



JUN 24 2004

William Han, Ph.D.
Chemron, Inc.
2 Apricot Court
North Potomac, Maryland 20878

Dear Dr. Han:

This is in response to your letter of April 8, 2004 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)).

The product **Sun-Ginseng** is using the claim "Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive." This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B) because it implies that the product will prevent a disease (i.e., cancer). In a April 1, 2003 letter in response to the court decision directing the FDA to consider qualified health claims for dietary supplement labeling (*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)) when the evidence in support of the claim does not meet the significant scientific agreement standard, we stated that FDA would exercise its enforcement discretion for a qualified claim with respect to antioxidant vitamin dietary supplements containing vitamin E and/or vitamin C when: (1) one of the disclaimers cited in the letter is placed immediately adjacent to and directly beneath the antioxidant vitamin claim, with no intervening material, in the same size, typeface, and contrast as the claim itself; and (2) the supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding the Tolerable Upper Intake Level established by the Institute of Medicine (IOM) of 2000 mg per day for vitamin C and 1000 mg per day for vitamin E (see May 4, 2001, letter at 4-6 and references cited therein).

A dietary supplement bearing a claim that is not eligible to use the claim (for example, it does not contain the antioxidant vitamins which the qualified claim is the subject of) or that is not properly qualified or consistent with the weight of the evidence is subject to regulatory action as a misbranded food under section 403(r)(1)(B) of the Act, a misbranded drug under section 502(f)(1), and as an unapproved new drug under section 505(a).

975-0163

LET 757

Page 2 - Dr. William Han

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal line extending to the right.

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

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

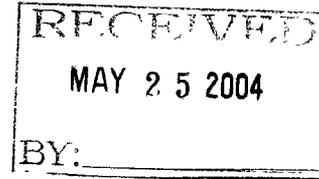
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Baltimore Office, Office of Compliance, HFR-CE240

Ginseng Science, Inc.
Seoul, Korea

April 8, 2004

Office of NPLDS
Division of Nutrition Programs and Labeling HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



RE: Notification of Nutritional Support Statements

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93(a) of FDA's regulations, I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in labeling of Dietary Supplement, Sun-Ginseng, which is manufactured by Ginseng Science Inc.

Statement: Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

To the best of my knowledge, and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete. Ginseng Science, Inc. possesses substantiation that the statements are truthful and not misleading.

William Han, Ph.D.
Official Correspondent of Ginseng Science, Inc.
Chemron, Inc.
2 Apricot Court
North Potomac, MD 20878
240 683 0971 ☎
240 683 0972 Fax

88441

William Han

William Han, Ph.D., C.E.O. of Chemron, Inc.