

- What First Amendment issues, if any, would be raised by establishing qualifying criteria for *trans* fat in *trans* fat claims and other nutrient content or health claims with existing criteria for saturated fat and by requiring a footnote or disclosure statement?

- How will manufacturers weigh the consumer concerns about both saturated and *trans* fats with the functional properties of those fats in the food. For example, if, as some manufacturers have claimed, functional considerations may sometimes cause *trans* fat to be replaced with equal or greater amounts of saturated fat, then how will consumers react to a potentially unhealthful substitution where a product lists fewer grams of *trans* fat, but lists more grams of saturated fat and reports a higher % DV for saturated fat? At what ratio of substitution of saturated fat for *trans* fat would it not be advantageous to a manufacturer to make such a substitution, even with a claim or footnote or disclosure statement? What steps could FDA take to encourage more healthful reformulation?

- In order to comply with the Small Business Regulatory Enforcement Fairness Act of 1996, what options for regulatory relief should we consider giving to small businesses?

### III. References

The following references have been placed on display in the Division of

Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal government holidays. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. IOM/NAS, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids," National Academy Press, Washington, DC, pp. S1–S17, 8–1 to 8–97, and 11–1 to 11–48, 2002 (Internet address: <http://www.nap.edu/books/0309085373/html/>).

2. U.S. Department of Agriculture and U.S. Department of Health and Human Services, *Nutrition and Your Health: Dietary Guidelines for Americans*, 5th ed., Washington DC; Home and Garden Bulletin No. 232, 2000 (Internet address: <http://www.health.gov>).

3. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), chapter II, "Rationale for Intervention" and Chapter V "Adopting Healthful Lifestyle Habits to Lower LDL Cholesterol and Reduce CHD Risk," 2001, (Internet address: <http://www.NHLBI.nih.gov/guidelines/cholesterol/index.htm>).

4. Committee on Diet and Health, Food and Nutrition Board, National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," chapter 28, Washington, DC, National Academy Press, 1989.

5. Population Panel, National Cholesterol Education Program, National Heart, Lung, and Blood Institute, National Institutes of Health, "Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction, Executive Summary" Bethesda, MD, NIH Publication No. 90–3047, November 1990.

### IV. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This ANPRM is issued under sections 201, 403, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, and 371) and under the authority of the Commissioner of Food and Drugs.

Dated: June 26, 2003.

**Mark B. McClellan,**

*Commissioner of Food and Drugs.*

[FR Doc. 03–17526 Filed 7–9–03; 8:45 am]

**BILLING CODE 4160–01–S**