DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1997D–0443]

Iron-Containing Supplements and Drugs: Label Warning Statement Requirements; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements; Small Entity Compliance Guide'' to revise and update an earlier SECG entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide.'' The revised SECG is being issued in response to the withdrawal, in part, of a final rule. The SECG is intended to set forth in plain language the requirements for label warning statements for iron-containing dietary supplement and drug products in solid oral dosage form and to help small businesses understand these requirements.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECG to *http://www.fda.gov/dockets/ecomments.*

Submit written requests for single copies of the SECG to the Iron Labeling, Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance document.

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 issued a final rule (1997 final rule) requiring: (1) Label warning statements on iron-containing products taken in solid oral dosage form to supplement the dietary intake of iron or to provide iron for therapeutic purposes, and (2) unit-dose packaging for iron-containing dietary supplement and drug products that contain 30 milligrams (mg) or more of iron per dosage unit. This final rule became effective July 15, 1997. In the **Federal Register** of December 12, 1997 (62 FR 65432), FDA announced the availability of a SECG entitled ''Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide'' (1997 SECG). The 1997 SECG was prepared in accordance with section 212 of the Small Business Regulatory Enforcement Act (Public Law 104–121) and was intended to help small businesses understand the requirements of the 1997 final rule.

Elsewhere in this issue of the **Federal Register**, FDA is withdrawing those parts of the 1997 final rule that established regulations in §§111.50 and 310.518(a) and (b) (21 CFR 111.50 and 310.518(a) and (b)) requiring unit-dose packaging for iron-containing dietary supplement and drug products that contain 30 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* (318 F.3d 92 (2d Cir. 2003)), in which the U.S. Court of Appeals for the Second Circuit invalidated the unit-dose packaging regulations based upon its conclusion that the Federal Food, Drug, and Cosmetic Act does not provide FDA with authority to regulate packaging of iron-containing dietary supplement and drug products for poison prevention purposes. The Court's ruling affects only the unit-dose packaging requirements of the 1997 final rule and not the label warning statement requirements. On remand, the U.S. District Court for the Eastern District of New York entered final judgment in accordance with the Court's decision, 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)). As a result, the 1997 SECG is being revised in accordance with the Court's ruling and FDA's withdrawal of the unit-dose packaging regulations.

Therefore, FDA is making available the revised SECG entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements; Small Entity Compliance Guide,'' which states in plain language the requirements of the final rule on label warning statements for iron-containing dietary supplement and drug products.

FDA is revising this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on this subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/guidance.html.*

Dated: October 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0231]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until December 16, 2003, the comment period for the draft guidance for industry