FOOD LABELING: NUTRIENT DESCRIPTORS, CLAIMS, AND OTHER INITIATIVES

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One of the Food and Drug Administration's (FDA's) current priorities is to foster good nutrition on a wider scale than previously. This is a challenge since knowledge of many nutrition issues is in flux although consumer interest is growing. To respond to consumer interest, we must find the best way to communicate current scientific knowledge to the public; food labels are a primary means by which we communicate.

For a brief historical overview, I will begin in 1969 when President Nixon called a White House Conference on Food, Nutrition, and Health to develop a national policy aimed at: 1) eliminating hunger and malnutrition due to poverty, and 2) improving the nutritional health of all Americans. Following the conference's recommendations, FDA implemented several significant initiatives, chief among them nutrition labeling and full ingredient labeling.

Nutrition labeling is required only if a food product makes a nutritional claim, such as "low calories" or "contains vitamin C" or when the food is enriched or fortified. Currently, over 55% of food labels carry nutrition labeling. On the actual label, the manufacturer must declare what is a serving size of the product, how many calories are in that serving, plus the amount of protein, carbohydrate, fat and sodium in that serving. That information is followed by the percentage of the U.S. Recommended Dietary Allowance (RDA) of protein, vitamins A and C, thiamine, riboflavin, niacin, calcium, and iron. The U.S. RDA's were developed by FDA to simplify the RDA into one set of values that could be used for all food labels (except those for infants and children less than 4 years of age). Manufacturers are given the option of listing other vitamins and minerals if they contribute at least 2% of the U.S. RDA. Also, fatty acids and cholesterol may be added under the fat designation.

These requirements satisfied most people's interest in nutrient information on foods for several years. However, consumer interest in nutrition and health increased dramatically subsequently. This interest has been fueled by many advances in nutrition science and education. Chief among them are: 1) *The Dietary Guidelines for Americans,* 2) *The Surgeon General's Report on Nutrition and Health*, and 3) The National Research Council's report entitled: *Diet and Health, Implications for Reducing Chronic Disease.*

For the past 10 - 15 years, a striking increase has occurred in consumers' perceptions of the health benefits to be gained through reducing certain food components to lower the risk of chronic diseases. The public is rapidly assimilating the idea that excessive dietary fats and cholesterol are bad for health. Manufacturers, eager to benefit from consumers' interest in diet and health issues, are taking an active role in developing new food products, or new marketing strategies for older well-established products, that highlight beneficial attributes of the foods.

To this end, the use of what we call "adjectival descriptors" has increased greatly in the past few years. These "adjectival descriptors" used in labeling or advertising describe the products by terms such as "low," "very low," "free," or "reduced" -- referring to the levels of calories, sodium, fat, cholesterol, or other components.

Such descriptors can certainly be of major value to consumers who, either on medical advice or on their own initiative, wish to modify their diets. However, FDA has been concerned over the use of such descriptors without precisely and quantitatively defining the terms so that they are understood by everyone, and used consistently across the market place. Accordingly, past regulatory action has been taken to define the terms. In 1978, after a lengthy public rule-making process which included public hearings, descriptors relating to calories were defined.

"Low calorie" foods were defined as foods containing 40 or less calories per serving and 0.4 or less calories per gram. Reduced calorie foods were defined as foods having a caloric reduction of at least 1/3 which are otherwise nutritionally equivalent to the foods for which they substitute. The label for such foods must

describe the comparison upon which the claim is made, including the calorie content of the food and that of the food for which it substitutes.

Final regulations governing sodium descriptors were published in 1984. These define "Sodium free" as "less than 5 mg sodium/serving", "very low sodium" is defined as "35 mg or less per serving", and "low sodium" as "140 mg or less/serving." "Reduced sodium" was defined as a reduction of at least 75% from the original product. A statement of comparison is required on the label.

Most recently, FDA published a proposed rule in November 1986 to define "cholesterol free," "low cholesterol," and "reduced cholesterol" and to make other revisions to current fat and cholesterol labeling rules.

The proposal defines "Cholesterol Free" as "less than 2 mg/serving". It defines "Low Cholesterol" as less than 20 mg/serving, and "reduced cholesterol" as a reduction in cholesterol of 75% or more from the food it resembles in organoleptic properties and for which it substitutes. For foods which cannot achieve a 75% reduction, yet have a substantial reduction from a reference food, it was proposed that comparative claims be allowed, provided that the label of such foods bears clear and concise quantitative information concerning the extent that the cholesterol was reduced, comparing the product's cholesterol content per serving with that of the food it replaces.

The goal of these actions is to assist the consumer in identifying the amount of fatty acids and cholesterol in foods. Thus, naturally, nutrition labeling will be required whenever such claims are made. Also, label declaration of either fatty acid or cholesterol content would require declaration of both. FDA feels strongly that it is misleading to declare one without the other, since the two are inter-related as causative factors in heart disease. The one exception to this rule is that fatty acid information will not be required on foods that do not contain enough fat to influence total intake of fatty acids. FDA has defined such low fat foods as any food that contains less than 2 g fat/serving or less than 10% fat on a dry weight basis. Therefore, with the exception of these low fat foods, food product labels which make a cholesterol claim must declare saturated and polyunsaturated fatty acid content.

Many comments were received to the proposed cholesterol rule that touched on issues outside of the rule. For instance, several commentors suggested that FDA develop similar adjectival descriptors relating to fat ("fat free," "low fat") and to fatty acids. In light of the dietary recommendations to lower fat intake, FDA agrees with the need for such terminology and has begun to develop a proposed rule to address such descriptors.

The calorie, sodium, and cholesterol labeling rules address simple truthful statements about the content of the food, such as "low calorie" or "low sodium" claims. These claims, or adjectival descriptors, make no statement about the ramifications of the nutritional characteristics of the food to health. In fact, FDA policy has in the past prohibited any explicit discussion of disease or health on food labels. FDA had enforced this policy by charging that a food so labeled was either a misbranded food or an illegal drug.

Faced with increasing interest on the part of industry and some nutrition educators to use the food label to convey health-related information to consumers, and faced with an increasing scientific database linking diet and disease, FDA opted to modify our long-standing policy in such a way as to permit appropriate health messages without opening the door to misleading, or outright fraudulent, claims. In August, 1987, FDA issued proposed regulations which would allow health-related claims or information to be placed on food labels if the messages are appropriately formulated for use on labels and are consistent with existing law and regulations.

As stated in the regulation, "Information on a food label representing, suggesting, or implying a food is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom will be deemed to be misbranded unless it complies with the criteria for health messages." The following criteria were proposed:

1) Information on food labeling should be educational in nature and limited to a discussion of the relationship between nutrition and health.

2) Information should be based on, and be consistent with, widely accepted, well-substantiated, peer-reviewed scientific data (including data derived from clinical studies) and generally recognized medical and nutritional principles.

3) The information must emphasize the importance of a total dietary pattern.

4) Information on food labeling must not overemphasize or distort the role of a food in enhancing good health. No one food will cure, or cause, a disease.

A draft of the final health claims rule was sent to the Office of Management and Budget last fall for policy review. It has not yet been released.

Another initiative is shelf labeling of foods. These in-store nutrition programs have been developed by many supermarkets to take advantage of shopping as an opportunity to communicate nutrition information to consumers. These programs have provided nutrition information through displays, posters, flyers, or shelf cards or tags. These labels are considered by FDA as an extension of food labeling, and therefore must use these definitions I've discussed earlier for calorie and sodium claims.

The same holds true for cholesterol claims; however, in the case of fat, definitions have not been developed by public rulemaking. Therefore, we have worked with many grocery chains to arrive at the following definitions for shelf labeling purposes: 1) Low fat = less than 2 g fat/serving and less than 10% fat on a dry weight basis, and 2) Reduced fat = a reduction of 50% or greater. If a company wants to make claims about fatty acids, they are to calculate polyunsaturated fatty acids as the sum of all cis-cis-methylene interrupted fatty acids, and saturated fatty acids as the sum of lauric, myristic, palmitic and stearic fatty acids.

Additionally, if fiber claims are desired, the shelf labeling program may claim that a product is a "fair" source if it contains 2 g fiber/serving, a "good" source if it contains 5 g/serving, and an "excellent" source if it contains 8 g/serving. Other nutrients for which there are U.S. RDAs may claim to be a source of that nutrient if they furnish 10% of the U.S. RDA, a "Good" source if they furnish 25% and an "excellent" source if they furnish 40% or more of the U.S. RDA.

Until these varied initiatives are completed, FDA would like to urge industry and consumers to make better use of the quantitative information within the nutrition label. The quantitative information is the most important factual information needed by the consumer. The use of this information will keep us out of the Good Food/Bad Food dichotomy that is so futile. Consumers must be made aware of the importance of the total diet rather than misplaced emphasis on particular foods. Only by having nutrition labeling on as many food products as possible, and by educating consumers on how to properly use this nutrient information, will consumers have a chance to sort through competing health messages and label claims to be able to select a diet with which they are satisfied and which will fulfill their nutritional needs.