DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 111 and 310

[Docket Nos. 91P–0186 and 93P–0306]

Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements; Removal of Regulations for Unit-Dose Packaging Requirements for Dietary Supplements and Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; removal of regulatory provisions in response to court order.

SUMMARY: The Food and Drug Administration (FDA) is removing, in part, a final rule that required unit-dose packaging for iron-containing dietary supplement and drug products that contain 30 milligrams (mg) or more of iron per dosage unit. FDA is taking this action in response to the Court's ruling in *Nutritional Health Alliance* v. *FDA*, in which the Court concluded that the Federal Food, Drug, and Cosmetic Act (the act) does not provide FDA with authority to require manufacturers of iron-containing dietary supplement and drug products to use unit-dose packaging for poison prevention purposes. Today's action takes the ministerial step of removing the unit-dose packaging provisions from title 21 of the Code of Federal Regulations.

DATES: This rule is effective October 17, 2003.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1441.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 15, 1997 (62 FR 2218), FDA published a final rule (1997 final rule) that, among other things, required unit-dose packaging[1] for iron-containing dietary supplement and drug products in solid oral dosage form that contain 30 mg or more of iron per dosage unit (§ 111.50 (21 CFR 111.50 (dietary supplements) and § 310.518(a) (21 CFR 310.518(a) (drugs)). These provisions were challenged by the Nutritional Health Alliance (NHA), an association including manufacturers and distributors of iron-containing dietary supplements, on the basis that FDA did not have authority under the act to issue and enforce regulations for the purpose of poison prevention. On November 1, 2000, the U.S. District Court for the Eastern District of New York upheld FDA's authority to issue the regulations under the act (*Nutritional Health Alliance* v. *FDA*, No. 97–CV–5042, 2000 U.S. Dist. LEXIS 22330 (E.D.N.Y. Nov. 1, 2000)). NHA appealed. On January 21, 2003, the U.S. Court of Appeals for the Second Circuit reversed the judgment of the District Court and remanded the case to the District Court to fashion an appropriate remedy. On May 9, 2003, the District Court signed a final judgment declaring the provisions of §§ 111.50 and 310.518(a) invalid and without legal force or effect (*Nutritional Health Alliance* v. *FDA*, No. 97–CV–5042 (E.D.N.Y. filed May 29, 2003).

II. Summary of the Final Rule

In accordance with the Court's ruling and the District Court's final judgment, FDA is removing those parts of the 1997 final rule that established regulations in §§ 111.50 and 310.518(a), which required unit-dose packaging for dietary supplement and drug products that contain 30 mg or more of iron per dosage unit. The agency is also revising § 310.518(b), which provided a temporary exemption from unit-dose packaging requirements for certain iron-containing drug products, and revising appropriate paragraphs in § 310.518 accordingly.

This rule does not affect the provisions of 21 CFR 101.17(e), which requires label warning statements on all iron-containing dietary supplements in solid oral dosage form, or the provisions of § 310.518(c) (which is redesignated in this rule as § 310.518(a)), which requires label warning statements on all iron-containing drugs in solid oral dosage form, except iron-containing inert tablets supplied in monthly packages of oral contraceptives. Nor does this rule affect the provisions of 16 CFR 1700.14(a)(12) and (a)(13), which require special packaging for iron-containing drug and dietary supplement products, respectively, to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances (16 CFR 1700.14(a), (a)(12), and (a)(13)). The regulations in 16 CFR 1700.14 were issued under the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 *et seq.*) (PPP Act). The authority to administer and enforce the PPP Act was transferred from FDA to the Consumer Product Safety Commission in 1972 under the enactment of the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*).

III. Authority for Issuing Final Rule

Section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) provides that when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. FDA has determined that there is good cause under 5 U.S.C. 553(b)(3)(B) and 21 CFR 10.40(d) to forgo notice and comment. As a matter of law, the decision issued by the U.S. Court of Appeals for the Second Circuit and the final judgment of the U.S. District Court for the Eastern District of New York invalidated the provisions of the 1997 final rule requiring unit-dose packaging for solid oral dosage form dietary supplement and drug products that contain 30 mg or more per dosage unit, thereby making these provisions nonbinding and unenforceable. FDA finds that it is therefore unnecessary to provide notice and opportunity for public comment on this action, which merely implements the Court's order. For the same reasons, FDA finds that there is good cause, within the meaning of 5 U.S.C. 553(d)(3) and in accordance with the Congressional Review Act (5 U.S.C. 801 *et seq.*, at 808(2)), to make this rule effective immediately.

IV. Environmental Impact

The agency has determined under 21 CFR 25.301(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

Under Executive Order 12866, this action is not a regulatory action that is subject to review by the Office of Management and Budget (OMB). Because the agency has determined that there is good cause to forgo notice and comment requirements under the Administrative Procedure Act or any other statute, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) do not apply.

However, FDA has examined the impacts of this final rule under those

[1] For purposes of the rule, ''unit-dose packaging'' means a method of packaging a product into a nonreusable container designed to hold a signle dosage intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units (62 FR 2218, n.1; see also §111.50(a) and 21 CFR 310.510(a)).

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.

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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,