

RE-EVALUATION OF LOW FAT CRITERION FOR HEART DISEASE HEALTH CLAIMS

I. BACKGROUND

Coronary heart disease risk is the subject of five health claims authorized by FDA regulations. Four out of five require the foods eligible for the heart disease risk claims be “low fat” foods. FDA’s justification for imposing the “low fat” eligibility criterion at the time of authorizing these claims is explained below.

Saturated Fat and Cholesterol/CHD Health Claim 21 CFR 101.75

The first coronary heart disease (CHD) risk health claim authorized by FDA is a claim that related diets low in saturated fat and cholesterol to reduced risk of CHD (101.75). In authorizing this health claim in 1993, FDA concluded that the scientific evidence linking diets low in saturated fat and cholesterol to reduced risk of CHD is strong. The eligibility criteria for a food to use this claim are that the food be “low saturated fat,” “low cholesterol,” and also “low total fat.” FDA noted that, while total fat is not as strongly or directly linked to increased risk of CHD as is saturated fat and cholesterol, it may have significant indirect effects. FDA justified the low fat eligibility criterion in that: 1) low fat foods generally help individuals in reducing their intake of saturated fat and cholesterol, and 2) excess calories, of which fat contributes more per g than the other energy nutrients, is associated with two health-related conditions (obesity and diabetes) that are risk factors for heart disease. In this health claim regulation FDA made a distinction between the direct causal effect of dietary saturated fat and cholesterol on CHD risk, and the strong but indirect relationship of dietary total fat and CHD risk. As such, the subject of the claim is “dietary saturated fat and cholesterol” and dietary total fat is addressed as an additional criterion that must be met by a food before it may use the “dietary saturated fat and cholesterol” health claim.

Meats, fish, and poultry play an important role in the U.S. dietary pattern, serving as entrees as well as rich sources of protein, bioavailable sources of many minerals, and rich sources of several vitamins. When eaten in moderation and prepared with little or no added fat, lean meats, fish, and poultry can play an important role in helping consumers to meet dietary guidelines. However, applying the saturated fat and cholesterol/CHD health claim’s low fat criterion virtually prohibits this category of foods from bearing the health claim and as a result, may inadvertently interfere with the dietary guidance goals of encouraging consumption of a variety of foods and of increased use of lean meats, fish, and poultry instead of higher fat cuts. To remedy this situation FDA created an exemption to the low fat criterion and instead provided for saturated fat and cholesterol/CHD claims on game meats and fish that meet the “extra lean” requirements for saturated fat, cholesterol and total fat, although these requirements are not as stringent as the definitions for “low saturated fat,” “low cholesterol,” and “low total fat.”

Fruits, Vegetable and Grain Products that contain Fiber/CHD Health Claim 21 CFR 101.77

In 1993 FDA also authorized the use of a health claim relating diets rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, and reduced risk

of CHD (101.77). Consistent with the requirements for the saturated fat and cholesterol/CHD health claim, eligibility criteria for this health claim include that foods bearing the health claim be “low saturated fat,” “low cholesterol,” and “low total fat.” The “low total fat” criterion was included because low total fat is one of the characterizing features of diets rich in fiber-containing fruits, vegetables, and grain products. Because the effects of saturated fat and cholesterol are not readily separated from the effects of other nutritive components of fruits, vegetables, and grain products, and because the scientific evidence linking diets low in saturated fat and cholesterol to reduced risk of heart disease is strong, saturated fat and cholesterol are specified as qualifying nutrients. Total fat is also specified as a qualifying nutrient because a low content of total fat is characteristic of dietary patterns which relate to lower heart disease risk, and because it facilitates the ability of consumers to achieve diets low in saturated fat and cholesterol.

Soluble Fiber from Certain Foods/CHD Health Claim 21 CFR 101.81

In 1997 FDA authorized a new health claim relating soluble fiber of whole oat foods and CHD risk (101.81). This health claim regulation was subsequently amended to add psyllium husk and oatrim as an additional sources of soluble fiber eligible for the claim. Again, FDA followed suit with the saturated fat and cholesterol/CHD health claim and required as eligibility criteria that foods using the soluble fiber/CHD health claim be “low saturated fat,” “low cholesterol,” and “low total fat.” As before, FDA noted that while total fat is not directly linked to increased risk of CHD, it may have significant indirect effects.

Soy Protein/CHD Health Claim 21 CFR 101.82

In 1999 FDA authorized a new health claim relating soy protein and CHD risk (101.82). Again, FDA followed suit with the saturated fat and cholesterol/CHD health claim and required as eligibility criteria that foods using the soy protein/CHD health claim be “low saturated fat,” “low cholesterol,” and “low total fat.” However, for the soy protein/CHD health claim the agency waived the “low fat” criterion for food products consisting of or derived from whole soybeans, as long as those products contained no additional fat not derived from the soybeans. FDA noted that products derived from whole soybeans are useful sources of soy protein that, like fish and game meats that are “extra lean,” can be appropriately incorporated in a diet that is low in fat, saturated fat, and cholesterol.

Plant Sterol and Stanol Esters/CHD Health Claim 21 CFR 101.83

In 2000 FDA authorized its fifth health claim regulation pertaining to CHD. 21CFR 101.83 authorizes the use of a health claim relating consumption of plant sterol and stanol esters with CHD risk. As in the previous CHD health claims eligibility criteria for foods bearing this CHD health claim include “low saturated fat” and “low cholesterol.” However, in a break with past practice, the plant sterol/stanol ester/CHD health claim does not require eligible foods to be low in total fat.

The Dietary Guidelines for Americans, 2000, modify the previous guideline for total fat intake. The new guideline states, “*Choose a diet that is low in saturated fat and cholesterol and moderate in total fat.*” This new guideline also states, “*Some kinds of fat, especially saturated fats, increase*

the risk for coronary heart disease by raising the blood cholesterol. In contrast, unsaturated fats (found mainly in vegetable oils) do not increase blood cholesterol.” This modification in the dietary guidelines, from the recommendation to choose a diet low in total fat in the 4th edition of the U.S. Dietary Guidelines to the recommendation to choose a diet moderate in total fat in the Dietary Guidelines for Americans, 2000, is based on current scientific evidence of the role of diet in CHD, which does not support assigning first priority to a diet low in total fat. The agency's reliance on dietary guidelines in the plant sterol/stanol ester/ and CHD health claim and in previous health claim regulations is based on provisions of the 1990 amendments that direct FDA to issue health claim regulations that take into account the role of the nutrients in food in a way that will enhance the chances of consumers maintaining healthy dietary practices (see section 403(r)(3)(A) and (r)(3)(B) of the FFD&C Act), along with legislative history that mentions the role of health claims in encouraging Americans to eat balanced, healthful diets that meet federal government recommendations.

The agency concluded that not imposing a “low fat” requirement for the sterol/stanol ester and CHD health claim is consistent with the emphasis in the Dietary Guidelines for Americans, 2000, on diets moderate in total fat. Inasmuch as fats were the only technically feasible carriers of plant sterol/stanol esters at the time, requiring foods bearing the health claim to be “low fat” would have greatly limited the number of foods that could use this health claim. Such a requirement would lessen the public health benefits of the rule. On the other hand, there were a number of foods, such as margarines and salad dressings, that could be formulated to contain plant stanol or sterol esters while still qualifying as “low saturated fat” and “low cholesterol.” Given the strength of the evidence supporting the cholesterol-lowering effects of plant sterol/ stanol esters, FDA required that foods bearing this health claim be “low saturated fat” and “low cholesterol,” but not “lowfat.”

Hypertext links to health claim regulations referenced:

§ 101.75 – http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/aprqr/pdf/21cfr101.75.pdf

§ 101.77 – http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/aprqr/pdf/21cfr101.77.pdf

§ 101.81 – http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/aprqr/pdf/21cfr101.81.pdf

§ 101.82 – http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/aprqr/pdf/21cfr101.82.pdf

§ 101.83 – http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/aprqr/pdf/21cfr101.83.pdf