



APPENDIX C

Nutritive Value of VOSE

The term “nutritive value” was first discussed in the preamble to the re-proposed rule on health messages in food labeling. 55 FR 5176 (Feb 13, 1990). It was stated that the concept of “nutritive value” was basic to the distinction between a food and a drug and defined “nutritive value” (also defined as nutritional value) as “the ability of food to supply nourishment, that is...necessary for maintaining life” *Id* at 5178. It further described “nutritional value” as including “the usefulness of a food component, consumed as part of the total diet, in reducing the risk, or forestalling the onset, of a chronic disease condition”. It provided the following example:

[A] dietary reduction of saturated fat has been associated with a reduction in blood cholesterol level, which is a known risk factor for cardiovascular disease. On the label of a food that is low in saturated fat, a discussion of the association, and of how the food could be used as part of a low fat diet, would arguably be a discussion of its nutritional value and not evidence that the intended use of the product is as a drug.

In the preamble to the proposed rule on health claims for food, additional information was provided concerning the term “nutritive value” 56 Fed. Reg. 60537 (Nov 27, 1991). Here “nutritive value” was defined as “value in sustaining human existence by such processes as promoting growth, replacing loss of nutrients, or providing energy.”

Thus, FDA considers health-related claims appropriate for foods and food substances that have nutritive value in the context of their effect on health. As discussed in detail in the scientific summary section, VOSE reduces blood cholesterol, especially LDL-cholesterol, by a normal digestive process, and in turn has an important effect on health. Reduced risk for chronic disease in vegetarians has been attributed, in part, to the higher intake of plant sterols in their diets (Nair, et al., 1984). Pollak (1987) has suggested that high blood cholesterol is the result of an imbalance

APPENDIX C

between dietary plant sterol intake on the one hand, and dietary cholesterol intake and endogenous production, on the other. The nutritive value of plant sterols is not unlike that of soluble fiber from oats or psyllium, which contributes no or few calories, yet influence the absorptive process for cholesterol.

A vegetable oil spread or dressing contains nutritive value, of course, in the form of nutrients declared in the Nutrition Facts panel, e.g. calories. Vegetable oil sterol esters do also, provide nutritive value in the form of digestible calories derived exclusively from the fatty acids esterified to the sterol.

In summary VOSE possess nutritive value because:

- i. VOSE are a naturally occurring component of our diet;
- ii. VOSE affect the absorption of cholesterol through the normal digestive process. The effect is to reduce blood LDL-cholesterol levels. As the sterols themselves are only absorbed to a small degree (less than 5%), they inhibit the harmful process of excess increased cholesterol absorption;
- iii. VOSE aid the control of normal lipid, in particular cholesterol, absorption and metabolism;
- iv. VOSE, by helping to promote healthy cholesterol levels, as part of an overall diet, help reduce the risk of a chronic disease;
- v. the nutritive effect of VOSE remains constant over a wide range of consumption levels;
- vi. the nutritive value derives from the same basis as that for the soluble fiber from oats and psyllium.

For these reasons the conditions set forth in 21 C.F.R. §101.14(b)(3)(i) are met.