



Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

January 10, 2003

Jonathan W. Emord
Emord & Associates, P.C.
1050 Seventeenth St., N.W.
Suite 600
Washington, D.C. 20036

Re: Petition for health claim for selenium and cancer
(Docket 02P-0457)
Petition for health claim for phosphatidylserine and
dementia in the elderly and for phosphatidylserine and
cognitive dysfunction in the elderly (Docket 02P-0413)

Dear Mr. Emord:

This follows up on our telephone conversation of January 9, 2003. Within two weeks, FDA will provide you with information about its concerns regarding the above-referenced health claims and will meet with you to discuss these concerns in approximately three weeks. In return, you agree, on behalf of your clients, Wellness Lifestyles, Inc. and Dr. Kyl Smith, to a five-week extension of the deadline for FDA action on the above-referenced petitions, pursuant to 21 CFR 101.70(d)(3)(iii). This extension sets the new date to February 20, 2003, for the selenium health claim petition and to February 14, 2003, for the phosphatidylserine health claim petition. Your clients and you understand that reasonable additional extensions on one or both petitions may be necessary if, for example, you supplement the petition with a new submission in anticipation of, or in response to, the upcoming meeting with FDA.

Please confirm your agreement in writing either by letter to me or by noting your agreement on this letter and signing, dating, and returning it to me. Thank you for your consideration.

Sincerely,

Daniel E. Troy
Chief Counsel

cc: Christine L. Taylor, Ph.D.

02P-0457

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