DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

FEB 21 2003

Jonathan W. Emord
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Suite 600
1050 17th Street, N.W.
Washington, D.C. 20036

Dear Mr. Emord:

Thank you for your February 12, 2003, letter stating Wellness Lifestyles, Inc.'s acceptance of the terms specified in our February 11, 2003 letter. This letter finalizes our agreement that FDA will consider exercising enforcement discretion for your client's claims with disclaimers as presented below:

> (1) "Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive."
>
> (2) "Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive."

As we have agreed, FDA will consider exercising enforcement discretion with respect to selenium supplements that bear your health claim(s) when: (1) the applicable disclaimer is placed immediately adjacent to and directly beneath your claim(s), 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 400 micrograms of selenium per day, which the National Academy of Sciences/Institute of Medicine (NAS/IOM) report[1] concluded is the tolerable upper intake level (UL) from foods and supplements likely to pose no risk of adverse health effects in almost all people. The agency notes that the same NAS/IOM report indicates that current intake of selenium from foods is estimated to be 100-200 micrograms per day and that 800 micrograms selenium per day is the no-observed-adverse-effect level (NOAEL).

Selenium supplements bearing the claim(s) and disclaimer(s) are still required to meet all applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act, including the applicable requirements for health claims.

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1 Food and Nutrition Board, Institute of Medicine, Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium and Carotenoids, 284-324 (2000).

02P-0457

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Pursuant to this letter, we will immediately begin considering the exercise of our enforcement discretion for supplements that your clients market with the above-referenced health claim(s) and disclaimer(s). We will be posting this letter on our website or otherwise providing guidance to the public regarding our advice in this letter.

As previously discussed, within 60 days of the date of this letter, we plan to issue the formal decision on the selenium and cancer health claim petition (Docket 02P-0457).

Sincerely Yours,

Christine Taylor

Christine L.Taylor, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
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and Applied Nutrition