



NATIONAL DAIRY COUNCIL®

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DAIRY MANAGEMENT INC.™

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September 19, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madame:

The National Dairy Council® appreciates the opportunity to comment on the proposed collection of information from consumers about their knowledge, perceptions, attitudes, and practices related to dietary supplements and food via the Health and Diet Survey. [Docket No. 01N-0319]

The National Dairy Council® is an organization that initiates nutrition research, develops nutrition education programs, and provides information on nutrition to health professionals and others concerned about good nutrition. The National Dairy Council has been a leader in nutrition research and education since 1915. Through its affiliated Dairy Council organizations, National Dairy Council is recognized throughout the nation as a leader in nutrition education.

We support FDA's proposed collection of information on consumers' use, knowledge and attitudes of dietary supplements through the Health and Diet Survey. We encourage FDA to include questions in the survey regarding consumers' use of and attitudes toward fortified foods. This information will help FDA assess the need to revise and update its food fortification policy guidelines and will provide initial direction for the process.

A recent report indicates that the use of dietary supplements is increasing, with approximately half of American adults using some type of nonprescription vitamin, dietary or mineral supplement daily.¹ Dietary supplements are increasingly advertised in the media and sold in drug stores and supermarkets, giving the public a false sense of security about their safety. In fact, while many

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¹ Blendon RJ, et al., Americans' views on the use and regulation of dietary supplements, *Arch Intern Med*, 161: 805-810, 2001.

are strongly convinced of the usefulness of dietary supplements to improve health, many are confused about government's role in overseeing their safety. About a third mistakenly believe that supplements are currently regulated by the government -- and there appears to be broad public support for a government role in reviewing safety, and setting standards for quality and purity of dietary supplements.¹ Therefore it is important to survey consumers about their use and attitudes toward dietary supplements and to assess the public's support for stronger government regulation of their safety and quality.

It is also important to understand consumers' perception of the relative role of food and dietary supplements in providing nutrient adequacy and promoting health in order to assess the need for public education. It is important, for example, to find out the proportion of people who believe the position of The American Dietetic Association that "the best nutritional strategy for promoting optimal health and reducing the risk of chronic disease is to obtain adequate nutrients from a wide variety of foods."² We believe dairy foods are the best source of calcium available to children and adults. Calcium fortified foods and supplements do not solve underlying problems of poor dietary patterns that lead to low nutrient intake. Fortified foods and dietary supplements are supplemental, only for those who cannot consume adequate dairy foods to meet required calcium needs.

Paralleling the increase of dietary supplements in the marketplace, is the proliferation of fortified foods. FDA discourages the "indiscriminant addition of nutrients to foods," and encourages food manufacturers to follow a list of rational principles regarding fortification.³ However, many food manufacturers are fortifying their products with high levels of calcium, apparently to gain a market advantage without considering the full impact on the population as a whole.

National Dairy Council® has communicated its concern in letters to the FDA Commissioner in 1995 and 2000 about the proliferation of foods in the marketplace fortified with high levels of calcium. Some well-known brands of cereal are fortified with an outrageously high amount of calcium -- 60% and 100% of the RDI or 600 and 1,000 mg of calcium per 1-cup serving. A serving of these cereals with ½ cup of milk provides either 750 or 1,100 mg of calcium. Clearly, some fortified foods are supplements in the guise of food. Researchers warn that a large bolus of calcium will be inefficiently absorbed, leading consumers to mistakenly believe they have met the daily recommended intake. In addition,

² Food fortification and dietary supplements, *J Am Diet Assoc*; 101:115, 2001. (Expires 2004)

³ Food and Drug Administration, HHS, Fortification Policy, 21 CFR Ch. 1, 104.20, 172, 2000

this practice increases the risk that certain subgroups of the population who are not in deficiency will over-consume calcium.

In response, FDA has indicated its interest in evaluating the impact of its present fortification policy. Gathering data from consumers about their use and attitudes toward fortified foods is a first step. Do consumers know what are the upper limits of intake for vitamins/minerals -- and do they understand the risks of overconsumption? Do consumers of fortified foods (or dietary supplements) pay attention to how much of a particular vitamin or mineral they obtain from fortified foods, supplements and natural food sources? Do people who consume one or two heavily fortified foods believe they are receiving adequate overall nutrition? Do consumers of calcium-fortified foods consider these foods an adequate substitute for consuming foods naturally rich in calcium, such as dairy foods? Finding out what consumers know about fortified foods, how they typically use them, and which subgroups in the population are the heaviest users, will clarify issues FDA will need to address in the future as it seeks to update its fortification policy.

However, there is also a need to gather quantitative data to support the benefits or evaluate the possible risks of fortifying the food supply with a particular nutrient. Currently we do not know how much calcium individuals are consuming from calcium fortified foods. Monitoring the impact of current levels of calcium fortification of foods on the target (those with insufficient calcium intakes) and non-target (those with adequate calcium intakes) population groups is critical for making decisions about both mandatory and voluntary calcium fortification of foods.

Thank you for the opportunity to comment on this proposal.

Sincerely,



Gregory D. Miller, PhD, FACN
Senior VP of Nutrition and Scientific Affairs



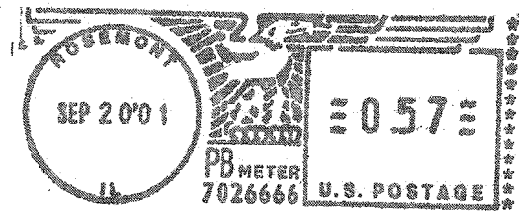
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