document draws the following conclusion:

> The preferred source of calcium is through calcium-rich foods such as dairy products. Calcium-fortified foods and calcium supplements are other means by which optimal calcium intake can be reached in those who cannot meet this need by ingesting conventional foods.

The agency has taken into consideration the expressed intent of the DSHEA and this finding from the 1994 consensus statement and tentatively concludes that revision of § 101.72(c)(2)(i)(E) is in order. The agency is proposing to raise the threshold for the required statement from 400 to 1,500 mg of calcium, along with other changes.

With regard to adverse effects and the risks associated with increased levels of calcium intake, the 1994 consensus statement states the following:

> Even at intake levels of less than 4 g/day, certain otherwise healthy persons may be more susceptible to developing hypercalcemia or hypercalciuria. Likewise, subjects with mild or subclinical illnesses marked by dysregulation of 1,25-dihydroxyvitamin D synthesis (e.g., primary hyperparathyroidism, sarcoidosis) may be at increased risk from higher calcium intakes. Nevertheless, in intervention studies (albeit of relatively short duration--less than 4 years), no adverse effects of moderate supplementation up to 1500 mg/day have been reported.

(Ref. 6.)

The same document concludes that daily calcium intake, up to a total of 2,000 mg, appears to be safe in most individuals (Ref. 6). For major segments of the U.S. population the 1994 consensus statement identifies an optimal calcium requirement of either 1,500 mg or a range of 1,200 to 1,500 mg of calcium per day. These population groups include adolescents and young adults 11 to 24 years of age, pregnant and lactating women, women over 50 (postmenopausal) who are not on estrogens, and men over 65 years of age (Ref. 6). Therefore, the agency tentatively finds that a level of 1,500 mg of calcium as the proposed threshold for the statement in § 101.72(c)(2)(i)(E) is not only consistent with current recommendations for dietary calcium intake but is also well within a range that is not known to cause adverse effects.

The agency is consequently proposing to require that the statement of limited benefit appear only on foods that provide more than 1,500 mg of calcium per day. FDA has expressed this proposed threshold level as a percentage of the Daily Values (DV's) for adults and children 4 or more years of age and for pregnant or lactating women. The agency notes that the calcium DV's for adults and children 4 or more years of age and for pregnant or lactating women have not changed and are 1,000 and 1,300 mg, respectively. (See § 101.9(c)(8)(iv) and 58 FR 2206 at 2213.) The agency intends to redesignate this requirement as § 101.72(c)(2)(i)(D).

A common form of a calcium dietary supplement in the marketplace is as a tablet containing either 500 or 600 mg of calcium as the sole nutrient with directions for use in labeling that recommend an intake of one or two tablets per day. A health claim in the labeling of such a product would not require the additional statement in proposed § 101.72(c)(2)(i)(D). FDA tentatively concludes that this proposed change is consistent with the recommendation from the 1994 consensus statement on dietary sources for this nutrient.

For consistency with the proposed revisions in § 101.72(c) and (d), FDA has revised the model health claims in proposed § 101.72(e). FDA has used the phrase ''Especially for teen and young adult women'' in example 1, which sets out how a claim that conforms with § 101.72(c) might look to reflect the effects on the risk of developing osteoporosis that may be realized by this population segment without implying that adequate calcium intake is without benefit for others.

The agency solicits comment on the proposed revisions to the calcium/osteoporosis health claim and is particularly interested in data on consumer understanding of this claim, and how such understanding can be improved.

2. Other Health Claims

A common requirement in the authorized claims for dietary fat and cancer (§ 101.73); sodium and hypertension (§ 101.74); dietary saturated fat and cholesterol and risk of coronary heart disease (§ 101.75); fiber-containing grain products, fruits, and vegetables and cancer (§ 101.76); fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease (§ 101.77); and fruits and vegetables and cancer (§ 101.78) is a statement that development of the particular disease depends on many factors.

It is well documented over the past 10 years that consumers are generally aware that development of major chronic diseases, such as cancer and coronary heart disease, is dependent on a number of different factors such as smoking, excess body weight, family history of the disease, exposure to environmental chemicals, and dietary and other factors (Refs. 9 and 10). Additionally, the requirement that authorized claims use the term ''may'' or ''might'' to relate the ability of the substance that is the subject of the claim to reduce the risk of the corresponding disease or health-related condition is an indication to consumers of the multifactorial nature of the disease or health-related condition. In responding to comments on the scientific standard for health claims as to whether or not a claim based on preliminary scientific data would be consistent with that standard, the agency said:

> * * * Further, absolute claims about diseases affected by diet are generally not possible because such diseases are almost always multifactorial. Diet is only one factor that influences whether a person will get such a disease. For example, in the case of calcium and osteoporosis, genetic predisposition (e.g., where there is a family history of fragile bones with aging) can play a major role in whether an individual will develop the disease. Because of factors other than diet, some individuals may develop the disease regardless of how they change their dietary patterns to avoid the disease. For those individuals, a claim that changes in dietary patterns will reduce the risk of disease would be false. Thus, health claims must be free to use the term ''may'' with respect to the potential to reduce the risk of disease. However, use of this term would not be appropriate for health claims on food labeling where significant scientific agreement does not exist that there is a high probability that a reduction in disease risk will occur.

(58 FR 2478 at 2505.)

Given these facts, as part of its review of required elements for all health claims the agency has reconsidered the need to remind consumers of the multifactorial nature of hypertension, heart disease, and cancer. Based on its review, FDA tentatively concludes that the statement of that fact in each claim can be made optional. In place of the requirement for stating the multifactorial nature of the disease, the agency proposes to substitute a requirement that the claim not imply that the substance that is the subject of the health claim is the only recognized risk factor for the corresponding disease or health-related condition. Thus, the agency tentatively concludes that the concept of the multifactorial nature of the disease or health-related condition for each health claim will be preserved without adding additional words to the claim. The agency requests comment on whether consumers will be misled to believe reduction of risk will be achieved if the multifactorial nature of