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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99P-2630]

Food Labeling: Added Sugars; Availability of Citizen Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a petition submitted by the Center for Science in the Public Interest (CSPI). The petition requested that FDA establish a Daily Reference Value (DRV) for added sugars with a corresponding Daily Value, require the declaration of added sugars, and revise criteria pertaining to nutrient content claims and health claims.

DATES: Submit written comments on the petition by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. **Electronic comments** may be submitted via the Internet to: www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm or via e-mail to: fdadockets@oc.fda.gov. All comments should be identified with the docket number found in brackets in the heading of this document. The petition is available for review at the Dockets Management Branch (address above) or electronically on the agency's web site at <http://www.fda.gov/ohrms/dockets/dockets.htm>. You may also request a copy of the petition from the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: Kathleen Smith, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-832), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5372.

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SUPPLEMENTARY INFORMATION:**I. The Citizen Petition**

CSPI, in a citizen petition filed on August 4, 1999, requested that the agency establish a DRV of 40 grams for added sugars and require the declaration of added sugars in nutrition labeling in both grams per serving and a corresponding percent Daily Value. CSPI also requested that FDA define nutrient content claims for added sugars. Finally, CSPI requested that, when nutrient content or health claims are made about a food, meal product, or main dish product, FDA set, in addition to the limits on other nutrients described in the current regulations, limits and require disclosure of the total amount of added sugars for these claims.

CSPI's ground for its petition is that the labeling provision for added sugars is necessary as a public health measure to give consumers the tools they need to reduce their intake of added sugars. CSPI states in the petition that based on U.S. Department of Agriculture (USDA) data, the per capita consumption of added sugars has risen 28 percent since 1983, and that, in some people, diets with large amounts of added sugars contribute to obesity, the prevalence of which has risen dramatically in the last two decades in both youths and adults. CSPI also asserts that diets with added sugars, from such foods as soft drinks, fruit drinks, candy, cakes, and cookies, include fewer healthier foods that provide nutrients that reduce the risk of osteoporosis, cancer, heart disease, stroke, and other health problems. In addition, CSPI states that frequent consumption of foods with added sugars promotes tooth decay.

CSPI asserts that it is impossible for consumers to determine how much sugar has been added to foods such as yogurt, ice cream, fruit snacks, and juice drinks using current labels. In addition, CSPI states that current labels fail to inform consumers about the proportion of a reasonable day's intake of added sugars that a serving of food provides. CSPI maintains that, although USDA provided quantitative dietary recommendations for added sugars in The Food Guide Pyramid, without labeling of added sugars, it is difficult for consumers to follow such recommendations.

USDA's quantitative recommendation serves as the basis for CSPI's request for a DRV of 40 grams for added sugars.

II. FDA Background

FDA addressed comments on added sugars in the January 6, 1993, final rule entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label" (58 FR 2079). Comments had recommended mandatory declaration of added sugars only, rather than total sugars, in nutrition labeling and either mandatory or voluntary declaration of both added and naturally occurring sugars (58 FR 2079 at 2098). FDA listed three reasons for deciding against implementing these recommendations: (1) The body does not make any physiological distinction between added and naturally occurring sugars in foods; (2) for most foods there is no analytical method to differentiate between added and naturally occurring sugars; and (3) the declaration of only added sugars could significantly underrepresent the sugars content of many foods that have a large quantity of naturally occurring sugars. Instead, the final rules required that total sugars be a mandatory component of nutrition labeling (21 CFR 101.9(c)(6)(ii)) (58 FR 2079 at 2176).

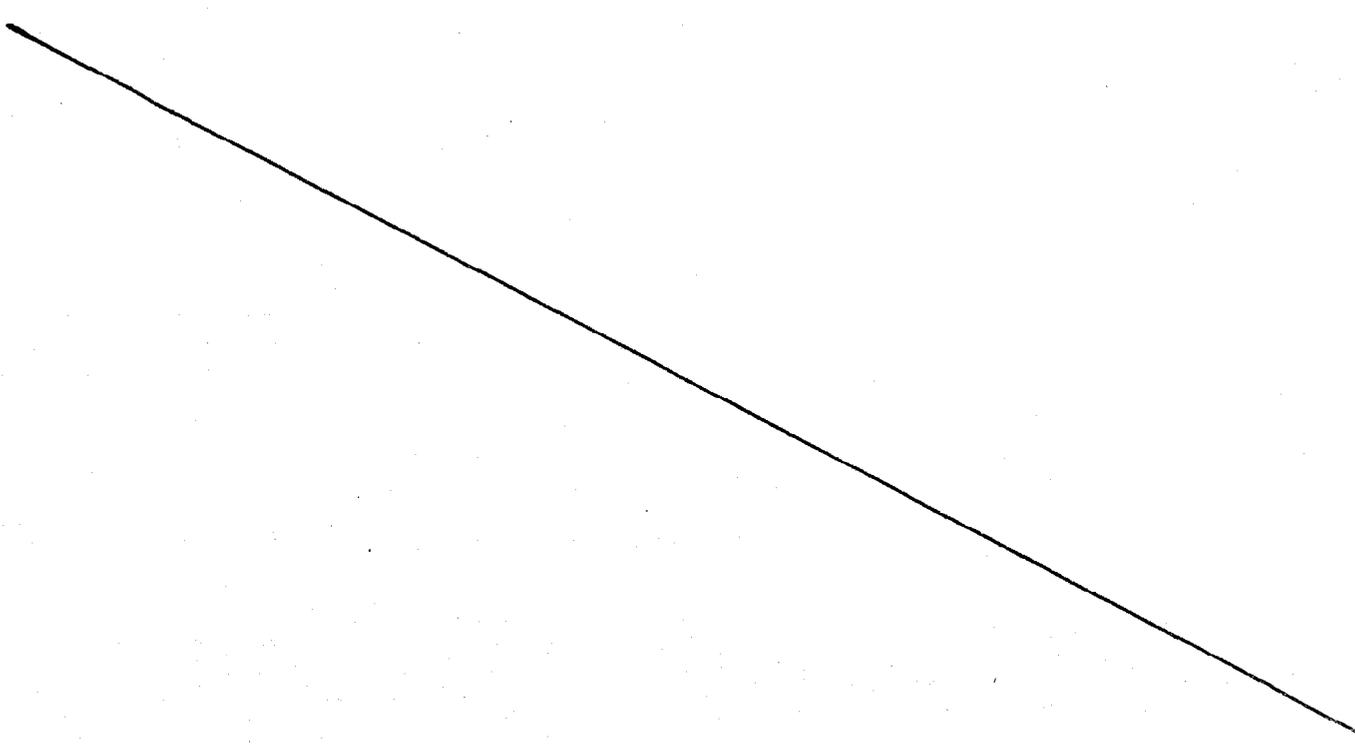
In the January 6, 1993, final rule entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (58 FR 2206), FDA concluded that there was not sufficient basis to establish a DRV for added sugars because there was no conclusive evidence that demonstrated that sugars intake from any source was associated with chronic disease conditions. Additionally, the agency noted the absence of analytical capabilities to distinguish between added sugars and naturally-occurring sugars and the lack of consensus concerning the specific proportion of total carbohydrate that should be attributed to total sugars and complex carbohydrate. In conclusion, FDA did not support the separate establishment of DRV's for added sugars, naturally-occurring sugars, and total sugars (58 FR 2206 at 2221 and 2222).

FDA's food labeling regulations do require that sugars that are used as ingredients in a food product (i.e., that are added) be declared in the ingredient list on the label or labeling of that

food (21 CFR 101.4(a)(1)). The listing of the added sugars must be by the common or usual name of the particular sugar and be in descending order of predominance among the other ingredients in the food product.

III. Comments

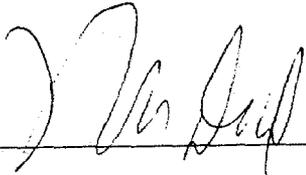
You may submit written or electronic comments to the Dockets Management Branch (address above), on or before *[insert date 90 days after date of publication in the Federal Register]*. Electronic comments may be submitted via the Internet to: www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm or via e-mail to: fdadockets@oc.fda.gov. Groups or organizations must submit two copies of any comments. Individuals may submit one copy of their comments. Identify your written comments by placing the docket number at the top of your



comment(s). If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Any comments submitted will be filed under the docket number identified in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

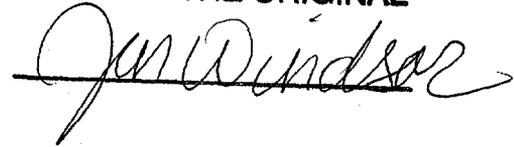
Dated: 6/16/00

June 16, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

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