

THE STATE UNIVERSITY OF NEW JERSEY

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January 26, 2007

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5360 Fishers Lane/Room 1061
Rockville, MD 20852

Attention: Dr. Barbara O. Schneeman, Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

RE: **Docket No. 2006P-0205/CP1**

Dear Dr. Schneeman,

Several scientific papers have appeared based on the Women's Health Initiative (WHI) studies of the effects of calcium and Vitamin D supplementation on (a) the risk of colorectal cancer, and (b) the risk of bone fracture and mineral density. The most important are listed below:

1. Wactawski-Wende J, Kotchen JM, Anderson GL, Assaf AR, Brunner RL, et al.: Calcium plus vitamin D supplementation and the risk of colorectal cancer. *N. Engl. J. Med.*, 345: 684-696, 2006.
2. Cauley JA, Robbins J, Chen Z, Cummings SR, Jackson RD, et al.: Effects of estrogen plus progestin on risk of fracture and bone mineral density: the Women's Health Initiative randomized trial. *JAMA*, 290: 1729-1738, 2003.
3. Jackson RD, LaCroix AZ, Gass M, Wallace RB, Robbins J, et al.: Calcium plus vitamin D supplementation and the risk of fractures. *N. Engl. J. Med.*, 354: 669-683, 2006.

The abstracts of the 2 papers in NEJM were inaccurate, and unduly negative. Unfortunately, most of the press, media, television news, etc. reported only the unduly negative abstract statements with few exceptions, e.g. The New York Times (Jane Brady) and particularly the Wall Street Journal (T. Parker-Pope).

In response to a request from the Editor of *Nutrition and Cancer*, a well known scientific journal, the enclosed classification of the WHI studies was prepared and published:

Newmark HL and Heaney RP.: Calcium, Vitamin D, and risk of colorectal cancer, *Nutrition and Cancer*, 56: 1-2, 2006.

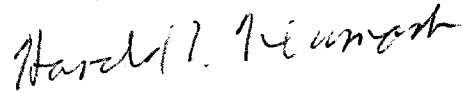
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This is applicable to both of the inter-related petitions to the FDA, aimed at adding Calcium (Docket No. 2005-0273/CP-1) and Vitamin D (Docket No. 2006P-0205/CP-1) as mandatory components of enrichment to cereal grain products.

We request that this communication be added to both petitions, aimed at classification of the WHI study reports, for the reviewers involved.

Sincerely yours,

A handwritten signature in cursive script that reads "Harold L. Newmark".

Harold L. Newmark, D. Sci. (Hon.)

HLN:ff
Enc.

cc: Dr. Robert Heaney