

agency's conclusions. The rule will result in total costs of approximately \$53 million and discounted benefits of between \$315 million and \$653 million over the next 20 years (discounted at 7 percent).

List of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 111

Current good manufacturing practices, Dietary supplements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical Devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the codified text as proposed in the **Federal Register** of October 6, 1994 (59 FR 51030), is republished in its entirety and is thereby superseded by this document. It is further proposed that Title 21, Chapter I be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.17 is amended by adding a new paragraph (e) to read as follows:

§ 101.17 Food labeling warning and notice statements.

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(e) *Dietary supplements containing iron or iron salts.* (1) The labeling of any dietary supplement in solid oral dosage form (e.g., tablets or capsules) that contains iron or iron salts for use as an iron source shall bear the following statement:

(i) If the product is packaged in unit-dose packaging as defined in § 111.1 of this chapter:

WARNING—Keep away from children. Keep in original package until each use. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(ii) If the product contains less than 30 milligrams of iron per dosage unit and is packaged by the manufacturer in other than unit-dose packaging as defined in § 111.1 of this chapter, e.g., a container with a child-resistant closure, its label shall bear the following statement:

WARNING—Close tightly and keep away from children. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(2) The statement required by paragraph (e)(1)(i) of this section shall appear prominently and conspicuously on the immediate container labeling in such a way that the warning is intact until all of the dosage units to which it applies are used. The statement required by paragraph (e)(1)(ii) of this section shall appear prominently and conspicuously on the immediate container labeling. In all cases where the immediate container is not the retail package, the warning statement shall also appear prominently and conspicuously on the principal display panel of the retail package. In addition, the warning statement shall appear on any labeling that contains warnings.

3. Part 111 is added to read as follow:

PART 111—CURRENT GOOD MANUFACTURING PRACTICE FOR DIETARY SUPPLEMENTS

Authority: Secs. 201, 402, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 371).

§ 111.1 Iron and iron salts in dietary supplements.

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).

PART 170—FOOD ADDITIVES

3. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

§ 170.55 [Removed]

4. Section 170.55 *Iron and iron salts in dietary supplements not in conventional food form* (as proposed in at 59 FR 51030, October 6, 1994) is removed.

PART 310—NEW DRUGS

5. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

6. New § 310.518 is added to subpart E to read as follows:

§ 310.518 Drug products containing iron or iron salts.

Drug products containing elemental iron or iron salts as an active ingredient in solid oral dosage form (e.g., capsules or tablets) shall meet the following requirements:

(a) *Packaging.* If the product contains 30 milligrams or more of iron per dosage unit, it shall be 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.

(b) *Labeling.* (1) If the product is packaged by the manufacturer in unit-dose packaging, its label shall bear the following statement:

WARNING—Keep away from children. Keep in original package until each use. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(2) If the product contains less than 30 milligrams of iron and is packaged by the manufacturer in other than unit-dose packaging, e.g., a container with a child-resistant closure, its label shall bear the following statement:

WARNING—Close tightly and keep away from children. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(3) The statement required by paragraph (b)(1) of this section shall appear prominently and conspicuously on the immediate container labeling in