

Food and Drug Administration, HHS

§ 1.20

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 §§ 101.105(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 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]

§ 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 any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.

§ 1.4 Authority citations.

(a) For each part of its regulations, the Food and Drug Administration includes a centralized citation of all of the statutory provisions that provide authority for any regulation that is included in that part.

(b) The agency may rely on any one or more of the authorities that are listed for a particular part in implementing or enforcing any section in that part.

(c) All citations of authority in this chapter will list the applicable sections in the organic statute if the statute is the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Fair Packaging and Labeling Act. References to an act or a section thereof include references to amendments to that act or section. These citations

will also list the corresponding United States Code (U.S.C.) sections. For example, a citation to section 701 of the Federal Food, Drug, and Cosmetic Act would be listed: Sec. 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371).

(d) If the organic statute is one other than those specified in paragraph (c) of this section, the citations of authority in this chapter generally will list only the applicable U.S.C. sections. For example, a citation to section 552 of the Administrative Procedure Act would be listed: 5 U.S.C. 552. The agency may, where it determines that such measures are in the interest of clarity and public understanding, list the applicable sections in the organic statute and the corresponding U.S.C. section in the same manner set out in paragraph (c) of this section. References to an act or a section thereof include references to amendments to that act or section.

(e) Where there is no U.S.C. provision, the agency will include a citation to the U.S. Statutes at Large. Citations to the U.S. Statutes at Large will refer to volume and page.

(f) The authority citations will include a citation to executive delegations (i.e., Executive Orders), if any, necessary to link the statutory authority to the agency.

[54 FR 39630, Sept. 27, 1989]

Subpart B—General Labeling Requirements

§ 1.20 Presence of mandatory label information.

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:

(a) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;

(b) Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail

§ 1.21

customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or

(c) Containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231-233), the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234-236), the Act of August 31, 1916 (39 Stat. 673, as amended; 15 U.S.C. 251-256), or the Act of May 21, 1928 (45 Stat. 635, as amended; 15 U.S.C. 257-257i).

(d) Containers used for tray pack displays in retail establishments.

(e) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part.

A requirement contained in this part that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or information also appears on the outer container or wrapper of the retail package of the article, or, as stated in paragraph (e) of this section, such information is easily legible by virtue of the transparency of the outer wrapper or container. Where a consumer commodity is marketed in a multiunit retail package bearing the mandatory label information as required by this part and the unit containers are not intended to be sold separately, the net weight placement requirement of §101.105(f) applicable to such unit containers is waived if the units are in compliance with all the other requirements of this part.

§ 1.21 Failure to reveal material facts.

(a) Labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are:

(1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or

(2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

21 CFR Ch. I (4-1-06 Edition)

(b) Affirmative disclosure of material facts pursuant to paragraph (a) of this section may be required, among other appropriate regulatory procedures, by

(1) Regulations in this chapter promulgated pursuant to section 701(a) of the act; or

(2) Direct court enforcement action.

(c) Paragraph (a) of this section does not:

(1) Permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, or cosmetics under the act.

(2) Permit a statement of differences of opinion with respect to the effectiveness of a drug unless each of the opinions expressed is supported by substantial evidence of effectiveness as defined in sections 505(d) and 512(d) of the act.

§ 1.23 Procedures for requesting variations and exemptions from required label statements.

Section 403(e) of the act (in this part 1, the term *act* means the Federal Food, Drug, and Cosmetic Act) provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 403(i) of the act provides for the establishment by regulation of exemptions from the required declaration of ingredients where such declaration is impracticable, or results in deception or unfair competition. Section 502(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 602(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 5(b) of the Fair Packaging and Labeling Act provides for the establishment by regulation of exemptions from certain required declarations of net quantity of contents, identity of commodity, identity and location of manufacturer, packer, or distributor, and from declaration of net quantity of