the disease or health-related condition is not stated in the claim.

Accordingly, the agency is proposing to revise §§ 101.73(c)(2)(i)(F), 101.74(c)(2)(i)(E), 101.75(c)(2)(i)(E), 101.76(c)(2)(i)(D), 101.77(c)(2)(i)(F), and 101.78(c)(2)(i)(I) in similar fashion to ensure that the health claim not imply that there is only one recognized risk factor for the development of the corresponding disease or health-related condition. The agency is also proposing to revise §§ 101.73(d)(1), 101.74(d)(1), 101.75(d)(1), 101.76(d)(2), 101.77(d)(1), and 101.78(d)(2) to state that development of the disease in question depends on many factors and to list the relevant factors for each disease. For consistency, the agency is also proposing to revise the model claims to reflect the proposed revisions to §§ 101.73, 101.74, 101.75, 101.76, 101.77, and 101.78.

In addition, the agency is proposing to correct § 101.77(e) by adding the phrase ''and the risk of coronary heart disease'' which was inadvertently omitted in the final rule.

The health claim for fruits and vegetables and cancer (§ 101.78) contains one additional element that FDA tentatively concludes could be optional instead of a mandatory part of the claim. In § 101.78(c)(2)(i)(D) the regulation states:

> The claim characterizes the food bearing the claim as containing one or more of the following, for which the food is a good source under § 101.54: dietary fiber, vitamin A, or vitamin C.

This required statement is very similar to the one required by § 101.78(c)(2)(i)(C):

> The claim characterizes fruits and vegetables as foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber.

The agency believes that the statement required by § 101.78(c)(2)(i)(C) is necessary to describe the relationship between the food and the disease. In the 1993 health claims final rule, FDA stated that by requiring that all characterizing nutrients be identified as characteristic of dietary patterns rich in fruits and vegetables without specifically attributing reduced cancer risk to a single nutrient, the claim is consistent with current scientific knowledge. However, the requirement in § 101.78(c)(2)(i)(D) identifies for the consumer which of the characterizing nutrients is contributed by the labeled food. FDA tentatively concludes that this information need not be a required element of the claim because it is available as part of the nutrition label.

Therefore, the agency has tentatively concluded that the information in § 101.78(c)(2)(i)(D) can be made optional. Accordingly, the agency is proposing to remove § 101.78(c)(2)(i)(D); redesignate § 101.78(d)(3) through (d)(5) as § 101.78(d)(4) through (d)(6), and add new § 101.78(d)(3) which reads:

> The claim may characterize fruits and vegetables that meet the requirements described in paragraph (c)(2)(ii) of this section as foods that are low in fat and that contain (or are a good source of) one or more of vitamin A, vitamin C, or dietary fiber.

FDA is also proposing to revise the model health claims in § 101.78(e) to reflect these changes.

3. Abbreviated Health Claims

In addition to eliminating some of the requirements for a full health claim, as stated above, NFPA requested that FDA permit the use of abbreviated health claims in labeling, such as on the principal display panel. FDA has reviewed the health claims as it is proposing to revise them to determine whether the required elements can be reorganized in accordance with proposed § 101.14(d)(2)(iv) to facilitate their use on the food label.

With the revisions to §§ 101.73, 101.74, 101.75, 101.76, 101.77, and 101.78 proposed in this document, the agency tentatively finds that all of the required elements for each of the claims are required under section 403(a) of the act to ensure that the claims are truthful and not misleading as well as under section 403(r) to ensure that they are scientifically valid. Accordingly, the agency tentatively concludes that there is no basis upon which it can propose to permit the splitting of these required elements between the principal display panel and another part of the food label.

Using the health claim for dietary fat and cancer as an example, the agency is proposing to remove the requirement that the claim state that cancer is a multifactorial disease. The remaining specific requirements in § 101.73(c)(2)(i)(A) through (c)(2)(i)(E) are necessary so that claims on the relationship between dietary fat and cancer are truthful, not misleading, and scientifically valid. A claim consistent with these requirements can be expressed in 11 or fewer words (e.g., ''A low fat diet may reduce the risk of some cancers''). These requirements also ensure that consumers will be able to understand the relative significance of the information presented in the claim in the context of a total daily diet. Accordingly, the agency tentatively finds that there is no need to divide the required elements of § 101.73 into those that must be included whenever the claim is presented and those that need only be included as part of the full claim. Based on the same reasoning, FDA has reached the same judgment about the elements of the claims authorized by §§ 101.74 through 101.78.

The agency tentatively concludes, however, that such a split is appropriate among the required elements of health claims on calcium and osteoporosis (§ 101.72). The various proposed revisions for the specific requirements in § 101.72(c)(2)(i) would produce a claim that is shorter than is provided for in the current regulation. Nonetheless, even with the proposed revisions, the length of the claim that would be required under § 101.72 is such that, to facilitate use of the claim, FDA is proposing to distinguish between those elements necessary to ensure that the claim is truthful and not misleading, and those elements that are necessary to understand the significance of the claim in the context of the total daily diet.

Section 101.72(c)(2)(i)(A), which the agency is proposing to revise, sets forth the most important requirement. It establishes the essence of the calcium/osteoporosis claim in that it requires clarity in a statement that associates adequacy of dietary calcium intake over a lifetime with a reduced risk of osteoporosis, a degenerative disease that affects more than 25 million Americans, particularly postmenopausal women and the elderly, and that is manifested by an incidence of 1.5 million bone fractures annually (Ref. 6). This provision sets out information that is fundamental if a claim associating calcium and osteoporosis is to be truthful and not misleading.

Section 101.72(c)(2)(i)(C), which requires that the claim not attribute any particular degree of risk reduction to adequate calcium intake is also necessary to ensure that claims are truthful, not misleading, and scientifically valid. Compliance with this requirement, however, does not add any words to the claim.

For the remaining requirements, § 101.72(c)(2)(i)(B) prohibits the implication that risk for the disease applies equally across the U.S. population. Instead, it requires identification of that segment of the population that is most at risk for developing the disease later in life, women in their bone forming years. The agency requires this information in response to section 403(r)(3)(b)(iii) of the act, which as stated above, requires that the claim accurately represent the relationship between calcium and osteoporosis in a manner that is comprehensible to the public. It is also under section 403(r)(3)(b)(iii) of the act