4164-01-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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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, 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.

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[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.

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.

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Dated: May 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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