Information received by CDRH and CBER during calendar year (CY) 2008. Elsewhere in this Federal Register, we are publishing a document announcing the availability of a draft guidance document entitled “Guidance for Industry and FDA Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act.” This guidance describes the procedures we recommend when seeking the Agency’s views about classification information and regulatory requirements that may be applicable to a particular device. The burden estimate is based on the amount of time needed to satisfy the completion of these procedures.

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

V. 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 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.


Leslie Kux,
Acting Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0210]

Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to obtain data and other information that will inform the agency’s deliberations about ways to enhance the usefulness to consumers of point-of-purchase nutrition information, such as information on the principal display panel of food products (“front-of-pack” labeling) or on shelf tags in retail stores. In particular, FDA is interested in the following: Data and information on the extent to which consumers notice, use, and understand nutrition symbols on front-of-pack labeling of food packages or on shelf tags in retail stores; research assessing and comparing the effectiveness of particular possible approaches to front-
of-pack labeling: graphic design, marketing, and advertising data and information that can inform and guide the development of better point-of-purchase nutrition information; and the extent to which point-of-purchase nutrition information may affect decisions by food manufacturers to reformulate products. The goal of this front-of-pack labeling effort is to maximize the number of consumers who readily notice, understand, and use point-of-purchase information to make more nutritious choices for themselves and their families. FDA is establishing this docket in order to provide an opportunity for interested parties to provide data and information and share views that will inform future agency actions with respect to these matters.

DATES: Submit electronic or written comments by July 28, 2010.

ADDRESS: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION:

I. Background

The Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535) amended the Federal Food, Drug, and Cosmetic Act (the act) to require nutrition labeling on packaged foods and to provide for the use of nutrient content claims and health claims in food labeling. The purpose of these amendments was to enable consumers to make more informed and healthier food choices in the context of their daily diet. In 1993, FDA established regulations that implemented NLEA. Among those regulations, FDA set forth general principles for nutrient content claims (21 CFR 101.13), which are claims that characterize the level of a nutrient in a food (e.g., “low fat,” “good source of fiber”) and for health claims, which are claims that characterize the relationship of a food substance to a disease or health-related condition (e.g., “calcium may reduce the risk of osteoporosis”). The cornerstone of the NLEA is the requirement that packaged foods bear product-specific information on serving size, calories, and nutrient content (21 CFR 101.2(b) and (d)). For conventional foods, this information is provided in a Nutrition Facts box on the package label. FDA’s final regulations establishing nutrition labeling were published in 1993 (58 FR 2079, January 6, 1993).

An important goal of NLEA was to make available to consumers nutrition information that can assist them in selecting foods that contribute to healthier diets. Research conducted by FDA and others shows that many consumers use the Nutrition Facts box in their food choices (Ref. 1). Yet, as Margaret A. Hamburg, the Commissioner of Food and Drugs, noted recently, “Today, ready access to reliable information about the calorie and nutrient content of foods is even more important, given the prevalence of obesity and diet-related diseases in the United States” (Ref. 2). Data published by the U.S. Centers for Disease Control and Prevention (CDC) indicate that 68 percent of the U.S. adult population is overweight or obese (Ref. 3), and among children 2 to 19 years old, nearly 32 percent were at or above the 85th percentile for body-mass index on CDC’s 2000 National Height and Weight-specific growth charts, which are based primarily on data from the 1960s and 1970s (Ref. 4). Body mass index (BMI) is a weight-to-height ratio. High BMI among children and adults is a significant public health concern in the United States. Children with high BMI often become obese adults, and obese adults are at risk for many chronic conditions such as diabetes, cardiovascular disease, and certain cancers. Healthy eating must be incorporated into the habits and diets of children to promote healthy lifelong practices to prevent obesity and chronic disease. First Lady Michelle Obama recently announced a coordinated national campaign to reduce the prevalence of overweight and obesity in the United States particularly among children (Ref. 5).

The prevalence of diet-related diseases in the U.S. population and the need to accommodate Americans’ increasingly busy lifestyles and demand for quick and nutritious food choices illustrate the importance of tailoring nutrition information to help consumers. FDA and others in the public health community, as well as consumer and industry groups, are actively exploring ways to improve the usefulness of food labeling to consumers.

A number of U.S. food processors and retailers are now incorporating nutrition symbols and other nutrition-related representations on food packages, particularly symbols intended to denote nutritious or unhealthful foods (e.g., the Kellogg’s Nutrition at a Glance (Ref. 7)), selected nutrient level disclosures (e.g., Kellogg’s Nutrition at a Glance (Ref. 7)), and nutrient content claims. Because this information is usually placed on the principal display panels (PDPs) of food packages, it is commonly referred to as front-of-pack (FOP) labeling, and we use that term as a synonym for principal display panel in this document. Nutrition symbol schemes have also been used in other countries, including the United Kingdom (Ref. 8) and Sweden (Ref. 9). In addition, some retailers have been adding nutrition symbols on the shelf tags of foods sold in the store to provide information about the overall nutritional quality of the food (e.g., Guiding Stars (Ref. 10)) or the levels of selected nutrients it contains.

FDA and the U.S. Department of Agriculture are working with public and private stakeholders to develop a voluntary FOP nutrition label that is driven by sound nutrition criteria, consumer research, and design expertise. Research should be designed to support the choice of an FOP label that will achieve the goal and satisfy the criteria for success outlined in the following paragraphs.

The goal of an FOP nutrition label is to increase the proportion of consumers who readily notice, understand, and use the available information to make more nutritious choices for themselves and their families, and thereby prevent or reduce obesity and other diet-related chronic disease. FDA believes that information in front-of-pack labeling can be useful to supplement the information in the Nutrition Facts box. In addition, because of its prominent location, front-of-pack labeling may provide a more convenient and effective information tool for consumers seeking quick and accurate information about the nutritional quality of the food they are purchasing and accessing, and using this information may serve to educate consumers and to help them make healthier food choices. It is also possible that information disclosed in front-of-pack labeling may foster industry reformulation of products because some consumers may notice the information and make their product selection accordingly. Through these mechanisms of improved consumer understanding and use of nutrition information and product reformulation, it is possible that a well-designed and science-based front-of-pack nutrition labeling program could bring about significant positive
changes in Americans’ diet and play a role in lowering the incidence and prevalence of diet-related disease in the United States.

To be successful in achieving this goal, a front-of-pack label should be:

- Based on standardized label criteria that are grounded in the Dietary Guidelines for Americans (Ref. 11), which provides science-based advice to promote health and reduce the risk of chronic disease.
- Widely adopted by food retailers and manufacturers:
  - In a standardized format consumers can readily notice, understand, and use;
  - Designed to enable consumers with a wide range of literacy, educational levels, age, and other characteristics to compare the relative healthiness of products within and across food categories in the context of routine food shopping.

FDA has already begun developing a scientific foundation for decisionmaking on nutrition symbols and front-of-pack labeling. The agency held a public hearing in September 2007 (Ref. 12) and completed a focus group study in April 2008 to obtain comments and information about consumer issues related to the use of nutrition symbols on front-of-pack labeling and shelf tags. The public hearing notice requested comments on a number of consumer research questions, including consumer attitudes about nutrition symbols, how consumers interpret such symbols, how the presence of multiple and different symbols on products in the same food category and across categories affects consumer perceptions, how nutrition symbols interact with the Nutrition Facts box, and whether such symbols affect consumers’ ability to make good dietary choices. On April 21, 2009, FDA released a document entitled “Comments on Symbols Public Hearing and Current Plans for Addressing Issues” (Ref. 13). This document describes the questions FDA requested comments on in the public hearing notice, the comments that FDA received at the public hearing and that were submitted to the public docket for the hearing, FDA’s remarks on the comments received, and FDA’s current plans for evaluating issues regarding the use of nutrition symbols in food labeling.

Although the public hearing generated some useful information on consumer issues related to nutrition symbols, very limited data and research were submitted to the agency. To fill remaining gaps in our knowledge base, in addition to opening this docket, FDA has designed and begun to implement a plan to conduct consumer research on nutrition symbols (Refs. 14 and 15). Currently, FDA is conducting two experimental studies to help enhance the agency’s knowledge about consumer understanding and use of a selected sample of nutrition symbol schemes currently in use in the domestic market, and to examine whether those schemes or certain others are better ways to impart useful nutrition information to U.S. consumers.

In addition, FDA believes the food industry has acquired extensive market experience with consumer reaction to nutrition symbols since 2005, when the voluntary use of nutrition symbols in food labeling began to proliferate in the U.S. market. FDA also is aware that many foreign governments, industry groups, food manufacturers, consumer advocacy groups, and academic researchers have conducted or are conducting consumer research on nutrition symbols. Although some of this research is publicly available (see Refs. 16 through 24), most of it remains unpublished and unavailable to the agency. Because there are limitations to the currently available published literature, we are particularly interested in obtaining access to unpublished research. For example, we are interested in research on a much wider range of nutrition symbol schemes than has been examined in the literature. In addition, studies seldom compare consumer responses to different symbol schemes. Finally, most of the publicly available research was done in European or other countries whose labeling requirements and regulatory framework are quite different from those in the United States. As a result, it is unclear whether and to what extent such findings derived from these studies are applicable to the U.S. market.

In addition to developing the scientific foundation for agency decisionmaking with respect to nutrition symbols and other front-of-pack labeling information, FDA is considering a number of other efforts to help guide food manufacturers in their use of front-of-pack labeling, such as issuance of a draft guidance on voluntary calorie declarations and a draft guidance and/or a proposed rule on dietary guidance statements.

II. Request for Comments and Information

FDA is interested in a range of data and information relevant to the use of front-of-pack nutrition symbol schemes on food packages or shelf tags, to include research concerning:

- Consumer perception and consumer behavior;
- The assessment and comparison of the effectiveness of particular possible approaches to front-of-pack labeling;
- Graphic design, package design, information architecture, advertising, marketing, and human factors that affect noticeability, understandability and use; and
- The extent to which point-of-purchase nutrition information may affect decisions by food manufacturers to reformulate products.

These data and other information will be used to inform the agency’s deliberations about approaches to enhancing the usefulness to consumers of point-of-purchase nutrition information, such as information on the front-of-pack or on shelf tags in retail stores, and to fostering decisions by food manufacturers to reformulate products.

FDA solicits comment, data, and information from all interested parties, domestic and foreign, including consumers, industry, graphic designers, package designers, marketing experts, the nutrition community, and others with specific expertise in nutrition and in conveying scientific information to ordinary citizens. FDA is particularly interested in the following topics:

Design Considerations

1. Design features from labels used in the United States or in other countries that are viewed as superior in ensuring consumer attention, understanding and use, i.e., features that attract attention, make it easier for consumers to understand how foods with a nutrition symbol fit into a healthy diet, enhance the credibility of the symbol, and encourage use of the symbol in purchase decisions. Examples of such features could include:

   - Color;
   - Location;
   - Contrast.

2. The risk of “too much clutter” on the label. For example:

   - The point at which a format is sufficiently “overpacked” to put off consumers;
   - How many nutrients can be included in a nutrient-specific approach without creating information overload or putting off consumers;
   - An easy-to-understand range (e.g., on a scale of 0 to 3 or 1 to 5) for use in ranking the overall nutritional value of a food; and
   - Whether a certain amount of blank space is needed around FOP nutrition symbols to maximize the chances that consumers will notice and comprehend them.
3. Whether certain shapes (such as stars or checks) have inherent meaning.
4. The size of an FOP symbol relative to the rest of the package.
5. Factors that influence ease of comprehension (e.g., whether a symbol scheme is easy enough for consumers to understand at a glance (3 seconds or less) in a crowded grocery store), particularly in terms of:
   • The amount of information;
   • The words (e.g., sodium versus salt; the term “daily value”); or
6. Whether a uniform FOP symbol across product categories helps consumer recognition, understanding, trust and use of the symbol.

B. Consumer Use and Understanding

7. Consumer attitudes toward nutrition symbols in general;
8. Consumer attitudes toward different types of symbols, e.g.:
   • FOP vs. shelf tag;
   • Nutrient-specific symbol (such as General Mills’ “nutrition highlights”) (Ref. 25) vs. a summary symbol (such as Smart Choices (Ref. 6)); and
   • Symbols with and without an explicit endorsement from a third party such as the American Heart Association (e.g., the Heart-Check Mark (Ref. 26));
9. Consumer attitudes toward products or brands that carry a nutrition symbol compared to:
   • Other products or brands in the same product category (e.g., breakfast cereals) that do not carry a nutrition symbol; and
   • Products or brands in other categories that do not carry such a symbol.
10. Consumer interpretations of symbol-carrying products or brands in terms of:
    • Their overall healthfulness and quality;
    • Specific health benefits;
    • Featured nutrition attributes;
    • Non-featured nutrition attributes; and
    • Any other non-nutrition attributes.
11. Consumer perception of and reaction to the presence of multiple and different nutrition symbols on the FOP shelf tags of different brands in a given product category (e.g., breakfast cereals);
12. Consumer interpretation of the co-existence on the food label of symbols and other nutrition messages (e.g., a nutrient content claim);
13. Consumer interpretation of the co-existence on the food label of nutrition symbols and quantitative nutrition information (e.g., the Nutrition Facts box);
14. Consumer interpretation of the co-existence of FOP nutrition symbols and nutrition symbols on shelf tags;
15. The extent to which consumers notice nutrition symbols;
16. When consumers use nutrition symbols and the purposes for which consumers use nutrition symbols, under time, pressure, and otherwise;
17. Whether and to what extent nutrition symbols on food labels and shelf tags direct consumers toward purchasing brands or foods that bear them and, if so, whether the shift in purchase is accompanied with a displacement of purchase of other brands or foods;
18. Whether symbols affect the nutritional quality of the overall diet of consumers who use the symbols and, if so, to what extent;
19. The differences, if any, in consumer response to nutrition symbols when all products in a given category carry symbols, compared to when only some products in the category carry symbols;
20. The differences, if any, in consumer response to nutrition symbols among various demographic subgroups, such as subgroups differentiated by:
   • Level of education;
   • Interest in or concern about nutrition or health;
   • Age;
   • Race;
   • Role as shopper (e.g., primary shoppers for the household vs. other consumers); and
   • Income.
21. The differences, if any, in consumer response to nutrition symbols in the labeling of various product categories, such as:
   • Snacks;
   • Meals;
   • Dairy products; and
   • Vegetables and fruits.
22. Evidence, if any, that use of symbols helps:
   • Reduce time needed for product selection;
   • Improve nutritional quality of choices; or
   • Both.
23. Consumer perceptions when there are multiple health messages or nutrition symbols (e.g., some related to nutrition and others related to organoleptic or process attributes) on a given package.

In addition to comments submitted in response to this document, FDA will consider those previously submitted to the agency for the following Federal Register documents and dockets:
• “Food Labels and the Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria; Public Hearing; Request for Comments” (72 FR 39815, July 20, 2007) (Docket No. 2007–N–0198, formerly Docket No. 2007N–0277);
• “Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Nutrition Symbols on Food Packages” (74 FR 26244, June 1, 2009) (Docket No. FDA–2009–N–0220); and
• “Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Studies of Nutrition Symbols on Food Packages” (74 FR 62786, December 1, 2009) (Docket No. FDA–2009–N–0220).

Data and information submitted to these previous dockets do not need to be resubmitted.

III. Submission of Comments and Information

FDA has established a public docket to provide an opportunity for interested parties to submit consumer research and design information to inform the development of a government-sponsored nutrition symbol program to help consumers make informed dietary choices and to provide the food industry incentives to make more nutritious food products available.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments regarding this document. Submit a single copy of electronic comments 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.

IV. References

FDA has placed the following references on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document is published in the Federal Register.)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory General Medical Sciences Council

Date: May 20–21, 2010.

Closed: May 20, 2010, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Open: May 21, 2010, 8:30 a.m. to Adjournment.

Agenda: For the discussion of program policies and issues, opening remarks, report of the Director, NIGMS, and other business of the Council.

Contact Person: Ann A. Hagan, PhD, Associate Director for Extramural Activities, NIGMS, NIH, DHHS, 45 Center Drive, Room 2AN24H, MSC6200, Bethesda, MD 20892–6200, (301) 594–4499, haganaa@nigms.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on the notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver’s license, or passport) and to state the purpose of their visit.

Information is also available on the Institute’s/Center’s home page: http://www.nigms.nih.gov/about/ advisory_council.html, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96,