

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 800, 801, 808, 814, 821, 860, 876, 882, 884, 886, 890, 1005, and
1010

[Docket No. FDA-2008-N-0332]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending certain medical device regulations to correct typographical errors and to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Paul S. Gadiock, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2343.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is amending its regulations in parts 800, 801, 808, 814, 821, 860, 876, 882, 884, 886, 890, 1005, and 1010 (21 CFR parts 800, 801, 808, 814, 821, 860, 876, 882, 884, 886, 890, 1005, and 1010) to correct typographical errors and to update addresses, telephone numbers, and wording to ensure accuracy and clarity in the agency's medical device regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined

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that notice and public comment are unnecessary because these errors are nonsubstantive.

II. Highlights of the Final Rule

FDA is making changes to correct typographical and other minor errors in certain device regulations in parts 800, 801, 808, 814, 821, 860, 876, 882, 884, 886, 890, 1005, and 1010.

1. FDA is revising § 800.12(d) by removing “This information collection requirement has been approved by the Office of Management and Budget under number 0910–0150.”

2. FDA is revising § 801.420(d) by replacing “Bureau of Medical Devices and Diagnostic Products, Division of Compliance, HFK–116, 8757 Georgia Ave., Silver Spring, MD 20910” with “Office of Compliance, Division of Enforcement A, 2094 Gaither Rd., Rockville, MD 20850.”

3. FDA is revising § 808.1(d)(9) by replacing “the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602 (42 U.S.C. 263b *et seq.*))” with “Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968).” FDA is also replacing “Atomic Energy act” with “Atomic Energy Act.”

4. FDA is revising § 814.20(b)(5) by replacing “the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b *et seq.*)” with “section 534 of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968).”

5. FDA is revising § 814.45(b) by replacing “515(d)(3)” with “515(d)(4).”

6. FDA is revising § 821.1(c) by replacing “501(t)(2)” with “502(t)(2).”

7. FDA is revising § 860.134(a) by replacing “513(f)(2)” with “513(f)(3).”

8. FDA is revising § 876.5250(b)(2) by replacing “subject to the limitations in § 876.9” with “the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.” FDA is also replacing “regulations” with “requirements of the quality system regulation.”

9. FDA is revising Subpart E of the Table of Contents of Part 882 by replacing “882.4700 Neurosurgical paddle” with “882.4700 Neurosurgical paddie.”

10. FDA is revising Subpart F of the Table of Contents of Part 882 by replacing “882.5800 Cranial electrotherapy stimulator” with “882.5800 Cranial electrotherapy stimulator.”

11. FDA is revising the section heading in § 882.5800 by replacing “electrotheraphy” with “electrotherapy.”

12. FDA is revising § 882.5800(a) by replacing “electrotheraphy” with electrotherapy.”

13. FDA is revising § 884.5435(b) by replacing “interlabial” with “intralabial.”

14. FDA is revising § 886.1 by adding paragraph (e) reading “Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/cdrh/guidance.html*.”

15. FDA is revising § 890.1 by adding paragraph (e) reading “Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/cdrh/guidance.html*.”

16. FDA is revising § 1005.11 by replacing “the Radiation Control for Health and Safety Act of 1968” with “Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968).”

17. FDA is revising § 1005.25(a) by replacing “section 360(d) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263h(d))” with “section 536(d) of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) (21 U.S.C. 360mm(d)).”

18. FDA is revising § 1005.25(c) by replacing “section 360(d) of the Radiation Control for Health and Safety Act of 1968” with “section 536(d) of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) (21 U.S.C. 360mm(d)).”

19. FDA is revising § 1010.1 by replacing “section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f)” with “section 534 of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) (21 U.S.C. 360kk).”

20. FDA is revising § 1010.4(a)(1) by replacing “the Radiation Control for Health and Safety Act of 1968” with “Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968).”

III. Environmental Impact

The agency has determined under 21 CFR 25.30(i) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded

Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule corrects only typographical and nonsubstantive errors in existing regulations and does not change in any way how devices are regulated, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

V. Paperwork Reduction Act of 1995

FDA has determined that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. The Technical Amendments

This rule updates and corrects existing regulations to ensure accuracy and clarity. This administrative action is limited to correcting typographical errors; updating changes in addresses, web site locations, and telephone numbers; and clarifying regulation terminology. It makes no changes in substantive requirements.

For the effective date of this final rule, see the **DATES** section of this document. Because this final rule is an administrative action, FDA has determined that it has no substantive impact on the public. It imposes no costs, and merely makes technical administrative changes in the Code of Federal Regulations (CFR) for the convenience of the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

List of Subjects*21 CFR Part 800*

Administrative practice and procedure, Medical devices, Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 808

Intergovernmental relations, Medical devices.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 821

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

21 CFR Part 876

Medical devices.

21 CFR Part 882

Medical devices.

21 CFR Part 884

Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 890

Medical devices.

21 CFR Part 1005

Administrative practice and procedure, Electronic products, Imports, Radiation protection, Surety bonds.

21 CFR Part 1010

Administrative practice and procedure, Electronic products, Exports, Radiation protection.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 800, 801, 808, 814, 821, 860, 876, 882, 884, 886, 890, 1005, and 1010 are amended as follows:

PART 800—GENERAL

■ 1. The authority citation for 21 CFR part 800 continues to read as follows:

Authority: 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360k, 361, 362, 371.

§ 800.12 [Amended]

■ 2. In § 800.12, paragraph (d) is amended by removing the last sentence.

PART 801—LABELING

■ 3. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

■ 4. In § 801.420, paragraph (d) is revised to read as follows:

§ 801.420 Hearing aid devices; professional and patient labeling.

* * * * *

(d) *Submission of all labeling for each type of hearing aid.* Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Office of Compliance, Division of Enforcement A, 2094 Gaither Rd., Rockville, MD 20850, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other labeling for each type of hearing aid on or before August 15, 1977.

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

■ 5. The authority citation for 21 CFR part 808 continues to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371.

■ 6. In § 808.1, paragraph (d)(9) is revised to read as follows:

§ 808.1 Scope.

* * * * *

(d) * * *

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy Act of 1954 (42 U.S.C. 2011 note), as amended, Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968), and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

* * * * *

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 7. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 8. In § 814.20, paragraph (b)(5) is revised to read as follows:

§ 814.20 Application.

* * * * *

(b) * * *

(5) Reference to any performance standard under section 514 of the act or under section 534 of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) in effect or proposed at the time of the submission and to any voluntary standard that is relevant to any aspect of the safety or effectiveness of the device and that is known to or that should reasonably be known to the applicant. The applicant shall—

(i) Provide adequate information to demonstrate how the device meets, or justify any deviation from, any performance standard established under section 514 of the act or under section 534 of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968), and

(ii) Explain any deviation from a voluntary standard.

* * * * *

■ 9. In § 814.45, paragraph (b) is amended by revising the last sentence to read as follows:

§ 814.45 Denial of approval of a PMA.

* * * * *

(b) * * * The order will include a notice of an opportunity to request review under section 515(d)(4) of the act.

* * * * *

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

■ 10. The authority citation for 21 CFR part 821 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, 374.

■ 11. In § 821.1, paragraph (c) is revised to read as follows:

§ 821.1 Scope.

* * * * *

(c) The primary burden for ensuring that the tracking system works rests upon the manufacturer. A manufacturer or any other person, including a distributor, final distributor, or multiple distributor, who distributes a device subject to tracking, who fails to comply with any applicable requirement of section 519(e) of the act or of this part, or any person who causes such failure, misbrands the device within the meaning of section 502(t)(2) of the act and commits a prohibited act within the meaning of sections 301(e) and 301(q)(1)(B) of the act.

* * * * *

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

■ 12. The authority citation for 21 CFR part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

■ 13. In § 860.134, paragraph (a) is amended by revising the first sentence of the introductory text to read as follows:

§ 860.134 Procedures for “new devices” under section 513(f) of the act and reclassification of certain devices.

(a) Section 513(f)(3) of the act applies to proceedings for reclassification of a device currently in class III by operation of section 513(f)(1) of the act.

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PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 14. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 15. In § 876.5250, paragraph (b)(2) is revised to read as follows:

§ 876.5250 Urine collector and accessories.

* * * * *

(b) * * *

(2) Class I (general controls). For a urine collector and accessories not intended to be connected to an indwelling catheter, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

PART 882—NEUROLOGICAL DEVICES

■ 16. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 17. In the Table of Contents of Part 882, in Subpart E, § 882.4700 is amended by removing the word “paddle” and adding in its place the word “paddie”.

■ 18. In the Table of Contents of Part 882, in Subpart F, § 882.5800 is amended by removing the word “electrotherapy” and by adding in its place the word “electrotherapy”.

■ 19. In § 882.5800, the section heading and paragraph (a) are revised to read as follows:

§ 882.5800 Cranial electrotherapy stimulator.

(a) *Identification.* A cranial electrotherapy stimulator is a device that applies electrical current to a patient’s head to treat insomnia, depression, or anxiety.

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PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 20. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 21. In § 884.5435, paragraph (b) is amended by revising the last sentence to read as follows:

§ 884.5435 Unscented menstrual pad.

* * * * *

(b) * * * This exemption does not include the intralabial pads and reusable menstrual pads.

PART 886—OPHTHALMIC DEVICES

■ 22. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

- 23. Section 886.1 is amended by adding paragraph (e) to read as follows:

§ 886.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

PART 890—PHYSICAL MEDICINE DEVICES

- 24. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

- 25. Section 890.1 is amended by adding paragraph (e) to read as follows:

§ 890.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

- 26. The authority citation for 21 CFR part 1005 continues to read as follows:

Authority: 42 U.S.C. 263d, 263h.

- 27. Section 1005.11 is revised to read as follows:

§ 1005.11 Payment for samples.

The Department of Health and Human Services will pay for all import samples of electronic products rendered unsalable as a result of testing, or will pay the reasonable costs of repackaging such samples for sale, if the samples are found to be in compliance with the requirements of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968). Billing

for reimbursement shall be made by the owner or consignee to the Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. Payment for samples will not be made if the sample is found to be in violation of the Act, even though subsequently brought into compliance pursuant to terms specified in a notice of permission issued under § 1005.22.

■ 28. Section 1005.25 is amended by revising paragraph (a) and the first sentence of paragraph (c) to read as follows:

§ 1005.25 Service of process on manufacturers.

(a) Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer’s agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 536(d) of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) (21 U.S.C. 360mm(d)) and this section. The agent may be an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

* * * * *

(c) Service of any process, notice, order, requirement, or decision specified in section 536(d) of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) (21 U.S.C. 360mm(d)) may be made by registered or certified mail addressed to the agent with return receipt requested, or in any other manner authorized by law. * * *

**PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS:
GENERAL**

- 29. The authority citation for 21 CFR part 1010 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 371, 381; 42 U.S.C. 263b–263n.

- 30. Section 1010.1 is revised to read as follows:

§ 1010.1 Scope.

The standards listed in this subchapter are prescribed pursuant to section 534 of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) (21 U.S.C. 360kk) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety.

- 31. In § 1010.4, paragraph (a)(1) is revised to read as follows:

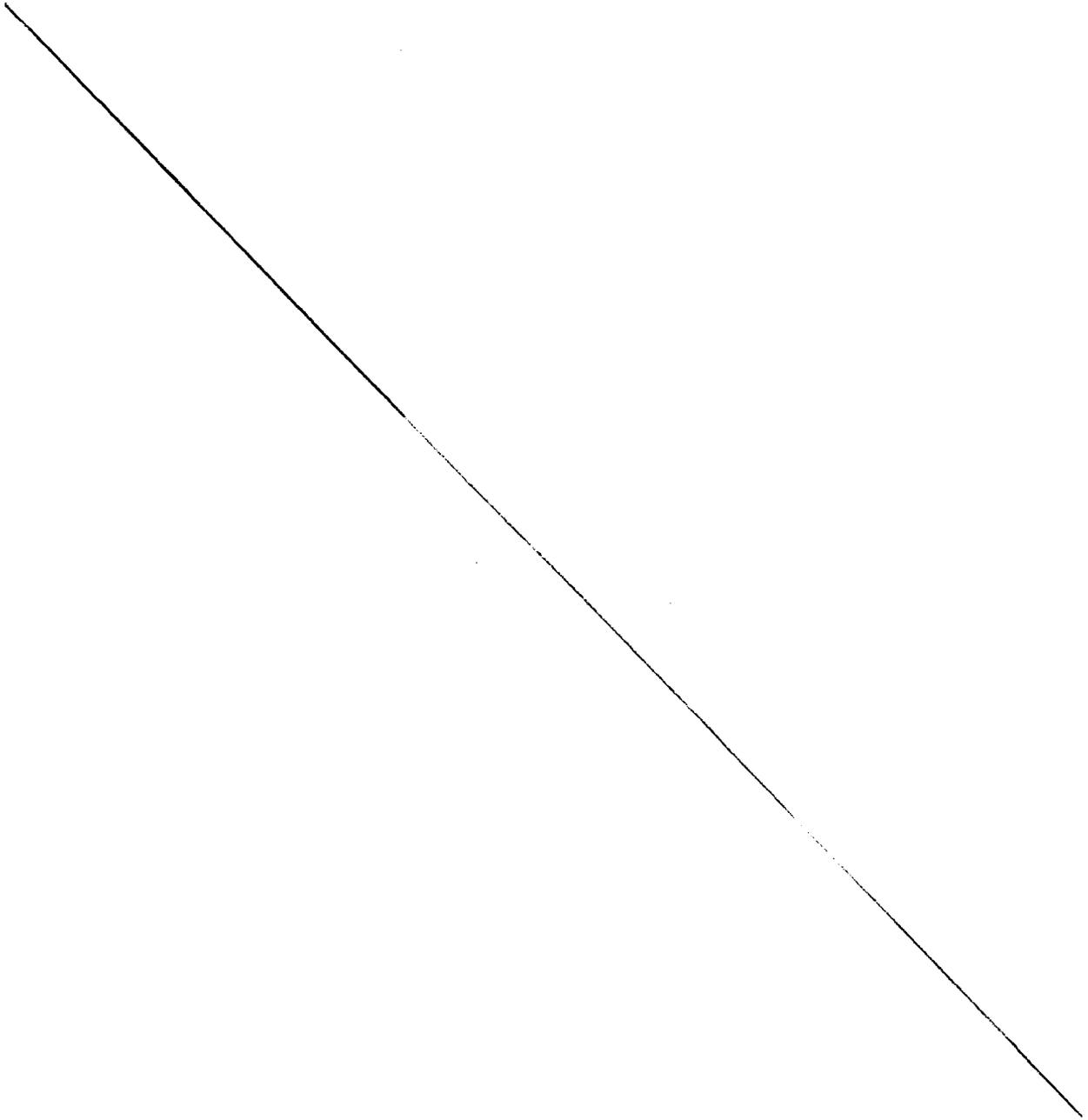
§ 1010.4 Variances.

(a) *Criteria for variances.* (1) Upon application by a manufacturer (including an assembler), the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant a variance from one or more provisions of any performance standard under subchapter J of this chapter for an electronic product subject to such standard when the Director determines that granting such a variance is in keeping with the purposes of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968), and:

(i) The scope of the requested variance is so limited in its applicability as not to justify an amendment to the standard, or

(ii) There is not sufficient time for the promulgation of an amendment to the standard.

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Dated: JUN 13 2008
June 13, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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