DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR - 1 2003

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Washington, D.C. 20036

Dear Mr. Emord:

This letter is a follow-up to the Food and Drug Administration's February 11, 2003, letter, pursuant to the opinion and order issued December 26, 2002, by the U.S. District for the District of Columbia in *Whitaker, et al. v. Thompson, et al.*, Civil No. 01-1539, and your response dated February 13, 2003. As you know, the United States withdrew its notice of appeal in this matter on March 28. The purpose of this letter is to formalize the contingent understanding we reached in mid-February.

In its opinion and order, the Court instructed FDA to draft one or more "short, succinct, and accurate disclaimers" for the health claim: "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer." Slip Op. at 37; see Order at 1-2.

As we explained in our February 11 letter, FDA considered the two disclaimers suggested by the Court, as well as a number of others, and concluded the following three alternative disclaimers best meet the criteria specified in the Court's decision:

(1) 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.

(2) Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA does not endorse this claim because this evidence is limited and not conclusive.

(3) FDA has determined that although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive.

Your February 13 letter indicated that your clients accept these disclaimers, and that the various petitioners in this matter wish to have the option of using any of three disclaimers on their products with the antioxidant vitamin claim.

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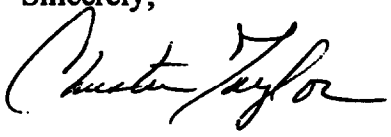
FDA intends to exercise its enforcement discretion with respect to antioxidant vitamin dietary supplements containing vitamin E and/or vitamin C when: (1) one of the above disclaimers is placed immediately adjacent to and directly beneath the antioxidant vitamin claim, with no intervening material, in 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).

Antioxidant vitamin supplements bearing the claim and one of the disclaimers 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.

Sincerely,



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