

Food and Drug Administration, HHS

§ 1.3

WAIVERS

- 1.1405 Under what circumstances will FDA waive one or more of the requirements of this subpart for an individual entity or a type of entity?
- 1.1410 When will FDA consider whether to waive a requirement of this subpart?
- 1.1415 How may I request a waiver for an individual entity?
- 1.1420 What process applies to a request for a waiver for an individual entity?
- 1.1425 What must be included in a petition requesting a waiver for a type of entity?
- 1.1430 What information submitted in a petition requesting a waiver for a type of entity, or information in comments on such a petition, is publicly available?
- 1.1435 What process applies to a petition requesting a waiver for a type of entity?
- 1.1440 What process will FDA follow when waiving a requirement of this subpart on our own initiative?
- 1.1445 Under what circumstances may FDA modify or revoke a waiver?
- 1.1450 What procedures apply if FDA tentatively determines that a waiver should be modified or revoked?

RECORDS MAINTENANCE AND AVAILABILITY

- 1.1455 How must records required by this subpart be maintained and made available?

CONSEQUENCES OF FAILURE TO COMPLY

- 1.1460 What consequences could result from failing to comply with the requirements of this subpart?

UPDATING THE FOOD TRACEABILITY LIST

- 1.1465 How will FDA update the Food Traceability List?

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, 342, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393, and 2223; 42 U.S.C. 216, 241, 243, 262, 264, 271.

SOURCE: 42 FR 15553, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 1.1 General.

(a) The provisions of regulations promulgated under the Federal Food, Drug, and Cosmetic Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 321 and 387) shall be applicable also to such terms when used in regulations promulgated under that act.

(c) The definition of *package* in § 1.20 and of *principal display panel* in §§ 101.1, 201.60, 501.1, 701.10 and 801.60 of this chapter; and the requirements pertaining to uniform location, lack of qualification, and separation of the net quantity declaration in §§ 101.7(f), 201.62(e), 501.105(f), 701.13(f) and 801.62(e) of this chapter to type size requirements for net quantity declaration in §§ 101.7(i), 201.62(h), 501.105(i), 701.13(i) and 801.62(h) of this chapter, to initial statement of ounces in the dual declaration of net quantity in §§ 101.7(j) and (m), 201.62(i) and (k), 501.105(j) and (m), 701.13(j) and (m) and 801.62(i) and (k) of this chapter, to initial statement of inches in declaration of net quantity in §§ 201.62(m), 701.13(o) and 801.62(m) of this chapter, to initial statement of square inches in declaration of net quantity in §§ 201.62(n), 701.13(p) and 801.62(n) of this chapter, to prohibition of certain supplemental net quantity statements in §§ 101.7(o), 201.62(o), 501.105(o), 701.13(q) and 801.62(o) of this chapter, and to servings representations in § 501.8 of this chapter are provided for solely by the Fair Packaging and Labeling Act. The other requirements part of this part are issued under both the Fair Packaging and Labeling Act and the Federal Food, Drug, and Cosmetic Act, or by the latter act solely, and are not limited in their application by section 10 of the Fair Packaging and Labeling Act.

[42 FR 15553, Mar. 22, 1977, as amended at 58 FR 17085, Apr. 1, 1993; 75 FR 73953, Nov. 30, 2010; 78 FR 69543, Nov. 20, 2013; 81 FR 59131, Aug. 29, 2016]

§ 1.3 Definitions.

(a) *Labeling* includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

(b) *Label* means any display of written, printed, or graphic matter on the immediate container of any article, or