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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]

BILLING CODE 4710–24–P

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.

which covers the procedures for issuing a ban with a special effective date. This rule corrects § 895.30(c) by restoring the incorrectly removed phrase.

FDA finds good cause for issuing this amendment as a final rule without notice and comment because this amendment only corrects the implementing regulation to restate the statute (5 U.S.C. 553(b)(B)). ''[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary.'' *Gray Panthers Advocacy Committee* v. *Sullivan,* 936 F.2d 1284, 1291 (D.C. Cir. 1991); see also *Komjathy* v. *Nat. Trans. Safety Bd.,* 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule ''does no more than repeat, virtually verbatim, the statutory grant of authority,'' notice-and-comment procedures are not required). This amendment to § 895.30(c) merely incorporates applicable requirements of the FD&C Act, making notice-and-comment procedures unnecessary in this case. Therefore, publication of this document constitutes final action on this change under the Administrative Procedure Act (APA) (5 U.S.C. 553).

In addition, FDA finds good cause for this amendment to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendment to § 895.30 does not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for this correction to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 895 is amended as follows:

PART 895—BANNED DEVICES

■ 1. The authority citation for 21 CFR part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

■ 2. Amend § 895.30 by revising paragraph (c) to read as follows:

§ 895.30 Special effective date.

* * * * *

(c) If the Commissioner makes a proposed regulation effective in accordance with this section, the Commissioner will, as expeditiously as possible, give interested persons prompt notice of this action in the **Federal Register** and will provide an opportunity for an informal hearing in accordance with part 16 of this chapter.

* * * * *

Dated: May 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13329 Filed 6–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0429]

Drawbridge Operation Regulation; Reynolds Channel, Nassau, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Long Beach Bridge, across Reynolds Channel, mile 4.7, at Nassau, New York. This temporary deviation is necessary to facilitate the City of Long Beach Annual Fireworks Display. This deviation allows the bridge to remain in the closed position during this public event.

DATES: This deviation is effective from 9:30 p.m. to 10:30 p.m. on July 10, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0429] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140, on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, contact Ms. Judy K. Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 514–4330, email *judy.k.leung-yee@uscg.mil.* If you have questions on viewing the docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Long Beach Bridge, mile 4.7, across Reynolds Channel has a vertical clearance in the closed position of 22 feet at mean high water and 24 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.799(g).

Reynolds Channel is transited by commercial fishing and recreational vessel traffic.

Nassau County Department of Public Works requested this temporary deviation from the normal operating schedule to facilitate a public event, the City of Long Beach Annual Fireworks Display.

Under this temporary deviation, the Long Beach Bridge may remain in the closed position between 9:30 p.m. and 10:30 p.m. on July 10, 2015 (rain date July 11, 2015).

There is no alternate route for vessel traffic; however, vessels that can pass under the closed draws during this closure may do so at any time. The bridge will be able to open in the event of an emergency.

The Coast Guard will inform the users of the waterway through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: May 21, 2015.

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2015–13396 Filed 6–1–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2015–0024]

RIN 1625–AA00

Safety Zone; Rotary Club of Fort Lauderdale New River Raft Race, New River; Fort Lauderdale, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on