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Critical Review

U.S. Food and Drug Administration on modernization of the Nutrition and Supplements Facts labels

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ABSTRACT

The U.S. Food and Drug Administration (FDA) issued an Advance Notice of Proposed Rulemaking (ANPRM) for obtaining public comments on modernizing the Nutrition and Supplements Facts label. Public comments to specific questions asked in the ANPRM will be considered by FDA for future rulemaking. There are numerous issues that FDA will consider during the rulemaking process, such as determining (1) which Dietary Reference Intakes (DRIs) to use for setting the Daily Values (DVs), (2) the approach for setting a single nutrient DV for adults and children over the age of 4 years, (3) which vitamins and minerals are of public health concern in the United States and therefore required to be declared in the Nutrition Facts label, (4) the definition of certain nutrients, such as total carbohydrate and fiber, (5) the labeling of *trans* fat, and (6) the use of International Units (IUs) for providing the amount of a vitamin. After reviewing the public comments, as well as any other new relevant information, FDA will publish a proposed rule in the Federal Register that provides the agency's proposed decisions for modernizing the Nutrition and Supplements Facts label. Publication of a final rule, along with the Code of Federal Regulations, will set forth the new regulatory requirements for the Nutrition and Supplements Facts labels.

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1. Introduction

On November 8, 1990, the Nutrition Labeling and Education Act (NLEA) of 1990 was signed into law (the 1990 amendments) amending the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments made the most significant changes in the act and had a direct bearing on Food and Drug Administration (FDA)'s revision of nutrition labeling in 1993. The 1990 amendments specified, in part, that: (1) with certain exceptions, food is to be considered misbranded unless its label or labeling bears nutrition labeling; (2) certain nutrients and food components are to be included in nutrition labeling, (3) nutrition labeling is to be provided for the most frequently consumed varieties of raw produce (fruits and vegetables) and raw fish according to voluntary guidelines or, if necessary, regulations; (4) a simplified nutrition label is to be used when the food contains insignificant amounts of most nutrients; and (5) FDA is to develop regulations governing labeling of foods to which to the act applies (i.e. vitamins and minerals).

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In response to the NLEA, in 1993, FDA issued several rules to modify how nutrition information is presented on food labels. When FDA issued those rules to modify the nutrition label information, it considered the diet and health information that was current at that time, including the National Academy of Science's (NAS) Recommended Dietary Allowances (RDAs) (National Research Council [NRC], 1968, 1980, 1989a), the NAS Diet and Health Report (NRC, 1989b), the Surgeon General's Report on Nutrition and Health (U.S. Department of Health and Human Services (HHS), 1988), and the 1990 Dietary Guidelines for Americans (U.S. Department of Agriculture [USDA] and HHS, 1990).

1.1. Daily Values

In the final rule on Food Labeling, Reference Daily Intakes (RDIs) and Daily Reference Values (DRVs) (the 1993 RDI/DRV final rule) (Federal Register, 1993a), FDA amended its regulations to establish two sets of label reference values: RDIs and DRVs for use in declaring the nutrient content of a food on its label or labeling. These two reference values were used to establish a single set of label reference values known as the Daily Values or DVs, which were intended to assist consumers via the Nutrition and Supplements Facts labels in both understanding the relative significance of nutritional information in the context of a total daily diet and comparing the nutritional values of food products.

FDA redesignated the label reference values known as the U.S. RDAs for vitamins and minerals as RDIs. In addition, FDA established a single set of label reference values for adults and children 4 or more years of age, in part, because of space constraints on the food label and the fact that children over the age of 4 years consume the same foods that the rest of the population consumes (Federal Register, 1993a). These RDIs were based on the NAS RDAs set in 1968. The 1993 RDI/DRV final rule used the highest NAS RDA for adults and children 4 or more years of age (excluding values for pregnant and lactating women) to serve as label reference values (Federal Register, 1993a). FDA referred to this approach as the "population-coverage approach."

In 1992, Congress passed the Dietary Supplement Act of 1992 that instructed FDA not to issue regulations before November 8, 1993 that would revise the U.S. RDAs (redesignated as RDIs) for vitamins or minerals (other than existing regulations that established the U.S. RDAs that were in effect prior to October 6, 1992). Thus, FDA used the existing RDAs rather than new nutrient values in the 1993 RDI/DRV final rule. In 1995, FDA amended certain RDIs based on the 1989 NAS RDAs and Estimated Safe and Adequate Daily Dietary Intakes (ESADDIs) (Federal Register, 1995). In addition, in 2001, a notification was submitted under the provisions of the Food and Drug Administration Modernization Act (FDAMA) of 1997 for the use of certain nutrient content claims for choline. These statements identify the daily value for choline as 550 milligrams (mg).[1] This value is based on the Adequate Intake (AI) set by the Institute of Medicine (IOM) of the NAS in 1998 (IOM, 1998).

DRVs were identified for those nutrients that are important to diet and health (e.g. total fat, saturated fat, cholesterol, total carbohydrate, protein, dietary fiber, sodium, and potassium). The DRVs are based on the NAS Diet and Health Report (sodium, potassium, fat, saturated fat, cholesterol, carbohydrate, and dietary fiber) (NRC, 1989a), the Surgeon General's Report on Nutrition and Health (dietary fiber) (HHS, 1988), and the 1990 Dietary Guidelines for Americans (USDA and HHS, 1990). The DRV for protein (50 g/day) was set at 10% of 2000 kcal based on an adjusted average of the 1989 RDA (NRC, 1989b). The DRVs in the 1993 RDI/DRV final rule were based on a 2000-kcal reference diet (Federal Register, 1993a). The 2000 kcal reference diet FDA adopted was consistent with the "population-coverage approach" as it selected a lower calorie basis for the DRVs for the group at risk (i.e. older women).

The act provides discretion to the FDA to require information about nutrients on the food label when it determines such information will "assist consumers in maintaining healthy dietary practices." The 1990 amendments state that nutrition labeling must "be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in context of a total daily diet." In 1993, FDA published a final rule entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label" (the 1993 nutrient content final rule) (Federal Register, 1993b). In the 1993 nutrient content final rule, FDA stated that "the nutrition label can and should help consumers make informed food choices, and that it can also contribute to consumers maintaining healthy dietary practices" (Federal Register, 1993b). While the DVs do not represent dietary goals for individuals, their intended use is to provide an overall population reference value on the food label for the consumer.

1.2. Mandatory and voluntary nutrients

With respect to nutrition labeling of foods, the 1993 nutrient content final rule declared that nutrition information on the label and in labeling of foods shall contain information about the level of the following nutrients: (1) calories or total calories; (2) calories from fat; (3) calories from saturated fat (voluntary); (4) total fat; (5) saturated fat; (6) polyunsaturated fat (voluntary); (7) monounsaturated fat (voluntary); (8) cholesterol; (9) sodium; (10) potassium (voluntary); (11) total carbohydrate (including sugars (mono- and disaccharides), oligosaccharides, starch, fiber, and organic acids); (12) dietary fiber; (13) soluble fiber (voluntary); (14) insoluble fiber (voluntary); (15) sugars; (16) sugar alcohol (voluntary); (17) other carbohydrate (voluntary); (18) protein; and (19) vitamins and minerals. In 2003, FDA amended its regulations on nutrition labeling to require *trans* fatty acids be declared in grams per serving in the Nutrition and Supplements Facts label (Federal Register, 2003a).

A statement about the percent of the RDI, expressed as the percent of the DV for vitamin A, vitamin C, calcium, and iron, in that order, is required. These four nutrients are required to be declared because of public health concerns relative to inadequate intake of these nutrients by specific portions of the population, as well as the possible association between the lack of several of these nutrients in the diet and the risk of chronic disease (Federal Register, 1993b). The declaration of other vitamins and minerals that have an RDI is required when they are added as a nutrient supplement or when a claim is made about them.

The Supplement Facts label is similar to the Nutrition Facts label in both content and format. The Supplement Facts label must include the amount and percent DV of the same nutrients that are required for conventional foods if the nutrients are present in the supplement, as well as the amount of other dietary ingredients present. The Supplement Facts label must state that percent DVs have not been established for these other dietary ingredients and must indicate these ingredients clearly with an asterisk (*).

2. Materials and methods

New information has since become available on nutrient values that the FDA believes can impact what nutrients it should consider requiring to be listed on the food label and what nutrient values it

[1] FDA has not acted to prohibit or modify the claims, and therefore, manufacturers may use the specified claims on the label and in the labeling of any food or dietary supplement product that qualifies for the claims described in the notification.