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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

May 29, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 22

Gary Olen
Chairman
www.sportsmansguide.com
The Sportsman's Guide
411 Farewell Avenue
South St. Paul, Minnesota 55075

Dear Mr. Olen:

This letter concerns the marketing of potassium iodate tablets on your firm's website, *www.sportsmansguide.com*, and in your catalog. Your Internet website and catalog display, from which the product may be ordered, promote potassium iodate tablets as a product that can protect the thyroid from radiation damage in the event of an emergency. Based on the intended use, your product 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 your firm's website and in your catalog, as follows:

> **...The 'anti-radiation pill' for the unthinkable emergency... FDA-approved pills proven to protect the thyroid from radiation damage.** These pills are 85 mgs. of 'good' iodine that block absorption of damaging radioactive iodine-131. **This KIO_3 formula, made only by Medical Corps,™ is the easiest and best potassium iodate for children (who are at greatest risk), as well as adults.** In a 'medium' 25-day fallout event, this 200-tablet bottle would protect the thyroids of:
> - 4 adults (ages 12 and up)
> - **8 children (ages 3-12)**
> - 16 kids up to 3 yrs., or
> - **32 newborns**.

> **Note:** Pills have an unlimited shelf life, and they are only to be taken in case of confirmed radioactivity. This is a vital protector your emergency medical kit may lack....

We are unaware of any evidence that establishes that this drug is generally recognized as safe and effective for the intended use. Therefore, your potassium iodate 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 applicatior (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.sportsmansguide.com* that are aimed at and accessible to American consumers stating in part, "...FDA-approved pills proven to protect the thyroid from radiation damage." This statement on your website causes the drug you distribute to be misbranded per Section 502(a) of the Act. The potassium iodate tablets are further misbranded within the meaning of Section 502(o) of the Act in that they are manufactured in an establishment not registered under Section 510 of the Act and they are not listed as required by Sectio 510(j) of the Act.

This letter is not intended to be an all-inclusive review of your Internet website 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 ensurin 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 Minnesota 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 th manufacturer and/or distributor of illegal products.

You are instructed to cease these practices, and you must notify this office in writin within 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 ar 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 Compliance Officer Brian D. Garthwaite, Ph.D., at the addres in the letterhead.

Sincerely,

for W. Charles Becoat
Director
Minneapolis District

BDG/ccl

xc: Dianne Mandernach
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