

§ 111.50 Packaging of iron-containing dietary supplements.

(a) The use of iron and iron salts as iron sources in dietary supplements offered in solid oral dosage form (e.g., tablets or capsules), and containing 30 milligrams or more of iron per dosage unit, is safe and in accordance with current good manufacturing practice only when such supplements are packaged in unit-dose packaging. “Unit-dose packaging” means a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units. The term “dosage unit” means the individual physical unit of the product (e.g., tablets or capsules). Iron-containing dietary supplements that are subject to this regulation are also subject to child-resistant special packaging requirements in 16 CFR parts 1700, 1701, and 1702.

(b)(1) Dietary supplements offered in solid oral dosage form (e.g., tablets or capsules), and containing 30 milligrams or more of iron per dosage unit, are exempt from the provisions of paragraph (a) of this section until January 15, 1998, if the sole source of iron in the dietary supplement is carbonyl iron that meets the specifications of § 184.1375 of this chapter.

(2) If the temporary exemption is not extended or made permanent, such dietary supplements shall be in compliance with the provisions of paragraph (a) of this section on or before July 15, 1998.

PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

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- AUTHORITY: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.
- SOURCE: 44 FR 16215, Mar. 16, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 113.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) *Aseptic processing and packaging* means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) *Bleeders* means openings used to remove air that enters with steam from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) *Come-up-time* means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) *Commercial processor* includes any person engaged in commercial, custom, or institutional (church, school, penal, or other organization) processing of food, including pet food. Persons engaged in the production of foods that are to be used in market or consumer tests are also included.