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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 800

[Docket No. FDA-1977-N-0222]

Administrative Detention; Corrections

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendment.

SUMMARY: The Food and Drug Administration (FDA) published a document in the Federal Register on Friday, March 9, 1979 (44 FR 13239). The document established administrative detention procedures for devices intended for human use believed to be adulterated or misbranded. The document was published with a citation in the first column on page 13240 that subsequently was changed by the Nutrition Labeling and Education Act Amendments of 1993. In addition, the document was published with one typographical error in the first column on page 13241. This document corrects these errors.

DATES: This correction is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION: FDA is correcting a final rule that appeared in the Federal Register on Friday, March 9, 1979 (44 FR 13239). The final rule established administrative detention procedures for devices intended for human use believed to be

adulterated or misbranded. The document was published with a citation to section 201(y) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(y)) (the FD&C Act) in the first column on page 13240 (§ 800.55(g)(1) (21 CFR 800.55(g)(1)) that subsequently was changed to section 201(x) of the FD&C Act by section 3(b) of the Nutrition Labeling and Education Act Amendments of 1993 (Pub. L. 103-80). In addition, the document was published with one typographical error in the first column on page 13241 (§ 800.55(k)(1)) in which the word "is" should have been the word "in". This document updates the statutory reference in § 800.55(g)(1) and corrects the typographical error in § 800.55(k)(1).

Publication of this rule constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). This amendment to the regulations provides only a technical change and corrects a nonsubstantive error. FDA therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) that notice and public comment are unnecessary, and under 5 U.S.C. 553(d)(3) that the rule can become effective upon publication.

FDA has determined under 21 CFR 25.30(i) that this final rule is of a type that, as a class, 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.

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 800.55 have been approved under OMB control number 0910-0114, which expires April 30, 2016.

List of Subjects in 21 CFR Part 800

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 800 is 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.

2. In § 800.55, revise paragraph (g)(1) and the first sentence of paragraph (k) to read as follows:

§ 800.55 Administrative detention.

* * * * *

(g) Appeal of a detention order. (1) A person who would be entitled to claim the devices, if seized, may appeal a detention order. Any appeal shall be submitted in writing to the FDA District Director in whose district the devices are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(x) of the act, the appellant shall request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which shall not be later than 20 calendar days after receipt of a detention order.

* * * * *

(k) Recordkeeping requirements. (1) After issuance of a detention order under paragraph (d) of this section, the owner, operator, or agent in charge of any factory, warehouse, other establishment, or consulting laboratory where detained devices are manufactured, processed,

packed, or held shall have, or establish, and maintain adequate records relating to how the detained devices may have become adulterated or misbranded, records on any distribution of the devices before and after the detention period, records on the correlation of any in-process detained devices that are put in final form under paragraph (h) of this section to the completed devices, records of any changes in, or processing of, the devices permitted under the detention order, and records of any other movement under paragraph (h) of this section. * * *

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Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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