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Dockets Management Branch (HFA-305)
Food and Drug Administration
200 C Street, SW
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November 2, 2000

Dear FDA Representative,

Thank you for the opportunity to submit comments regarding the Interim Final Rule title Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease 65 FR 54685-54739, September 8, 2000. Our comments are attached.

Thank you for your consideration of these points.

Sincerely,



Amy Joy Lanou, Ph.D.
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Comment to the FDA regarding the Margarine Health Claims

Submitted by Amy Joy Lanou, Ph.D., Nutrition Director
November 2nd, 2000

On September 8th, 2000, the FDA announced that it would permit health claims about the role of plant sterol and plant stanol esters in reducing the risk of coronary heart disease for foods containing these substances based on their ability to lower cholesterol levels. The FDA's Interim Final Rule on Food Labeling: Health Claims, Plant Sterol/Stanol Esters and Coronary Heart Disease (hereinafter, "FDA's Interim Final Rule"), 65 Fed. Reg. 54685, was issued in response to petitions filed by Lipton (plant sterol esters petitioner) for TakeControl spread and McNeil Consumer Healthcare (plant stanol esters petitioner) for Benecol spread seeking approval to make a health claim for each of these margarine products which contain these plant esters. The Interim Final Rule granted provisional approval for both of these margarine products to make a label health claim. Both companies plan to add the plant sterol and plant stanol esters to other products, such as dressings for salad and snack bars, as well.

The Physicians Committee for Responsible Medicine (PCRM) is a nonprofit organization of health professionals that conducts clinical research and advocates for more healthful diets. PCRM requests that the provisional permission for these products to carry a health claim be withdrawn. If this request is not granted, we request that a statement such as "This product does not protect against all potential risks of fatty foods, such as obesity, hypertension, diabetes, and certain cancers" be added to the language of the label's health claim.

Margarine is not a healthy, nutritious food, even under FDA standards, and consumers should not be encouraged to consume such a product. Rather governmental public health efforts should be focused on encouraging consumers to reduce their intake of total fat, saturated fat, and cholesterol and increase their consumption of wholesome foods—fruits, vegetables, legumes, and grains—which naturally contain small amounts of plant sterol and stanol esters to reduce their risk of chronic disease, including heart disease.

However, instead of encouraging responsible eating habits, the FDA has chosen to promote the consumption of an unhealthy product by making exceptions to its carefully considered rules regarding when foods can carry a health claim. In particular, the FDA has relaxed its rules on maximum total fat content and minimum nutrient content in order to allow these margarines and dressings for salad containing plant stanol or plant sterol esters to carry a health claim. Health claims should be reserved for healthy foods that meet the nutritional standards set by the FDA and that make up an important part of an individual's diet.

1. Disqualifying Level of Total Fat

A single serving of a food product that contains, in relevant part, more than 13 grams of total fat is disqualified from bearing any health claim on its label. Further, if the labeled serving size is less than 30 grams or 2 tablespoons, a reference serving of 50 grams must be used as a basis for determining disqualifying nutrient levels. 58 Fed. Reg. 2478 101.14 (a) (5).

The fat content of the two margarine products that have been provisionally approved for the label health claim are as follows.

Benecol

- The 14-gram labeled serving of regular Benecol contains 9 grams of fat and 1 gram of saturated fat.
- A 50-gram reference serving of regular Benecol contains 32 grams of fat and 3.5 grams of saturated fat.

TakeControl

- The 14-gram labeled serving of regular TakeControl contains 6 grams of fat and 1 gram of saturated fat.
- A 50-gram reference serving of regular TakeControl contains 21 grams of fat and 3.5 grams of saturated fat.

Because the labeled serving for both Benecol and TakeControl are less than 30 grams, a referenced serving size of 50 grams must be used to establish disqualifying levels of fat. As these special margarine products contain far too much fat to meet the FDA requirement that foods must have 13 grams of fat or less per 50 grams of product to be permitted to make a health claim, a provisional exception to this rule was granted by the FDA. This provisional approval should not be made permanent.

The high fat content of American diets is one of the key nutritional problems leading to high rates of obesity, diabetes, heart disease, hypertension and some types of cancer. With the amount of fat that the average American eats, it is irresponsible and unjustifiable to relax the rules on health claims and fat content for one type of high-fat product, regardless of its cholesterol-lowering effects.

2. Minimum Nutrient Contribution Requirement

Congress' stated intent for permitting food labels to carry health claims was that these claims "be used to help Americans maintain a balanced and healthful diet." 58 Fed. Reg. 2478 at 2489 and 2521. Therefore, in its health claims regulations, the FDA stated that conventional foods bearing a health claim must contain 10 percent or more of the Reference Daily Intake (RDI) or the Daily Reference Value (DRV) for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed *before any nutrient addition.*" 21 C.F.R.101.14(e)(6). The FDA stated that this "is necessary to ensure that the value of health claims will not be trivialized or compromised by their use on foods of little or no nutritional value." 58 FR 2478 at 2521.

The dressings for salad and margarines at issue in this comment do not contain the requisite levels of vitamin A, vitamin C, iron, calcium, protein or fiber without nutrient addition.

Therefore, the petitioners for these margarines and other products containing plant stanol and plant sterol esters requested an exception from this minimum nutrient content rule for margarine, dressings for salad and other foods. The FDA approved a provisional exception for dressings for salad in reliance on the fact that they are often used on nutrient rich foods, but did not approve an exception for other products. In neither the FDA's Interim Final Rule nor through multiple calls to the FDA is this apparent exception explained. However, according to representatives from the companies that make these products, Benecol and TakeControl margarine currently attempt to meet this requirement by addition of the nutrient vitamin A rather than through naturally occurring vitamin A.

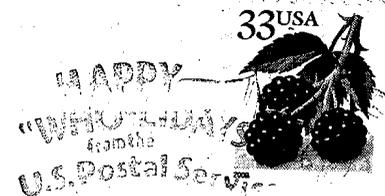
Neither margarine nor salad dressing is an important or necessary part of a balanced and healthful diet. Without these added substances extracted from plants, these products—salad dressings and margarine—are ones that professional nutritionists recommend limiting or avoiding to reduce the risk of obesity and chronic disease.

Allowing these products to carry a health claim without requiring that the products themselves be healthy and nutritious by the FDA's own definition sets an unfortunate precedent. In light of this action, we find ourselves asking, what will be next—a health claim for a cola product that reduces risk of diabetes?

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