

consumers with information they need to help them make healthy food choices in the context of their total daily diet.

In addition to the information on the Nutrition Facts panel, nutrient content and health claims are important tools for providing consumers with information about the level of one or more nutrients in a food product. Because the level of scientific evidence does not currently support the establishment of an appropriate reference value for daily consumption of *trans* fat, such as a DRI level, from which the agency could derive a DRV for *trans* fat, the agency decided, in the *trans* fat final regulation, to withdraw those provisions of the proposed *trans* fat rule pertaining to the establishment of a definition of “*trans* fat free,” consideration of “reduced *trans* fat” and “reduced saturated fat and *trans* fat” claims and limits on the amounts of *trans* fat wherever saturated fat limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels. However, the agency plans to continue to evaluate the emerging science and revisit the need for establishing nutrient content claims related to *trans* fat, and limits on *trans* fat in certain nutrient content claims, health claims, and disclosure and disqualifying levels through a new rulemaking once the scientific evidence has evolved to a point at which the agency believes the scientific evidence would support such a rulemaking. If a company wants to make a statement about the fat content of a product that is demonstrably true, balanced, adequately substantiated, and not misleading, FDA would have to consider the exercise of its enforcement discretion.

The agency is concerned about ensuring that consumers obtain the best possible information related to *trans* fat and other cholesterol-raising lipids on the food label. Therefore, we are interested in receiving information from scientific bodies concerning recommended or upper intake levels of *trans* fat. We are also requesting interested persons to submit, as part of their comments on this ANPRM, scientific information and data, including consumer research data and analyses of risk inherent in selecting specific levels of *trans* fat, that would assist the agency in establishing qualifying criteria for *trans* fat in *trans* fat nutrient content claims, current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids, and, in addition, as disclosure and disqualifying levels. Alternatively, in

the absence of evidence to support the establishment of such qualifying criteria, the agency is interested in receiving any available data to support the usefulness of or need for a disclosure statement, in conjunction with nutrient content or health claims, concerning levels of saturated fat, *trans* fat, or cholesterol in a food or in the diet or a message about the role of such cholesterol-raising lipids in increasing the risk of CHD.

The agency is also interested in comments on the impact on consumers’ shopping choices of a qualifying criterion for *trans* fat in saturated fat, cholesterol, lean and extra lean nutrient content claims and in health claims that contain a message about cholesterol-raising lipids. What kinds of products would consumers buy more or less of because of such claims and a *trans* fat criterion?

B. Footnote Statements

We are asking interested persons and those with expertise in consumer research to submit, as part of their comments on the ANPRM, information and consumer research data on any of the following footnote statements:

- Intake of saturated fat and *trans* fat should be kept low while maintaining a nutritionally adequate diet;
- Intake of *trans* fat should be kept low while maintaining a nutritionally adequate diet;
- Intake of saturated fat, *trans* fat, and cholesterol should be kept low while maintaining a nutritionally adequate diet;
- As part of a nutritionally balanced diet, intake of saturated fat, *trans* fat, and cholesterol should be kept low;
- Healthy diets start with diets low in saturated fat, *trans* fat, and cholesterol; and
- Nutritionally adequate diets include diets low in saturated fat, *trans* fat, and cholesterol.

Other footnote statements may also be considered.

In particular, we are interested in information about whether a footnote about *trans* fat, alone or in combination with saturated fat and cholesterol, would be helpful to consumers and what kinds of footnote statements are likely to be helpful to consumers to achieve the goal of conveying information about *trans* fat and/or other cholesterol-raising lipids in a manner which “enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.” (Section 2(b) of Public Law 101–535). Such information might consist of tests of the ability of various

footnotes to assist consumers in making product choices or to draw correct inferences about product characteristics. It might also be useful to know how different footnote statements are comprehended by consumers and whether they are: (1) Seen as credible, (2) understood as statements of dietary guidance or as product warning statements, or (3) seen as confusing. As always, we will take into account the adequacy of the sample, sample size, response rates, study design, and the representativeness of the products and product comparisons used in the study when we evaluate and/or design a study.

We intend to conduct consumer research of this kind in the near future.

C. Specific Questions to be Considered

Comments are also requested on the following questions:

- How will nutrient content or health claims or a footnote or disclosure statement about *trans* fat, either alone or in combination with saturated fat and cholesterol, change, if at all, the way consumers are likely to respond to the required declaration of the amount of saturated and *trans* fats in the Nutrition Facts panel?
- Will a claim or a footnote or disclosure statement have an impact on consumers’ shopping choices, and, if so, what kinds of products will consumers buy more of and less of?
- Is there any information, other than claims or a footnote or disclosure statement, that FDA should consider requiring in labeling that would be more helpful to consumers with respect to cholesterol-raising lipids in maintaining a healthy diet and in getting accurate and reliable nutrition information, or that would help consumers make better use of the information about cholesterol-raising lipids on the label?
- Since the amount of *trans* fat will be listed in the Nutrition Facts panel right below the amount and % DV of saturated fat, what additional effect will claims or a footnote or disclosure statement about *trans* fat, either alone or in combination with saturated fat and cholesterol, have on the line of products that manufacturers choose to make?
- What kinds of existing products will manufacturers reformulate because of claims or a footnote or disclosure statement?
- What kinds of new products will manufacturers develop because of claims or a footnote or disclosure statement?
- What kinds of products will manufacturers stop producing because of claims or a footnote or disclosure statement?