that FDA is requiring in § 101.72(c)(2)(i)(D) that the claim disclose that further benefit does not derive from a daily dietary intake of calcium that exceeds 2,000 mg.

Given these bases for the calcium/osteoporosis claim, an abbreviated claim consistent with the principles proposed earlier in this document may be developed that sets out the information required under § 101.72(c)(2)(i)(A) and (c)(2)(i)(C). To reflect this fact, the agency is proposing to renumber current § 101.72(c)(2)(ii), which deals with the nature of a food bearing a calcium/osteoporosis health claim, as § 101.72(c)(2)(iii), and it is proposing a new § 101.72(c)(2)(ii) that describes how the health claim is to be presented on the label or in labeling. This proposed new paragraph states that all of the elements listed in § 101.72(c)(2)(i) must be included in one presentation of the claim on the label or labeling. However, it also provides that a short, simple statement of the claim that includes the elements in § 101.72(c)(2)(i)(A) and (c)(2)(i)(C), and thus that is truthful, not misleading, and scientifically valid, may be used on the principal display panel as long as the full claim appears on the label or in the labeling, and, there is a referral statement to the full claim in immediate proximity to the abbreviated statement.

The referral statement that FDA is proposing accompany the abbreviated claim is consistent with that provided for in the general requirements for nutrient content claims (§ 101.13) and health claims (§ 101.14(d)(2)(iv)). Because this referral statement is short, it is also consistent with the use of an abbreviated claim.

In the 1993 health claims final rule, the agency stated that it did not believe that it is appropriate to use abbreviated health claims as referral statements (58 FR 2478 at 2512). The agency was concerned that an abbreviated claim did not include facts that are material in light of the representation that is made and that are necessary to understand the claim in the context of the daily diet. The agency was concerned that such confusion is possible whenever the full health claim information is in a location different from that of the reference statement, and that such confusion is especially likely to occur when a multiplicity of labeling is associated with a product. If these concerns can be addressed, however, the use of an abbreviated claim on the principal display panel would facilitate use of the claim and, as a result, the communication of information that will assist consumers in achieving healthful dietary practices.

The agency has tentatively concluded that this proposed rule addresses these concerns. It is providing for an abbreviated statement that reflects the facts that are material under section 201(n) of the act (21 U.S.C. 321(n)) and that are necessary to ensure that the claim is scientifically valid. It is also providing for an accompanying referral statement to additional information that is necessary for a full understanding of the claim. The agency is concerned, however, about the possibility that consumers may not read the complete claim, and thus that they will not have all the facts necessary to fully understand the significance of the claim being made and to comprehend the claim in the context of the daily diet. For this reason, the agency is asking for data to demonstrate that permitting an abbreviated claim in the manner that FDA has proposed will not significantly decrease the likelihood that consumers will read the full claim.

In § 101.72(c)(2)(ii)(A) and (c)(2)(ii)(B), the agency is proposing requirements for the type size and location of the referral statement that are consistent with those for nutrient content claims in § 101.13(g)(1) and (g)(2).

FDA has long held that accompanying information should be in a size reasonably related to that of the information that it modifies. Section 403(f) of the act requires that information required under the act be placed on the label with such conspicuousness as to render it likely to be read. Section 403(r)(2)(B) of the act requires that a referral statement for nutrient content claims appear prominently, although it does not specify requirements such as to type size or style.

For nutrient content claims, FDA established type size requirements for referral and disclosure statements that are related to the area of the surface bearing the principal display panel rather than to the type size used for the nutrient content claim. The proportionality between size of the referral statement and the size of the label panel ensures that the referral statement is presented with appropriate prominence. However, when the claim is less than twice what the minimum size of the referral statement would be, given the size of the label and § 101.105(i), the type size of the referral statement may be less than that required under § 101.105 for net quantity of contents. In such circumstances, the referral statement is of appropriate prominence if it is at least one-half the size of the claim and not less than one-sixteenth of an inch. This approach to the type size requirement for the referral statement provides additional flexibility to firms in utilizing label space but still ensures adequate prominence for this statement.

Because, under this proposal, health claim referral statements are to be used in a manner that is similar to how nutrient content claim referral statements are used, and because they are likely to appear on the principal display panel, the agency tentatively concludes that a health claim referral statement should be subject to the same type size requirements as those for nutrient content claims. Therefore, the agency tentatively concludes that the requirements for the referral statement set forth in § 101.72(c)(2)(ii)(A) and (c)(2)(ii)(B) are appropriate when an abbreviated health claim is used, and it is including them in this proposed rule.

In concert with the proposed requirements for an abbreviated health claim, the agency is including an abbreviated health claim among the examples of other model claims in proposed § 101.72(e).

E. Disclosure Versus Disqualifying Nutrient Levels for Health Claims

Section 403(r)(3)(A)(ii) of the act provides that a health claim may only be made for a food that ''does not contain, as determined * * * by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet.'' This section helps to ensure that consumers who rely on health claims will be consuming foods that will assist them in structuring a healthful diet that meets dietary guidelines.

As discussed more fully in the preamble to the 1993 health claims final rule, the agency implemented this provision by considering a food's role in the total daily diet and calculating levels of total fat, saturated fat, cholesterol, and sodium that would increase the risk of disease or health-related conditions in the general population. FDA calculated these levels by considering the number of foods consumed each day, as well as the number of foods that are likely to contain significant levels of these nutrients.

The agency has established different disqualifying levels for different types of foods, depending on the role that they play in the daily diet. Section 101.14(a)(5) defines the disqualifying level for individual foods as 20 percent of the DV's for total fat, saturated fat, cholesterol, and sodium. These levels