

provisions. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. When applicable, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule is merely technical in nature and imposes no new burdens on small entities. Indeed, the effect of this rule is to remove a requirement that manufacturers package certain iron-containing dietary supplement and drug products in unit-dose packaging. Finally, a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is required only for nonprocedural rules that impose costs of \$110 million or more on either the private sector or State, local, and tribal governments in the aggregate. This rule imposes no such costs.

## VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that this final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

### List of Subjects

#### 21 CFR Part 111

Dietary foods, Drugs, Foods, Packaging and containers.

#### 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, 21 CFR parts 111 and 310 are amended as follows:

### PART 111—CURRENT GOOD MANUFACTURING PRACTICE FOR DIETARY SUPPLEMENTS

■ 1. The authority citation for 21 CFR part 111 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 371.

### PART 111—[REMOVED AND RESERVED]

■ 2. Part 111, consisting of §111.50, is removed and reserved.

### PART 310—NEW DRUGS

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

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

■ 4. Section 310.518 is revised 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., tablets or capsules shall meet the following requirements:

(a) *Labeling.* (1) The label of any drug 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:

**WARNING:** Accidental overdose or iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

(2)(i) The warning statement required by paragraph (a)(1) of this section shall appear prominently and conspicuously on the information panel of the immediate container label.

(ii) If a drug product is packaged in unit-dose packaging, and if the immediate container bears labeling but not a label, the warning statement required by paragraph (a)(1) of this section shall appear prominently and conspicuously on the immediate container labeling in a way that maximizes the likelihood that the warning is intact until all of the dosage units to which it applies are used.

(3) Where the immediate container is not the retail package, the warning statement required by paragraph (a)(1)

of this section shall also appear prominently and conspicuously on the information panel of the retail package label.

(4) The warning statement shall appear on any labeling that contains warnings.

(5) The warning statement required by paragraph (a)(1) of this section shall be set off in a box by use of hairlines.

(b) The iron-containing inert tablets supplied in monthly packages of oral contraceptives are categorically exempt from the requirements of paragraph (a) of this section.

Dated: October 7, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–26188 Filed 10–16–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE TREASURY

### 31 CFR Part 50

**RIN 1505-AA99**

### Terrorism Risk Insurance Program; State Residual Market Insurance Entities

**AGENCY:** Departmental Offices, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Treasury (Treasury) is issuing this final rule as part of its implementation of Title I of the Terrorism Risk Insurance Act of 2002 (Act). The Act established a temporary Terrorism Risk Insurance Program (Program) under which the Federal Government will share the risk of insured loss from certified acts of terrorism with commercial property and casualty insurers until the Program ends on December 31, 2005. Treasury published a proposed rule with a request for comment on April 18, 2003. This rule is issued pursuant to section 103(d)(1) of the Act, which directs Treasury to issue regulations that apply the provisions of the Act specifically to State residual market insurance entities and State workers' compensation funds. This rule is the third final rule in a series of regulations that Treasury is issuing to implement the Program.

**DATES:** This final rule is effective October 17, 2003.

#### FOR FURTHER INFORMATION CONTACT:

Mario Ugoletti, Deputy Director, Office of Financial Institutions Policy (202) 622–2730, or Martha Ellett or Cynthia Reese, Attorney-Advisors, Office of the Assistant General Counsel (Banking & Finance), (202) 622–0480, or C. Christopher Ledoux, Senior Attorney,