4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2010-N-0560]

Amendments to General Regulations of the Food and Drug Administration; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) published a final rule in the Federal Register on November 30, 2010, amending certain regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The final rule inadvertently deleted an authority citation and language related to the definition of "package." We are restoring the inadvertent deletions and making a corresponding technical change.

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

FOR FURTHER INFORMATION CONTACT: Felicia Billingslea, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-2371.

SUPPLEMENTARY INFORMATION: We are making technical amendments to our regulations under 21 CFR part 1.

In the Federal Register of November 30, 2010 (75 FR 73951), we amended certain regulations in part 1 (21 CFR part 1), "General Enforcement Regulations," in light of our authority under the Tobacco Control Act. The final rule, among other things:

- Revised the authority citation for part 1 by removing a reference to section 302 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 332);
- Revised § 1.1(c), "General," by removing the terms "package in § 1.20 and of", and
- Revised § 1.20, "Presence of mandatory label information," by removing the terms "package in § 1.20 and of".

The preamble to the final rule explained that the revisions to part 1 reflected our authority over tobacco products under the Tobacco Control Act (75 FR 73951 at 73952). However, the revisions inadvertently created one inconsistency (in that other provisions in part 1 did, in fact, rely on section 302 of the FD&C Act as part of their legal authority) or created confusion over whether the definition of "package" was limited to the regulations in part 1 or whether it also applied to other FDA regulations.

Therefore, through this rule, we are amending part 1 as follows:

- We are restoring section 302 of the FD&C Act to the authority citation for part 1. Because the authority citation is expressed in terms of the U.S. Code, the amendment is to insert "332" in the list of U.S. Code sections.
- We are revising §1.1 (c) to restore the terms "package in § 1.20 and of".
- We are revising § 1.20 to add a cross-reference to § 1.1 (c).

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). These amendments are merely correcting

inadvertent deletions. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, 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 1 is amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

§ 1.1 [Amended]

2. Amend § 1.1 by adding the phrase "of package in § 1.20 and" after the word "definition" in the first sentence of paragraph (c).

3. In § 1.20, revise the introductory text to read as follows:

§ 1.20 Presence of mandatory label information.

In the regulations specified in § 1.1(c) of this chapter, the term package means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

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Dated: November 14, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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