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**Wyeth**

May 28, 2004

Dr. Kathleen Ellwood, Director  
Division of Nutrition Programs and Labeling (**HFS-830**)  
Office of Nutritional Products, Labeling and Dietary Supplements  
Food and Drug Administration / Center for Food Safety and Applied Nutrition  
5100 Paint Branch Parkway  
College Park, MD 20740

**Subject: Comments to Docket: 2004Q-0097 - Qualified Health Claim (QHC):  
Calcium and Various Cancers**

Dear Dr. Ellwood:

Wyeth Consumer Healthcare (WCH), a division of Wyeth®, is submitting comments to Docket Number 2004Q-0097, Qualified Health Claim (QHC): Calcium and Various Cancers. As discussed with Dr. James Hoadley on April 23 and May 17, 2004, we are specifically limiting our comments to the effects of calcium on recurrent colon polyps and on the risk of colorectal cancer.

In the Health Claim Petition dated October 9, 2003 for Calcium and Various Cancers, an extensive literature summary of the effects of calcium on several aspects of colon cancer was included. This review addressed the important considerations of the scientific research available for:

- maintaining normal colorectal epithelium;
- the conversion of normal epithelium to neoplastic epithelium;
- the effect of bile acid solubility on epithelium;
- the effects of calcium on chemically induced colorectal cancer in animal models; and,
- the effects of calcium on colorectal cell proliferation and apoptosis.

The literature review also contained a comprehensive section on the direct effect of dietary calcium on colorectal cancer in humans. We have concluded that the information, as submitted in the Health Claim Petition, is an extensive review of the literature.

Of the numerous claims proposed in the Health Claim Petition, WCH supports the following health claim in our comments:

*Calcium may reduce the risk of recurrent colon polyps*

Additionally, we are requesting that FDA also approve a modified version of this health claim:

*Calcium may reduce the risk of recurrent colon polyps, a major risk factor for colon cancer*

We are therefore submitting additional information to support both of these health claims. Our comments in the attached “Comments to Docket: Calcium and the Risk of Recurrent Colon Polyps” include a review of the current Guideline on colorectal polyps from the Digestive Disease Societies (i.e., Polyp Guideline: Diagnosis, Treatment, and Surveillance for Patients with Colorectal Polyps) and expert opinions and assessments from four eminent scientists in the field of colon cancer prevention (i.e., Drs. Martin Lipkin, Peter R. Holt, Richard S. Rivlin and Phillip P. Toskes). Curricula vitae are included for these experts.

We appreciate FDA’s assurance that our comments will be considered and we hope that the additional information we are providing will be viewed as important in its review of the qualified health claim petition for calcium and the risk of colon polyps. Since adenomas are so common in the US population, recommending calcium provides the public with a simple, safe and inexpensive method to help reduce their risk of developing recurrent polyps.

If you have any questions or would like any additional information related to these comments, please contact me at 973-660-5848 or, in my absence, contact Elle Barbo at 973-660-5751.

Sincerely,



Marie C. Vicinanzo, MS, RD  
Associate Director, Regulatory Affairs

enclosures

cc: James E. Hoadley, PhD. (w/ enc.)