

borrower to RUS and the annual auditor's report on the borrower's operations. However, RUS may inspect the borrower's records at any time during the year to determine borrower compliance. If a borrower's most recent annual financial and statistical report shows the aggregate of the borrower's investments, loans and guarantees to be below the 15 percent level, that in no way relieves the borrower of its obligation to comply with its RUS mortgage, RUS loan contract, and this subpart with respect to Administrator approval of any additional investment, loan or guarantee that would cause the aggregate to exceed the 15 percent level.

§ 1717.658 Effect of this subpart on RUS loan contract and mortgage.

(a) Nothing in this subpart shall affect any provision, covenant, or requirement in the RUS mortgage, RUS loan contract, or any other agreement between a borrower and RUS with respect to any matter other than the prior approval by RUS of investments, loans, and guarantees made by the borrower. Also, nothing in this subpart shall affect any rights which supplemental lenders have under the RUS mortgage, or under their loan contracts or other agreements with their borrowers, to limit investments, loans and guarantees by their borrowers to levels below 15 percent of total utility plant.

(b) RUS reserves the right to change the provisions of the RUS mortgage and loan contract relating to RUS approval of investments, loans and guarantees made by the borrower, on a case-by-case basis, in connection with providing additional financial assistance to a borrower after [Date 30 days after the final rule is published in the **Federal Register**].

Dated: February 7, 1995.

Bob J. Nash,

Under Secretary, Rural Economic and Community Development.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 111, 170, and 310

[Docket Nos. 91P-0186 and 93P-0306]

Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Supplemental proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a supplemental proposed rule to set forth its legal authority, after the passage of the Dietary Supplement Health and Education Act (DSHEA), to require unit-dose packaging of iron-containing dietary supplements that contain 30 milligrams (mg) or more iron per dosage unit. On October 6, 1994, the agency proposed this packaging requirement as part of a broader proposal to require unit-dose packaging of all iron-containing products in solid oral dosage form containing 30 mg or more iron per dosage unit and to require label warning statements on all iron-containing products in solid oral dosage form. The agency's authority to establish the labeling requirements and the packaging requirements for iron-containing products other than dietary supplements (i.e., iron-containing drugs) is unaffected by the DSHEA. To ensure that there is adequate time to comment on this supplemental proposed rule, as well as on the issues raised by the initial proposal, FDA is reopening the comment period for this rulemaking until April 17, 1995.

DATES: Written comments to the initial proposal (published at 59 FR 51030, October 6, 1994) and this supplemental proposal by April 17, 1995. The agency is proposing that any final rule that may be issued based upon this proposal become effective 180 days after its publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John N. Hathcock, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 8301 Muirkirk Rd., Laurel, MD 20708, 301-594-6006.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 6, 1994 (59 FR 51030), FDA issued a proposal on actions that it tentatively concluded were necessary to stem the recent epidemic of pediatric poisonings from accidental overdoses of iron-containing products. The available evidence shows that since the mid 1980's, there has been an upsurge in reported accidental pediatric poisonings from ingestion of iron-containing products (59 FR 51030). This upsurge in poisonings, and the many resultant injuries and deaths of children, have created a dilemma with respect to how

to ensure that iron sources are available while still minimizing the risks to children.

To protect children, FDA proposed two new requirements: First, to ensure that consumers are fully informed about the consequences of consuming iron-containing products, FDA proposed to require a warning statement about the adverse effects of acute, high-dose iron ingestion by children to be included in the labeling of all iron-containing products in solid oral dosage form. FDA found that the fact that poisonings continue to occur, even though there have been at least 37 deaths from accidental iron ingestion, strongly suggests that many adults are not aware of the potential for serious harm or death in young children from accidental ingestion of iron-containing products. Support for this finding is provided by statements made by the parents of the victims in several of the poisoning incidents, described in the case reports obtained from the U.S. Consumer Product Safety Commission (CPSC). FDA proposed that this requirement apply to iron-containing drugs and dietary supplements based on its authority under sections 201(n), 403(a)(1), 502(a), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(n), 343(a)(1), 352(a), and 371(a)). Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 502(a) of the act establishes the same rule for drugs. Section 201(n) of the act states:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

These statutory provisions, combined with section 701(a) of the act, which grants the agency authority to issue regulations for the efficient enforcement of the act, clearly authorize FDA to issue a regulation designed to ensure that persons using iron-containing drugs and dietary supplements will receive information that is material with respect to consequences that may result from the use of the product.