

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:

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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 packaging¹ 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))

¹ For purposes of the rule, "unit-dose packaging" means a method of packaging a product into a nonreusable container designed to hold a single 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)).

(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