

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.*

[FR Doc. 98-7825 Filed 3-24-98; 8:45 am]

BILLING CODE 4910-13-M

## 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.*

[FR Doc. 98-7664 Filed 3-24-98; 8:45 am]

BILLING CODE 4160-01-F

## 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

devices. This reexamination of device remarketing issues is being undertaken, in part, because of competing interests and equity concerns raised by manufacturers, device remarketers, and others, during the rulemaking process for the agency's Quality System (Q/S) regulation part 820 (21 CFR part 820). It provides a method of addressing whether, and to what degree, current good manufacturing practice requirements in the Q/S regulation should be applied by the agency to firms, other than manufacturers and remanufacturers, which process and/or remarket previously used devices outside the control of the device's original manufacturer.

The agency's reassessment is also being undertaken, in part, because of FDA's experience in implementing CPG's 7133.20 and 7124.28. These guides identify what statutory and regulatory requirements, which control the activities of manufacturers, are applicable to the activities of firms considered to be x-ray tube reloaders, or device reconditioners or rebuilders. Agency experience indicates that many firms are unaware of these compliance guides or their own compliance responsibilities, or use other terms to describe their activities. The reassessment is also warranted on the basis of FDA's knowledge of changes in industry practices in the remarketing of used devices.

As a consequence of the previous factors, and for purposes of discussion and public comment during the agency's reevaluation of device remarketing compliance issues, FDA is proposing to define the activities of device refurbishers, servicers, and "as is" remarketers on the basis that their various activities, in contrast to the activities of device remanufacturers defined in 21 CFR 820.3(w), do not significantly change a finished device's performance or safety specifications, or intended use(s). Having proposed to characterize such device processing and remarketing activities in this fashion,

the agency is also considering alternative schemes or methods for applying certain regulatory controls to these activities on a voluntary or partial basis, or not at all. Comments, proposals for alternative regulatory schemes, and information were solicited by FDA from the public, the affected industry and other interested parties, in response to the ANPRM.

FDA received two requests to extend the comment period. One requested 30 additional days to focus resources on the referenced matter. The other requested an extension of 180 days so that issues may be discussed further at the multi-day conference of a device industry association, scheduled for September 1998.

FDA believes there is good cause to extend the comment period. However, FDA believes that a 180-extension period would unduly delay the process. Therefore, FDA is extending the comment period for 90 additional days.

Interested persons may, on or before June 29, 1998, submit to the Dockets Management Branch (address above) written comments regarding the December 23, 1997, ANPRM described above. 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 4, 1998.

**D. B. Burlington,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. 98-7668 Filed 3-24-98; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[REG-209463-82]

RIN 1545-AV82

**Required Distributions From Qualified Plans and Individual Retirement Plans; Correction**

**AGENCY:** Internal Revenue Service, Treasury.

**ACTION:** Correction to notice of proposed rulemaking.

**SUMMARY:** This document contains corrections to REG-209463-82, which was published in the **Federal Register** on Tuesday, December 30, 1997 (62 FR 67780). The amendments to existing proposed regulations make changes to the rules that apply if a trust is named as a beneficiary of an employees benefit under a retirement plan.

**FOR FURTHER INFORMATION CONTACT:** Thomas Foley, (202) 622-6030 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

The notice of proposed rulemaking that is the subject of these corrections is under section 401(a)(9) of the Internal Revenue Code.

**Need for Correction**

As published, REG-209463-82 contains errors which may prove to be misleading and are in need of clarification.

**Correction of Publication**

Accordingly, the publication of the notice of proposed rulemaking (REG-209463-82), which is the subject of FR Doc. 97-33393, is corrected as follows:

**§ 1.409(a)(9)-1 [Corrected]**

1. On page 67783, § 1.409(a)(9)-1 is corrected as set out in the following table:

Section	Location	Incorrect language	Corrected language
1.409(a)(9)-1	Q&A D-5, column 2, paragraph (a) of A, line 10.	"paragraph (b) of this D-5A are met,"	"paragraph (b) of this D-5 are met,"
1.409(a)(9)-1	Q&A D-5, column 2, paragraph (a) of A., line 24.	"paragraph (b) of this D-5A are not met,"	"paragraph (b) of this D-5 are not met,"
1.409(a)(9)-1	Q&A D-5, column 3, paragraph (c) of A., line 10 from the top of the column.	"5A are satisfied with respect to such".	"5 are satisfied with respect to such"
1.409(a)(9)-1	Q&A D-6, column 3, paragraph (a) of A., line 3.	"requirements of paragraph (b) of D-5A".	"requirements of paragraph (b) of D-5"
1.409(a)(9)-1	Q&A D-6, column 3, paragraph (a) of A., line 13 from the bottom of the paragraph.	"5A of this section are satisfied with".	"5 of this section are satisfied with"
1.409(a)(9)-1	Q&A D-6, column 3, paragraph (a) of A., line 8 from the bottom of the paragraph.	"paragraph (b) of D-5A of this section are".	"paragraph (b) of D-5 of this section are"