

Wyeth

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April 30, 2004

Dr. Kathleen Ellwood, Director
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject: Request for Extension of Comment Period
Docket No. 2004Q-0097: Qualified Health Claim (QHC): Calcium
and Various Cancers

Dear Dr. Ellwood:

Wyeth Consumer Healthcare ("Wyeth") hereby requests an extension of 30 days in the time permitted for submission of comments on the above referenced docket concerning Qualified Health Claim (QHC): Calcium and Various Cancers. This would extend the comment period until June 17, 2004.

We are very interested in the proposed health claim on calcium and a reduced risk of recurrent colon polyps, a major risk factor for colon cancer. It is the intention of Wyeth to provide comment that is substantive evidence in support of the relationship between calcium and the reduced risk of recurrent colon polyps. Since we are preparing an evidence-based review of the relevant literature and obtaining written summaries from qualified experts on the scientific evidence supporting the relationship between calcium and recurrent colon polyps, Wyeth does not believe there is sufficient time to fully develop a meaningful response before the current 60-day comment period closes on May 17, 2004.

Therefore, we respectfully request an additional 30 days to provide comment that represents the highest available level of scientific evidence in support of this proposed qualified health claim.

Thank you for your cooperation and attention in this matter.

Sincerely,



Marie C. Vicinanza, MS, RD

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