

under contract. Both FDA and AHRQ are agencies within the Department of Health and Human Services. This process should provide the scientific expertise and additional resources that FDA needs to conduct its scientific reviews within acceptable timeframes.

7. Competent and Reliable Scientific Evidence

FDA's July 2003 interim evidence-based ranking guidance (Ref. 2) describes a process for systematically evaluating the scientific evidence relevant to a substance/disease relationship that is the subject of a health claim petition. The scientific rating system provides a means by which the totality of the publicly available scientific evidence relevant to a substance/disease relationship can be assigned to one of four ranked levels.

The interim evidence-based ranking system presupposes that FTC's requirement of "competent and reliable scientific evidence" to substantiate a claim related to health or safety has been met. For purposes of FDA's evaluation of qualified health claims based upon credible evidence under *Pearson*, the Task Force recommended that FDA consider scientific evidence only if it is competent and reliable. FTC defines "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence" based upon the expertise of professionals in the relevant area, that has been "conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted" in the profession to "yield accurate and reliable results." *In Re: Great Earth International, Inc.*, 110 F.T.C. 188 (1988).

FDA is requesting comments on the meaning and/or relevance of "competent and reliable scientific evidence" for the purposes of supporting a qualified health claim. FDA seeks these comments within the specific context of qualified health claims only. Any agency interpretation of "credible evidence" in the context of qualified health claims would not apply to the meaning of that term in other regulatory contexts within FDA's purview.

C. Issues for Future Consideration

Although the regulatory alternatives discussed previously focus primarily on assessing scientific data as a basis for qualified health claims, the Task Force recognized that there may be merit in developing greater flexibility in other areas of health claim regulation. The Task Force believed that more flexibility in regulating the use of health claims

would further advance the use of reliable diet and health information to consumers via food labels. With respect to increased flexibility, the Task Force recommended that FDA solicit comments on two issues, in particular: (1) Disqualifying nutrient levels, and (2) minimum nutrient content requirements (referred to in the Task Force report as "minimal nutrient limits").

Disqualifying nutrient levels—Under existing regulations in § 101.14(a)(4), a health claim generally is not allowed on a food label or in food labeling when the food contains more than a specified level of total fat, saturated fat, cholesterol, or sodium.¹² However, when there is a public health benefit, FDA has made exceptions to these disqualifying nutrient levels. For example, FDA authorized a health claim in § 101.83 for plant sterol/stanol esters and reduced risk of CHD in labeling for dressings for salad and spreads even though these products exceed the disqualifying level for total fat because they contain more than 13 grams of fat per reference amount customarily consumed (RACC) (see § 101.83(c)(1)).

Minimum nutrient content requirement—Under § 101.14(e)(6) of FDA's general health claim regulations, a food may not bear a health claim unless the food contains 10 percent or more of the Reference Daily Intake or Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per RACC prior to any nutrient addition. FDA has provided for some flexibility in this requirement in that nutrients that traditionally have been added through fortification in accordance with FDA's fortification policy may be considered to meet the 10-percent requirement (see, e.g., 58 FR 44036 at 44037; August 18, 1993). In addition, FDA has excepted some unqualified health claims from this general requirement (see, e.g., § 101.83(c)(1) (health claim about plant sterol/stanol esters and reduced risk of CHD on dressings for salad)). Here again, additional flexibility may be appropriate for considering health claims for foods that may not meet the minimum nutrient content requirement.

As the Task Force report noted, FDA received a petition from the National Food Processors Association (NFPA) on these two issues, among others. In response to the NFPA petition and a separate petition from the American

Bakers Association, in the **Federal Register** of December 21, 1995 (60 FR 66206 (the 1995 proposed rule)), FDA proposed to amend its regulations on nutrient content claims and health claims to provide additional flexibility in the use of these claims on food products. The 1995 proposed rule proposed refinements to the agency's current regulations to allow additional synonyms for nutrient content claims without specific preclearance by the agency, to permit health claims on certain foods that do not currently qualify because they do not meet the minimum nutrient content requirement, to permit the use of shortened versions of authorized health claims under certain circumstances, to eliminate some of the required elements for health claims, and to specify the criteria that FDA will consider in evaluating petitions seeking exemption from the disqualifying nutrient levels.

FDA is identifying these two issues (i.e., disqualifying nutrient levels and minimum nutrient content requirement) in this ANPRM to acknowledge the Task Force report's recommendation that FDA solicit comment on them.

However, because these issues were raised in the 1995 proposed rule, FDA intends, in the near future, to re-open the comment period on the 1995 proposed rule to solicit additional comments on these issues. Thus, to avoid duplication and confusion, FDA is not requesting comments on disqualifying nutrient levels and minimum nutrient content requirements for health claims in this ANPRM.

III. Dietary Guidance

Through the years, the Federal Government has worked to provide consistent and scientifically sound recommendations to consumers about healthy eating patterns and wise food choices. Such advice originated with the "Basic Four" and has progressed through today's "Dietary Guidelines for Americans" (developed jointly by U.S. Department of Health and Human Services and U.S. Department of Agriculture (USDA)) and USDA's "Food Guide Pyramid." The agency believes that encouraging the use of dietary guidance statements on food labels is an important component of the Consumer Health Information for Better Nutrition Initiative.

The Task Force recommended that FDA not only seek opportunities to exercise flexibility in its evaluation of health claims in the areas discussed previously, but also to seek opportunities to promote the development and use of more dietary guidance statements on foods. The

¹² The disqualifying nutrient levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed (RACC), per label serving size, and, only for foods with an RACC of 30 g or less or 2 tablespoons or less, per 50 g (§101.14(a)(4)).