



APR 26 2006

Mr. Keith Edberg  
Operations Manager  
Robinson Outdoor Products  
110 N. Park Drive  
Cannon Falls, Minnesota 55009

Dear Mr. Edberg:

This is in response to your letter of April 10, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Robinson Outdoor Products is making the following claim, among others, for the product **Sportsmens Edge** :

“[R]esistance to Altitude Sickness.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely altitude sickness. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,

for Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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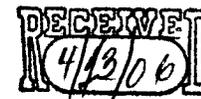
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-CE840

2006-3404



Office of Nutritional Products, Labeling, and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

April 10, 2006

**Subject:** Notification of general well-being or structure/function claims made on the label of a dietary supplement.

The following is notification of claims made in accordance with 21 CFR 101.93, on a new product called Sportsmens Edge that Robinson Outdoor Products started marketing to the public on March 27, 2006.

**Distributor:** Robinson Outdoor Products  
110 N. Park Dr.  
Cannon Falls, MN 55009

**Product:** *Sportsmens Edge* High Potency MultiVitamin/MultiMineral Supplement

**Statement on label:** \*Medical Research Suggests: Improved Concentration, Resistance to Cold, Improved Vision, Reduced Body Odor, Improved Hearing, and Resistance to Altitude Sickness.

**Ingredients** which are subject of, or contribute to, the statement:

Vitamin A, Vitamins B1, B2, B3, B6, and B12, Vitamin C, Bilberry Extract, Chlorophyll, Vitamin D, Vitamin E, Ginko Biloba Extract, Lutein, Magnesium, Selenium, Zinc

**Disclaimer:** The label includes the FDA disclaimer "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

**Certification:**

"I certify that the information provided in this notification is complete and accurate. I also certify that Robinson Outdoor Products has at its disposal substantiation for the general well-being or structure/function claims made on the label that are the subject of this notification."

*Keith Edberg*  
Keith Edberg  
Operations Manager

Date 4-10-06

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