

radius of Dubuque Regional Airport and within 2.6 miles each side of the 321° radial of the Dubuque VORTAC extending from the VORTAC to 7 miles northwest of the airport and within 3 miles each side of the 133° radial of the Dubuque VORTAC extending from the VORTAC to 13.5 miles southeast of the airport and within 3 miles each side of the 189° radial of the Dubuque VORTAC extending from the VORTAC to 7.4 miles south of the airport.

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Issued in Kansas City, MO, on March 5, 1998.

Bryan H. Burleson,

Acting Manager, Air Traffic Division, Central Regional.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 96P-0023 and 96P-0179]

Food Labeling; Serving Sizes; Reference Amounts for Candies; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to May 26, 1998, the comment period for the proposal to amend the nutrition labeling regulations pertaining to reference amounts for certain candy products that published in the **Federal Register** of January 8, 1998 (63 FR 1078). The agency is taking this action in response to a request for an extension of the comment period. This extension is intended to provide interested persons with additional time to submit comments to FDA on its proposal.

DATES: Written comments by May 26, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lori A. LeGault, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5269.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 8, 1998 (63 FR 1078), FDA published a proposed rule to amend the nutrition labeling regulations to modify the product

category "Sugars and Sweets: Hard Candies, others" by adding "after-dinner mints, caramels, fondants (e.g., plain mints, candy corn), and liquid and powdered candies" as kinds of products included under the category, and a reference amount customarily consumed per eating occasion (reference amount) of 15 milliliters (mL) for liquid candies; create a new product category under "Sugars and Sweets," identified as "Chocolate-covered fondants (e.g., chocolate-covered creams, chocolate-covered mints), taffy, and plain toffee," with a reference amount of 30 grams; and clarify what kinds of candies belong to the "All other candies" product category by expanding the category name to include specific examples. Interested persons were given until March 24, 1998, to submit comments on the proposal.

FDA has received a letter from two trade associations requesting that the agency grant a 60-day extension of the comment period on the proposed rule. The requests contend that additional time is needed to coordinate comments with numerous member companies. The agency acknowledges that the proposed rule is quite technical in nature and, after consideration, has decided to grant an extension of the comment period until May 26, 1998.

Interested persons may, on or before May 26, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 18, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 804, 806, 807, 810, 820, 821, 1002, and 1020

[Docket No. 97N-0447]

RIN 0910-ZA09

Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements for Refurbishers, Rebuilders, Reconditioners, Servicers and "As Is" Remarketers of Medical Devices; Request for Comments and Information; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to June 29, 1998, the comment period for the advance notice of proposed rulemaking (ANPRM) that appeared in the **Federal Register** of December 23, 1997 (62 FR 67011). This advance notice announced FDA's intention to review and, as needed, to revise compliance policy guides, amend regulatory requirements and, as appropriate, exercise alternative regulatory approaches regarding the remarketing of used medical devices. The agency is taking this action in response to two requests for extensions. This extension of comment period is intended to allow interested persons additional time to submit comments on the ANPRM.

DATES: Written comments by June 29, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4692.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 23, 1997 (62 FR 67011), FDA published an ANPRM announcing the agency's intention to review and, as needed, to revise compliance policy guides (CPG's), amend regulatory requirements and, as appropriate, exercise alternative regulatory approaches with respect to the remarketing of used medical