



Vitamin D FDA Revised Health Claim

As a result of a petition from The Coca-Cola Company's Beverage Institute for Health & Wellness (BIHW), the US Food and Drug Administration (FDA) has proposed to amend the regulation governing the FDA-approved calcium and osteoporosis risk reduction health claim to add a claim for both calcium and vitamin D together, and to reflect the importance of both calcium and vitamin D in promoting long-term bone health. The amended regulation also provides a broader definition of the populations that could benefit from consuming calcium and vitamin D to include both men and women at all ages and of all races. Once finalized, the amended regulation will allow food manufacturers to state on their label, and in labeling, that adequate vitamin D and calcium as part of a healthful diet, together with physical activity, may reduce the risk of osteoporosis in later life.

"A majority of Americans are not obtaining adequate intake levels of vitamin D," said Dr. Michael Holick, Professor of Medicine, Physiology and Dermatology at Boston University School of Medicine, and Chief of Endocrinology, Metabolism and Nutrition at Boston Medical Center. "Scientific evidence now demonstrates that adequate intake of both vitamin D and calcium reduces the risk of low bone density and osteoporosis among men and women regardless of ethnicity."

According to the National Osteoporosis Foundation, osteoporosis is a major public health threat, with about 55 percent of the U.S. population aged 50 and older at risk. Currently, more than 44 million American men and women suffer from low bone mass or osteoporosis, and the incidences of these conditions are projected to increase dramatically during the next twenty years as the baby-boom population ages. It is also estimated that direct medical costs associated with osteoporosis are approximately \$18 billion per year in the US.

One important defense against developing osteoporosis is adequate calcium and vitamin D intake, coupled with physical activity, beginning at an early age, and continuing throughout life.

The Coca-Cola Company's Beverage Institute for Health and Wellness petitioned the FDA in 2004 to amend the current calcium and osteoporosis health claim to add a claim for both calcium and vitamin D together, and a reduced risk of osteoporosis, to expand the claim to include men, and to include all ethnic groups.

"Updating the calcium and osteoporosis risk reduction health claim to include both vitamin D and calcium will help the food industry communicate the importance of these nutrients to consumers," said Don Short, president of the Company's Beverage Institute for Health & Wellness. "We initiated this petition with the FDA because we knew consumers would benefit from efforts that increased awareness of the link between calcium and vitamin D and bone health."

A recent survey by Opinion Research Corporation of more than 1,000 randomly selected adults living in the US found that although 94 percent of Americans correctly identified the bone-strengthening benefits of calcium, only 51% were aware of the role that vitamin D plays in reducing the risk of osteoporosis.

Dr. Carolyn E. Moore, Principal Scientist for The Company's The Beverage Institute of Health & Wellness, collaborated with leading bone health experts at the Boston University Medical Center and ENVIRON Health Sciences on two studies, published in peer-reviewed journals in 2004 and 2005, that assessed the vitamin D dietary intake of Americans. "The research, which utilized data from the National Health and Nutrition Examination Survey (NHANES), indicated that many consumers are not getting enough Vitamin D from food and dietary supplements. The groups at greatest risk in the U.S. include teenage girls, women, the elderly, and African American and Mexican American adults," Moore said.

According to Moore, vitamin D production by the skin is markedly reduced in northern latitudes (those above the 37th parallel) during winter months due to seasonal changes in the duration and angle of natural sunlight, which significantly reduces exposure to the sun's vitamin D-producing UV radiation. US cities at or just above the 37th parallel include Oakland (CA), Cedar City (UT), Durango (CO), Wichita (KS), Joplin (MO), Carbondale (IL), Paducah (KY), Bluefield (WV), and Lynchburg (VA).

Dr. Moore and The Company's Beverage Institute for Health and Wellness also worked closely with the FDA while seeking approval to add vitamin D to calcium-fortified juices. Research initiated by Moore, and conducted in conjunction with the Vitamin D and Bone Health Research Laboratory at Boston University Medical School, demonstrated that vitamin D is readily absorbed by the body when added to skim milk and orange juice. The FDA approved the addition of vitamin D to calcium-fortified juices in 2003.

The Importance of Vitamin D in Bone Health

Vitamin D requirements of all age groups can be met under conditions of adequate exposure to sunlight. However, several factors can reduce the production of vitamin D from the skin including the use of sunscreens, increased skin pigmentation, normal aging, and insufficient exposure to sunlight.

The primary function of Vitamin D is to aid in the body's absorption of calcium, helping to form and maintain strong bones. When a person is deficient in vitamin D, the body absorbs only about 10 – 15 percent of the calcium consumed in the diet. With adequate Vitamin D, calcium absorption increases to about 30 percent.

"...One of the most important defenses against osteoporosis is adequate calcium and vitamin D intake..."