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July 3, 1996

Dockets Management Branch
Food & Drug Administration
Department of Health & Human Services, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

FAXED
2:20 PM
JH

By mail and FAX to 301-594-3215

The undersigned submits this petition to the Commissioner of Food and Drugs to issue an order in the form of administrative action.

A. Action requested

That the FDA require that all sellers of "antioxidant" supplements be required to put appropriate consumer protection warnings on their labels, as follows:

CAUTION: The beta carotene in this product is synthetic and can promote cancer in smokers.

CAUTION: The vitamin C in this product is synthetic and can promote the generation of harmful free radicals in the 12% of Americans with high body iron.

CAUTION: The vitamin E in this product is synthetic and prohemorrhagic and dangerous for people with a family history of hemorrhagic stroke.

B. Statement of grounds

The scientific proof for the necessity of the above warnings is contained in the following recent peer-reviewed articles in the scientific literature (and the references at the end of each article):

Herbert V. The antioxidant supplement myth. *Am J Clin Nutr* 1994;60:157-8

Herbert V. Editorial: Vitamin C supplements and disease-Counterpoint. *J Am Coll Nutr* 1995; 14:112-113.

The Symposium on Prooxidant Effects of Antioxidant Vitamins (*J Nutrition* 1996;126 [Suppl 4; April]:1197S-1227S)(including the V Herbert "Introduction" [pp. 1197S-1200S], the M Gerber et al. paper on "Oxidant-Antioxidant Status Alterations in Cancer Patients: Relationship to tumor progression," [pp. 1201S-1207S], the JA Olson paper on "Benefits and Liabilities of Vitamin A and Carotenoids," [pp.1208S-1212S], the paper by V Herbert et al. on "Vitamin C-driven free radical generation from iron" [pp.1213S-1220S]), and the JL Schwartz paper on "The Dual Role of Nutrients

as Antioxidants and Prooxidants: Their effects on tumor cell growth" [pp 1221S-1227S]).

The three papers and editorial in the May 2, 1996 issue of *The New England Journal of Medicine* (CH Hennekens et al. Lack of effect of long-term supplementation with beta carotene on the incidence of malignant neoplasms and cardiovascular disease. *N Engl J Med* 1996;334:1145-9; GS Omenn et al. Effects of a combination of beta carotene and vitamin A on lung cancer and cardiovascular disease. *N Engl J Med* 1996;334:1150-5; HHL Kushi et al. Dietary antioxidant vitamins and death from coronary heart disease in postmenopausal women. *N Engl J Med* 1996;334:1156-62, and ER Greenberg and MB Sporn. Antioxidant vitamins, cancer, and cardiovascular disease. *N Engl J Med* 1996;334:1189-90).

In addition to the peer-reviewed scientific literature, much of the information on harms from "antioxidant" supplements is delineated in the following three books written for health professionals and the public:

S Barrett, V Herbert *The Vitamin Pushers: How the "Health Food" Industry is Selling America a Bill of Goods.* (Amherst, NY, Prometheus Press, 1994, 536 pp.)

Herbert V, Subak-Sharpe GJ (Eds). *Total Nutrition: The Only Guide You'll Ever Need: From the Mount Sinai School of Medicine.* (New York, NY, St. Martin's Press, 1995. 811 pp.)


Simopoulos, A., Herbert, V., Jacobson, B.: *Genetic Nutrition: Designing A Diet Based on Your Family Medical History.* (Macmillan Publishing Co., New York, 1993, 335 pp.)

The peer-reviewed literature on the prohemorrhagic action of vitamin E is summarized in V Herbert. Reply to J Whittam et al. *Am J Clin Nutr* 1995;62:1026 (references 2, 3, 4, 10, 11).

C. Impact

Implementation of these warnings will protect American health and save American lives.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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