4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 16

[Docket No. FDA-2016-N-0011]

Regulatory Hearing Before the Food and Drug Administration; 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 correct an error in the lists of statutory and regulatory provisions that provide an opportunity for an informal hearing so that the lists correctly reference the statutory and regulatory provisions that provide such an opportunity in connection with a ban of a device. This action is being taken to align the regulations with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and avoid any potential confusion the erroneous lists may cause.

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. 5515, Silver Spring, MD 20993-0002, 301-796-5678.

SUPPLEMENTARY INFORMATION: FDA is correcting an error in the regulations that identify the statutory and regulatory provisions that provide an opportunity for a regulatory hearing, also known as an informal hearing (§ 16.1 (21 CFR 16.1)). In the list of statutory

provisions at § 16.1(b)(1), the Agency is adding a reference to subsection (b) of section 516 of the FD&C Act (21 U.S.C. 360f), which provides for a reasonable opportunity for an informal hearing when FDA proposes a medical device ban with a special effective date (21 U.S.C. 360f(b)(2)). The list of statutory provisions does not currently specify subsection (b) of section 516 of the FD&C Act, and it incorrectly refers to 21 CFR 895.21(d). An opportunity for a hearing is not required under section 516 of the FD&C Act or part 895 (21 CFR part 895) for bans that do not have a special effective date.

Further, the list of regulatory provisions at § 16.1(b)(2) does not include any reference to part 895. We are correcting this by adding a reference to § 895.30(c), which provides for an opportunity for an informal hearing under 21 CFR part 16 when FDA proposes a medical device ban with a special effective date. These corrections will align § 16.1(b) with section 516 of the FD&C Act and part 895 to avoid confusion regarding when an opportunity for hearing is required for a device ban.

Prior to the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629), 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

[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.").

effective date (21 U.S.C. 360f(b)) while subsection (a), the general rule for medical device bans, does not (see 21 U.S.C. 360f(a)).

On December 10, 1992 (57 FR 58400), FDA published a final rule implementing the SMDA. The final rule of 1992 amended § 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] FDA incorrectly removed the same language from § 895.30, which covers the procedures for issuing bans with special effective dates; the Agency issued a technical amendment restoring this language in the Federal Register of June 2, 2015 (80 FR 31299). However, FDA did not correct the language in § 16.1 to list section 516(b) of the FD&C Act and § 895.30(c) as the provisions that provide for regulatory (informal) hearings, nor did the Agency remove the reference to § 895.21(d). FDA does so now.

FDA finds good cause for issuing this amendment to § 16.1(b)(1) as a final rule without notice and comment because this amendment corrects the regulations 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). Further, the change to remove the erroneous cross-reference to § 895.21(d) and add the correct cross-reference to§ 895.30(c) is merely technical, insignificant in nature and impact, and

[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 beginning in 1994. On March 5, 2015 (80 FR 11865), the Office of the Federal Register published a correction document fixing this publication error.

inconsequential to industry and the public. See Mack Trucks, Inc. v. EPA, 682 F.3d 87, 94 (D.C. Cir. 2012). This is because this correction in no way changes when FDA is required to provide an opportunity for a hearing, which is determined by section 516 of the FD&C Act and part 895, nor does it impact the availability of such a hearing to any entity impacted by the proposed ban. It merely corrects a citation error to avoid confusion. This amendment to § 16.1(b) thus merely corrects the references to the applicable requirements of the FD&C Act and its implementing regulations, 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 § 16.1 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 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 16 is amended as follows:

PART 16--REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

2. Amend § 16.1 as follows:

a. In paragraph (b)(1), remove from the list the entry "Section 516 of the act relating to a proposed banned device regulations (see § 895.21(d) of this chapter)." and add in its place "Section 516(b) of the act regarding a proposed regulation to ban a medical device with a special effective date."

b. In paragraph (b)(2), add an entry in numerical sequence for "§ 895.30(c), regarding a proposed regulation to ban a medical device with a special effective date."

Dated: August 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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