

Food and Drug Administration, HHS

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necessary to link the statutory authority to the agency.

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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 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.

(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

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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 servings represented, based on a finding that full compliance with such required declarations is impracticable or not necessary for the adequate protection of consumers, and a further finding that the nature, form, or quantity of the packaged consumer commodity or other good and sufficient reasons justify such exemptions. The Commissioner, on his own initiative or on petition of an interested person, may propose a variation or exemption based upon any of the foregoing statutory provisions, including proposed findings if section 5(b) of the Fair Packaging and Labeling Act applies, pursuant to parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

§ 1.24 Exemptions from required label statements.

The following exemptions are granted from label statements required by this part:

(a) *Foods.* (1) While held for sale, a food shall be exempt from the required declaration of net quantity of contents specified in this part if said food is received in bulk containers at a retail establishment and is accurately weighed, measured, or counted either within the view of the purchaser or in compliance with the purchaser's order.

(2) Random food packages, as defined in § 101.105(j) of this chapter, bearing la-

bel statements declaring net weight, price per pound or per specified number of pounds, and total price shall be exempt from the type size, dual declaration, and placement requirements of § 101.105 of this chapter if the accurate statement of net weight is presented conspicuously on the principal display panel of the package. In the case of food packed in random packages at one place for subsequent shipment and sale at another, the price sections of the label may be left blank provided they are filled in by the seller prior to retail sale. This exemption shall also apply to uniform weight packages of cheese and cheese products labeled in the same manner and by the same type of equipment as random food packages exempted by this paragraph (a)(2) except that the labels shall bear a declaration of price per pound and not price per specified number of pounds.

(3) Individual serving-size packages of foods containing less than ½ ounce or less than ½ fluid ounce for use in restaurants, institutions, and passenger carriers, and not intended for sale at retail, shall be exempt from the required declaration of net quantity of contents specified in this part.

(4) Individually wrapped pieces of *penny candy* and other confectionery of less than one-half ounce net weight per individual piece shall be exempt from the labeling requirements of this part when the container in which such confectionery is shipped is in conformance with the labeling requirements of this part. Similarly, when such confectionery items are sold in bags or boxes, such items shall be exempt from the labeling requirements of this part, including the required declaration of net quantity of contents specified in this part when the declaration on the bag or box meets the requirements of this part.

(5)(i) Soft drinks packaged in bottles shall be exempt from the placement requirements for the statement of identity prescribed by § 101.3 (a) and (d) of this chapter if such statement appears conspicuously on the bottle closure. When such soft drinks are marketed in a multiunit retail package, the multiunit retail package shall be exempt from the statement of identity declaration requirements prescribed by § 101.3