may be ordered, promote KI-Spray as a product that can effectively prevent thyroid related cancers and other diseases during a nuclear disaster. Based on the intended uses, KI-Spray is a "drug" as defined in Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act) because it is intended to cure, mitigate, treat or prevent disease.

The product's intended use is documented on both of your firm's websites, as follows:

"KI-Spray™ is the only immediately absorbable Potassium Iodide available." "No water needed, no pills to swallow, just spray like a breath freshener." "Just spray to protect yourself and your loved ones." "When a nuclear disaster strikes, be prepared to shield yourself and your family against thyroid related cancers and

other diseases that crippled and killed thousands for years after the Chernobyl nuclear plant disaster, ..." "Radioactive iodine that damages your thyroid gland spreads by air, and can travel thousands of miles with the wind." "You can protect yourself from this damaging radiation with KI-Spray™ (Potassium Iodide)." "Potassium Iodide, KI, such as used in KI-Spray™ is known to help prevent long-term thyroid cancer in the event of a radiation emergency." "In a radiation emergency, radioactive iodine may be released into the air." "This material may be breathed or swallowed or ingested with food and drinks." "If you take Potassium Iodide, it will block the uptake of dangerous radioactive iodine." "If you take Potassium Iodide, it will block the uptake of dangerous radioactive iodine."

The product's intended use is documented on www.kispray.com, as follows:

"This is the anti-radiation formula you've been hearing about in the news but couldn't find in your pharmacy." "KI-Spray™ is the fastest acting, easiest to use, KI on the market." "KI-Spray™ is safe for everyone, from infants to adults." "Meets all FDA requirements for potassium iodide as a radiation protective, ..." "Has demonstrated all quality controls and passed all requirements for purity, quality, safety, and efficacy." "Comes full strength (130 mg of potassium iodide per dose, 8 sprays) in accordance with FDA demands for complete thyroid blocking." "KI-Spray™ [potassium iodide] is manufactured in the United States under strict guidelines, in FDA approved facilities." "For Complete Protection and Assured Quality, KI-Spray™!" "Potassium Iodide, Potassium Iodide [sic], such as used in KI-Spray™ is known to help prevent long-term thyroid cancer in the event of a radiation emergency." "KI-SprayTM uses a formulation that is child friendly." "Produced in an FDA approved facility and uses approved labeling."
We are unaware of any evidence that establishes that this drug is generally recognized as safe and effective for the intended use. 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 these products without an approved NDA is a prohibited act as set forth in Section 301(d) of the Act.

False promotional statements are being made by you on www.kispray.com that are aimed at and accessible to American consumers stating in part, "...Meets all FDA requirements for potassium iodide as a radiation protective, and is labeled and packaged in accordance with US government guidelines. ... Comes full strength (130 mg of potassium iodide per dose, 8 sprays) in accordance with FDA demands for complete thyroid blocking. ... manufactured in the United States under strict guidelines, in FDA approved facilities." These statements on your website cause the drug you distribute to be misbranded per Section 502(a) 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 Arizona 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 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 the U.S. Food and Drug Administration, 19900 Mac Arthur Blvd., Ste. 300, Irvine, California 92612-2445, Attention: Scott A. Goff, Acting Director of Compliance.

Sincerely,

Alonza E. Cruse
Director
Los Angeles District

cc:
Dr. Catherine R. Eden
Acting Director
State Department of Health Services
1740 West Adams Street
Phoenix, Arizona 85007

Mr. Llyn A. Lloyd
State Board of Pharmacy
4425 West Olive Avenue, #140
Glendale, Arizona 85302-3844