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DEPARTMENT OF STATE

2 CFR Part 600

22 CFR Parts 135 and 145

[Public Notice: 9160]

RIN 1400-AD57

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (“Department”) finalizes its portion of the uniform federal assistance rule published by the Office of Management and Budget.

DATES: This rule is effective on June 2, 2015.

FOR FURTHER INFORMATION CONTACT: Jeffrey D. Johnson, Director, Federal Assistance, 703-812-2526, johnsonjd4@state.gov.

SUPPLEMENTARY INFORMATION: On December 19, 2014, the Office of Management and Budget published an interim final rule that provided comprehensive modifications to the principles and requirements for federal awards. 79 FR 75871. The uniform rules were published as 2 CFR part 200. As part of that rulemaking, the Department of State adopted part 200, along with an agency-specific addendum in a new part 600. In addition, the Department removed 22 CFR parts 135 and 145, as they became obsolete with the publication of the interim final rule. *See* 79 FR at 76019.

The Department received no relevant comments in response to the rule. Therefore, 2 CFR part 600, as described in the interim final rule, is adopted with no changes.

Regulatory Findings

For the regulatory findings regarding this rulemaking, please refer to the analysis prepared by OMB in the interim final rule, which is incorporated herein. 79 FR at 75876.

List of Subjects in 2 CFR Part 600 and 22 CFR Parts 135 and 145

Accounting, Colleges and universities, Grant programs, Hospitals, Indians, Intergovernmental relations, Nonprofit organizations, Reporting and recordkeeping requirements.

Accordingly, the interim rule adding 2 CFR part 600 and amending 22 CFR parts 135 and 145, which was published at 79 FR 75871 on December 19, 2014, is adopted as a final rule without change.

Dated: May 27, 2015.

Jeffrey D. Johnson,

Director, Federal Assistance, Department of State.

[FR Doc. 2015-13437 Filed 6-1-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 895

[Docket No. FDA-2015-N-0011]

Banned Devices; General Provisions; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to clarify that the Agency will provide an opportunity for an informal hearing in connection with a proposed rule to ban a device with a special effective date. This action is being taken to align the regulations with the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: This rule is effective June 2, 2015.

FOR FURTHER INFORMATION CONTACT: Ian Ostermiller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 66, Rm. 4432, Silver Spring, MD 20993-0002, 301-796-5678.

SUPPLEMENTARY INFORMATION: FDA is correcting an error in the regulations that set forth the procedures for banning a medical device using a special effective date (§ 895.30 (21 CFR 895.30)). Specifically, the Agency is restoring a phrase that was incorrectly deleted from § 895.30(c). The regulations are being amended to ensure clarity and consistency with the requirements of the FD&C Act (21 U.S.C. 321 *et seq.*).

In this case, the regulations became inconsistent after the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629) amended the FD&C Act. Prior to the SMDA, the FD&C Act required the Secretary of Health and Human Services to afford an opportunity for informal hearings about any proposed rule to ban a medical device, regardless of effective date. One of the SMDA’s provisions removed the requirement that FDA provide an opportunity for an informal hearing when FDA does not establish a special effective date for a proposed ban.¹ However, the SMDA did not eliminate the informal hearing provision for a proposed ban issued with a special effective date. Thus, section 516(b) of the FD&C Act continues to require that FDA “provide reasonable opportunity for an informal hearing” on a proposed ban with a special effective date (21 U.S.C. 360f(b)).

On December 10, 1992 (57 FR 58400), FDA published a final rule implementing the SMDA. The final rule of 1992 correctly amended 21 CFR 895.21(d), which covers the procedures for issuing a ban without a special effective date, by removing the requirement that FDA provide an opportunity for an informal hearing when there is no special effective date.² However, the final rule incorrectly removed the same phrase from § 895.30,

¹ Specifically, the SMDA deleted the then-last sentence of section 516(a). See Pub. L. 101-629, section 18(d)(2) (“Section 516(a) (21 U.S.C. 360f(a)) is amended . . . by striking out the last sentence.”); 21 U.S.C. 360f(a) (1989) (stating, in the last sentence, “The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection.”).

² Although the hearing provision was validly removed from § 895.21(d)(8) in 1992, the removed language erroneously reappeared in the Code of Federal Regulations starting in 1994. On March 5, 2015 (80 FR 11865), the Office of the Federal Register published a correction document fixing this publication error.