



The SCHWAN FOOD COMPANY™

January 14, 2005

Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket Nos. 1994P-0390 and 1995P-0241

Food Labeling: Nutrient Content Claims, General Principles, Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period

Federal Register, November 18, 2004 (69 Fed. Reg. 67513)

Dear Sir or Madam:

The Schwan Food Company welcomes the opportunity to submit comments on the docket referenced above.

The Schwan Food Company is one of the largest branded frozen food companies in the world. The company employs more than 25,000 people in the processing, manufacturing, transportation, distribution and sales of frozen foods nationally and internationally.

Schwan commends FDA for its thoughtful consideration of policy that enhances consumer education and advances public health issues by providing industry with flexibility to communicate accurate, truthful and non-misleading health claims, nutrient content claims and other types of food label statements.

Specifically, we recommend:

- Dropping the minimum nutrient contribution requirement ("jelly bean" rule) for health claims;
- Replacing disqualifying nutrient levels for health claims with disclosure statements;
- Eliminating the use of the word "may" in unqualified health claims;
- Establishing a policy of notification for establishing synonyms for nutrient content claims.

1. **Drop the Minimum Nutrient Contribution Requirement ("Jelly Bean" Rule) for Health Claims.** The current health claim requires that in order to make a health claim, a food must provide not less than 10% Daily Value per serving of at least one of the following nutrients (vitamin A, vitamin C, calcium, iron, protein or dietary fiber) prior to any nutrient fortification.

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The Schwan Food Company believes that the minimum nutrient requirement prohibits some foods that make valuable contributions to the diet from communicating certain health claims. Many fruit products, vegetable side dishes and breads that are an important part of a healthful diet and are recommended in the 2005 Dietary Guidelines, would be ineligible for health claims because they do not meeting the "good source" criteria.

Schwan further recommends that the minimum nutrient contribution requirement be eliminated and that foods fortified with 10% Daily Value of one or more of the required nutrients (i.e., vitamin A, vitamin C, calcium, iron, protein or dietary fiber), be allowed to make health claims.

- 2. Replace Disqualifying Nutrient Levels for Health Claims with Disclosure Statements.** The Schwan Food Company applauds FDA for exempting a variety of foods, such as nuts, walnuts, omega-3-fatty acids in fish and olive oil from complying with the disqualifying nutrient levels (i.e., elevated levels of total fat, saturated fat, cholesterol or sodium). Consumers recognize that these foods can make positive health contributions to the diet despite the "disqualifying" nutrients present in the food.

Therefore, Schwan recommends allowing health claims on foods that are eligible to make a health claim regardless of whether the food exceeds the disqualifying nutrient level, provided the disqualified nutrient is not directly or adversely associated with the disease referred to in the claim.

To facilitate truthful and non-misleading communication about the healthfulness of a food, Schwan recommends that elevated levels of total fat, saturated fat, cholesterol or sodium content of a food be referenced or disclosed adjacent to the health claim, provided that nutrient is not linked adversely to the health claim.

- 3. Eliminate Use of the Word "May" in Unqualified Health Claims.** The Schwan Food Company recommends eliminating the word "may" from health claims where "significant scientific agreement" exists. All health claim language already emphasizes that a specific type of ingredient or diet "may reduce" risk of a particular disease.

Therefore, Schwan recommends that the degree of scientific agreement be evaluated and where adequate, the use of the word "may" is not adding to the accuracy of the claim. In fact, many consumers indicate the use of the word "may" conveys uncertainty surrounding the science supporting the claim and casts doubt on the validity of the claim.

4. **Establish a policy of notification for establishing synonyms for nutrient content claims.** The Schwan Food Company supports nutrient content and health claims that are consistent with existing science, that are truthful and non-misleading and that enhance consumers' ability to select a healthful diet. The use of descriptors to define nutrient levels in foods is due in large part to scientific development.

Schwan supports the use of undefined synonyms with notification to the Agency. While recognizing that the use of undefined synonyms has the potential of adding to consumer confusion regarding the healthfulness of a food, we support the benefit of prior notification for establishing new synonyms for claims.

The structure function required notification process should be modeled here. When a synonym is used in place of the specific verbiage allowed in the appropriate regulation for a nutrient content claim there should be a notification sent to the FDA with-in thirty days after entering interstate commerce. This notification will inform the FDA of the synonym used and to which nutrient content claim it is being anchored. No substantiation should be required as this notification is not to justify the nutrient content claim; it is to notify the use of synonymous verbiage i.e., "loaded with calcium" being used in place of "excellent source of calcium".

The FDA can respond appropriately to those uses of synonyms it believes that consumers may not reasonably be expected to understand in the same way as the approved nutrient content claim. Companies can either respond in defense or change packaging

The Schwan Food Company encourages FDA to give consideration to comments presented and to promulgate final rules on the important issue outlined in this petition. Thank you for the opportunity to comment on this important issue.

Respectfully submitted,



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