

fleshy scales have a watersoaked condition; and,

(l) Watery scales when more than the equivalent of the entire outer fleshy scale is affected by an off-color, watersoaked condition. The off-color must be of some shade of brown or yellow.

§ 51.3211 Serious damage.

Serious damage unless otherwise specifically defined in this section, means any defect which seriously affects the appearance, or the edible or shipping quality of the onions. Any one of the following defects, or any combination of defects the seriousness of which exceeds the maximum allowed for any one defect, shall be considered as serious damage:

- (a) Seedstems when more than one-half inch in diameter;
- (b) Dry sunken areas when extending deeper than one fleshy scale, or when affecting an area equivalent to that of a circle 1 inch in diameter on an onion 2¾ inches in diameter, or correspondingly lesser or greater areas on smaller or larger onions;
- (c) Sprouting when any visible sprout is more than one-half inch in length;
- (d) Staining, dirt or foreign material when more than 25 percent of the onions in any lot are badly stained. Onions with adhering dirt or other foreign matter shall be judged on the same basis as stained onions;
- (e) Mechanical when any cut extends deeper than two fleshy scales, or when cuts seriously damage the appearance of the onion; and,
- (f) Watery scales when more than the equivalent of two entire outer fleshy scales are affected by an off-colored, watersoaked condition. The off-color must be of some shade of brown or yellow.

§ 51.3212 Diameter.

Diameter means the greatest dimension of the onion at right angles to a line running from the stem to the root.

Metric Conversion Table

§ 51.3213 Metric conversion table.

Inches	Millimeters (mm)
1/8	3.2
1/4	6.4
3/8	9.5
1/2	12.7
5/8	15.9
3/4	19.1
7/8	22.2
1	25.4
1¼	31.8
1½	38.1

Inches	Millimeters (mm)
1¾	44.5
2	50.8
2½	63.5
2¾	69.9
3	76.2
3½	88.9
4	101.6

Dated: February 9, 1995.
Lon Hatamiya,
Administrator.
 [FR Doc. 95-3787 Filed 2-15-95; 8:45 am]
BILLING CODE 3410-02-P

Rural Utilities Service

7 CFR Part 1717

Investments, Loans, and Guarantees by Electric Borrowers

AGENCY: Rural Utilities Service, USDA.
ACTION: Proposed Rule.

SUMMARY: The Rural Utilities Service (RUS) hereby proposes to revise its policies and requirements governing restrictions on investments, loans and guarantees made by electric borrowers. This proposed rule is intended to clarify RUS's policies and requirements, reduce uncertainty by borrowers, and improve compliance.

DATES: Written comments must be received by RUS or carry a postmark or equivalent by April 17, 1995.

ADDRESSES: Written comments should be addressed to Mr. F. Lamont Heppe, Jr., Deputy Director, Program Support Staff, U.S. Department of Agriculture, Rural Utilities Service, Ag Box 1522, room 2234-S, 14th Street and Independence Avenue, SW., Washington, DC 20250-1500. RUS requires a signed original and 3 copies of all comments (7 CFR 1700.30 (e)). Comments will be available for public inspection during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Mr. Alex M. Cockey, Jr., Deputy Assistant Administrator—Electric, U.S. Department of Agriculture, Rural Utilities Service, Ag Box 1560, room 4037-S, 14th Street & Independence Avenue, SW., Washington, DC 20250-1500. Telephone: 202-720-9547.

SUPPLEMENTARY INFORMATION: This proposed rule has been determined to be not significant for the purposes of Executive Order 12866, and therefore has not been reviewed by the Office of Management and Budget (OMB). The Administrator of RUS has determined that the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) does not apply to this

rule. The Administrator of RUS has determined that this rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an environmental impact statement or assessment. This rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require consultation with State and local officials. A Notice of Final Rule titled Department Programs and Activities Excluded from Executive Order 12372 (50 FR 47034) exempts RUS electric loans and loan guarantees from coverage under this Order. This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule; (2) Will not have any retroactive effect; and (3) Will not require administrative proceedings before any parties may file suit challenging the provisions of this rule.

The program described by this rule is listed in the Catalog of Federal Domestic Assistance Programs under number 10.850 Rural Electrification Loans and Loan Guarantees. This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC 20402-9325.

Information Collection and Recordkeeping Requirements

The existing recordkeeping and reporting burdens contained in this rule were approved by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), under control numbers 0572-0017, 0572-0032, and 0572-0103. Additional information collection and recordkeeping requirements contained in this proposed rule have been submitted to OMB for review.

Send questions or comments regarding these burdens or any other aspect of these collections of information, including suggestions for reducing the burden, to the Office of Information and Regulatory Affairs, Office of Management and Budget, room 10102, NEOB, Washington, DC 20503. Attention: Desk Officer for USDA.

Background

On December 22, 1987, section 312 was added to the Rural Electrification Act of 1936. This section allows electric borrowers to invest their own funds or make loans or guarantees, not in excess of 15 percent of their total utility plant,

without restriction or prior approval of the Administrator of the Rural Utilities Service (RUS). On June 29, 1989, RUS issued a final rule codifying this provision (at 54 FR 27325), and the provision became effective for all electric mortgages executed after July 31, 1989. Mortgages executed prior to that date contained a provision granting the Administrator the right to approve investments, loans and guarantees by the borrower once the aggregate of such investments, loans and guarantees reached 3 percent of total utility plant.

This proposed rule is intended to clarify RUS's policies and requirements regarding restrictions on borrower investments, loans and guarantees. Over the past several years borrowers have raised a number of questions about such issues as: Which investments, loans or guarantees are subject to RUS approval and which are excluded; the criteria used by RUS in approving an investment, loan or guarantee; whether RUS approval of an investment, loan or guarantee means that it is no longer counted in determining the ratio to total utility plant; whether RUS will approve an investment, loan or guarantee if the borrower is under the 15 percent limit; whether a borrower will be in default under its mortgage because net profits earned on its investments pushed its total above the 15 percent limit. This proposed rule attempts to resolve such questions.

RUS is also in the process of updating its mortgage and loan contract used with electric borrowers. RUS published a proposed mortgage for electric distribution borrowers on September 29, 1994 at 59 FR 49594. In that rule it is proposed that RUS controls over borrower investments, loans and guarantees be moved from the mortgage to the RUS loan contract. Such a move would have no effect on RUS's controls or their enforceability under the RUS mortgage.

The following discussion of the proposed rule published today focuses on the major provisions and more significant changes proposed to the existing regulation.

Section 1717.651 Policy

No change is proposed to this section. It would remain RUS policy that borrowers are encouraged to use their own funds to foster the economic development of rural areas, provided that such actions do not in any way put government funds at risk or impair the borrower's ability to repay its indebtedness to RUS and other lenders.

Section 1717.652 Definitions

Several changes are proposed to this section, mostly to accommodate changes proposed elsewhere in the rule. For example, definitions are added for "Default," "Equity," "Operating DSC," "Operating TIER," "Regulatory Created Assets," and "Total Assets." These relate primarily to proposed § 1717.655, under which borrowers that meet certain criteria would be exempt from RUS approval of investments, loans and guarantees.

Technical changes are proposed to the definition of "Own Funds." These are not intended to make any substantive change to what investments, loans and guarantees are or are not controlled by RUS. The proposed changes are intended to more closely reflect the approach actually used by RUS in monitoring investments, loans and guarantees. The current definition may give the erroneous impression that all cash deposits and other assets held by a borrower are first divided into "Own Funds" and "other funds" and that only "Own Funds" are subject to controls. In fact, all of a borrower's investments, loans and guarantees are subject to controls except those made under the 15 percent limit and those excluded under § 1717.654. The definition of "Own Funds" serves primarily to make clear that, for the purposes of the 15 percent exclusion, a borrower cannot treat funds lent by RUS as its "Own Funds".

In addition, four new terms would be defined: "Natural Gas Distribution System," "Solid Waste Disposal System," "Telecommunication and Other Electronic Communication System," and "Water and Waste Disposal System." Under proposed § 1717.654 investments by borrowers in these four types of community infrastructure located in the borrowers' service territories would be excluded from RUS control.

Finally, it is proposed that the current definition of "Invest" be supplemented by allowing borrowers to submit any proposed transaction to RUS for an interpretation of whether the action is an investment for the purposes of RUS controls.

Section 1717.653 Transactions Below the 15 Percent Level

Proposed paragraph (a) of new § 1717.653 is the same substantively as existing § 1717.653. It would continue to provide that a borrower in compliance with all provisions of its RUS mortgage, RUS loan contract, and any other agreement with RUS would not need prior approval from RUS to make investments, loans and guarantees

up to the 15 percent level. For purposes of clarity, the proviso that the borrower must not be in default would be included at this point rather than in the definition of borrower, as in the existing rule. Similarly, a proviso would be included to make it clear that funds necessary to make timely payments of principal and interest on loans secured by the RUS mortgage would remain subject to RUS controls. This issue is currently addressed in the definition of "Own Funds" in the existing rule.

Proposed paragraph (b) is substantively the same as existing § 1717.654(b).

Proposed paragraph (c) is new, and is intended to clarify RUS policy that it will not "approve" investments, loans or guarantees made below the 15 percent level. In the past, some borrowers have sought to obtain RUS approval of transactions below the 15 percent limit and to have these transactions excluded when determining the aggregate amount of investments, loans and guarantees made by the borrower. Such approvals would not be consistent with the restriction imposed on RUS by section 312 of the RE Act. They also would not be consistent with protecting loan security since a borrower might seek approval and exclusion of low-risk transactions below the 15 percent limit in order to make room for high-risk transactions below the limit that would be immune from RUS review.

Section 1717.654 Exclusion of Certain Investments, Loans and Guarantees

Proposed paragraph (a) would remain substantively the same as existing paragraph (a). The exclusions set forth in proposed paragraph (b) are the same as those in existing paragraph (b)(2), except that it would be made clear that all investments made in the National Rural Utilities Cooperative Finance Corporation and the National Bank for Cooperatives would be excluded from RUS controls, as they are now under current RUS policy.

Certain other exclusions currently followed by RUS would continue. These include exclusions for any investment, loan or guarantee that the borrower is required to make by RUS or other USDA agency; investments included in an irrevocable trust for the purpose of funding post-retirement benefits of the borrower's employees; and reserves required by a reserve bond agreement or other legally binding agreement that are dedicated to making required payments on debt secured under the RUS mortgage, not to exceed the amount of reserves specifically required by such agreement.

All dollar amounts excluded by RUS from the calculation of aggregate investments, loans, and guarantees pursuant to the RUS mortgage, RUS loan contract, and/or RUS regulations, bulletins, memoranda (including the memorandum of March 28, 1985 cited below), or other written notice as of the date of this proposed rule will continue to be excluded in the future. However, profits, interest and other returns (regardless of whether or not they are reinvested) from such investments, loans, and guarantees after the date of this proposed rule will be excluded only if they are excluded under proposed § 1717.654. Also, any new commitment of funds to such investments, loans, and guarantees will not be exempted after the date of this proposed rule unless they are excluded under proposed § 1717.654. Moreover, the memorandum issued to all electric borrowers by the Administrator of the Rural Electrification Administration, dated March 28, 1985, regarding the approval of certain investments is hereby rescinded.

Several new exclusions are proposed under paragraph (c) of this section. There would be no restrictions on investments in or loans to the following types of community infrastructure located in the borrower's service territory: water and waste disposal systems; solid waste disposal systems; telecommunication and other electronic communication systems; and natural gas distribution systems. Guarantees of the obligations of such systems would also be excluded so long as the aggregate amount of such guarantees does not exceed 20 percent of the borrower's equity.

RUS believes that borrowers should be able to minimize the risks associated with investing in these types of community infrastructure because of the similarities in structure and operation between them and the borrowers' main electric utility business, and the opportunities for sharing overhead in such areas as billing, communications, system control, repair and maintenance, and construction supervision. Excluding these investments complements the approach in the proposed new mortgage for distribution borrowers, which would allow borrowers meeting certain criteria to issue up to 20 percent of their total secured debt for such community infrastructure, without the approval of the mortgagees.

It is also proposed that amounts "invested" in customer accounts receivable and other accounts receivable be excluded from the calculation of total investments, loans and guarantees. These "investments" represent

commitments made for a period of less than a year, and should not present a significant on-going risk to the borrower or RUS.

Other proposed editorial changes to existing 1717.654, such as shifting paragraph (b)(1) to 1717.653(b) would not change the substance of the rule.

Section 1717.655 Exemption of Certain Borrowers From Controls

Proposed new § 1717.655 would exempt borrowers that meet certain criteria from RUS approval of investments, loans and guarantees. The proposed criteria are as follows:

- The borrower must be in compliance with all provisions of its RUS mortgage, RUS loan contract, and any other agreement with RUS.
- The average revenue per kWh for residential service received by the borrower must not exceed 130 percent of the average revenue for residential service for all residential consumers in the state or states served by the borrower. The criterion would apply only to distribution borrowers.
- In the most recent calendar year the borrower must have achieved an operating TIER and an operating DSC of at least 1.0, in each case based on the average of the two highest ratios achieved in the three most recent years.
- The borrower's ratio of net utility plant to long-term debt must be at least 1.1.
- The borrower must have equity equal to at least 27 percent of its total assets.

Both distribution and power supply borrowers that meet these criteria would be exempt from RUS approval of investments, loans and guarantees. It is estimated that about 83 percent of distribution borrowers and 3 power supply borrowers currently would meet the proposed criteria for exemption. Borrowers not meeting the criteria would be subject to RUS approval of investments, loans and guarantees above 15 percent of total utility plant.

The first qualification criterion would require the borrower to be in good standing with respect to all covenants of its RUS mortgage, RUS loan contract or any other agreement with RUS, such as adequately maintaining the property, having adequate insurance coverage, meeting all financial obligations, and achieving margins sufficient to meet TIER and DSC requirements.

The second criterion would exclude borrowers that are more likely to face risks of substantial downward pressure on rates and the possible loss of load and revenues. While comparing a borrower with the state average, as proposed, is less reliable analytically

than a detailed comparison with the borrower's neighboring competitors, setting the threshold at 130 percent should ensure that borrowers that fail the test most likely face an increased risk of rate competition. At a borrower's request, the Administrator of RUS could waive this criterion if he found that the borrower's strength on the other qualification criteria offset the borrower's weakness in rate disparity.

The third criterion would ensure that the borrower is usually able to cover all of the expenses of its utility operation from utility revenues, and normally should not be dependent on income from investments or loans to meet the expenses of its primary business.

The fourth criterion would provide substantial assurance that the borrower's long-term debt is adequately collateralized and that RUS loan security normally should not need to depend on the borrower's investments and loans, which may not be secured or effectively secured under the RUS mortgage and whose liquidation value may vary substantially over time.

The fifth criterion would provide an equity cushion in the event the borrower defaulted and foreclosure and liquidation became necessary. It also would provide an incentive for profitable investments and a disincentive for unprofitable investments, since the ratio of equity to total assets would increase in the first case and decrease in the second. A borrower could lose its exemption status if bad investments reduced equity below 27 percent.

While distribution and power supply borrowers that meet the proposed criteria would be exempt from RUS approval of their investments, loans and guarantees, these borrowers would continue to be obligated to maintain adequate records and to report annually on their transactions. Such records and reports would be needed in the event an exempt borrower lost its exemption because of failure to meet one or more of the criteria, and also to monitor borrower performance in making investments in rural development.

If an exempt borrower ceases to meet the criteria for exemption, it would become subject to the controls set forth in this proposed rule upon receiving written notice from RUS. Such borrower could regain its exemption if subsequently it met the qualification criteria and was so notified in writing by RUS.

If an exempt borrower is over the 15 percent level at the time it loses its exemption, it could ask the Administrator to exclude a portion of its investments, loans and guarantees up to

the aggregate amount of net profit earned on all of its transactions over the past 10 years. If the net profits are insufficient, or if the Administrator does not exclude an amount sufficient to bring the borrower to or below the 15 percent level, the borrower would be required to reduce or restructure its portfolio (e.g., divest or shift some investments to excluded investments) in order to come within the 15 percent limit. If the borrower failed to do this within a timeframe set by RUS, the borrower would be in default of its RUS loan contract and/or RUS mortgage upon receiving written notice from RUS of the default.

Section 1717.656 Investments, Loans, and Guarantees in Excess of 15 Percent of Total Utility Plant

Proposed new § 1717.656 would establish policies and requirements for RUS approval of investments, loans and guarantees above 15 percent of total utility plant. The section would apply only to borrowers that do not qualify for an outright exemption from RUS approval under § 1717.655. In the case of distribution borrowers that do not qualify for an exemption, they would not be given approval to make controlled investments, loans and guarantees above the 15 percent level.

These borrowers currently represent less than 20 percent of all distribution borrowers, and all but one of them are below the 15 percent level at the present time. These borrowers would retain the latitude to make unlimited investments, loans and guarantees within those categories excluded from control under § 1717.654. Moreover, RUS believes that many of these borrowers could improve their economic and financial condition in order to qualify for the outright exemption under § 1717.655, if they want the additional latitude to make controlled investments, loans and guarantees above the 15 percent level.

In the case of power supply borrowers that do not qualify for an exemption under § 1717.655, RUS would consider requests to make controlled investments, loans and guarantees above the 15 percent level. To be eligible to submit a request, a power supply borrower would have to meet the following criteria:

- The borrower must be in compliance with all provisions of its RUS mortgage, RUS loan contract and any other agreement with RUS.
- The borrower cannot be in financial workout nor had its government debt restructured.
- The borrower must have equity of at least 5 percent of total assets.

- After approval of the request, the aggregate of the borrower's investments, loans and guarantees cannot exceed 20 percent of total utility plant. Beyond this level RUS believes that further investments, loans or guarantees outside of the "excluded categories" would present unacceptable risks in the case of borrowers that do not qualify for an exemption under § 1717.655.

If a power supply borrower meets the above criteria, its request would be considered on a case by case basis. In considering the request, the Administrator would take the following factors into consideration:

- The repayment of all loans secured by the RUS mortgage must continue to be assured and security must continue to be reasonably adequate even if the entire investment, loan or guaranteed amount were lost. This "total loss" approach would expedite review by RUS by eliminating the need to assess the probability of a loss occurring and its probable size. The effect of the loss of the entire investment, loan or guaranteed amount would be considered along with all other risks facing the borrower.

- In the case of an investment, the investment would have to be made in an entity separate from the borrower, such as a subsidiary, whereby the borrower would be protected from any liabilities incurred by the separate entity, unless the borrower is able to demonstrate that making the investment directly rather than through a separate entity would present no substantial risk beyond that of possibly losing part or all of the investment.

- The borrower must be economically and financially sound as indicated by its costs of operation, competitiveness, operating TIER and operating DSC, physical condition of the plant, ratio of equity to total assets, ratio of net utility plant to long-term debt, and other factors.

- Other factors affecting the security and repayment of government debt, as determined on a case by case basis.

This proposed new section 1717.656 would also clarify existing policy that if RUS approves an investment, loan or guarantee, such investment, loan or guarantee would continue to be included when calculating the borrower's ratio of aggregate investments, loans and guarantees to total utility plant. In other words, just because an investment has been approved by RUS doesn't mean it will not continue to be counted toward the borrower's total investments.

Proposed paragraph (d) of this section would deal with the situation where profits earned on investments increase

the aggregate amount of investment and could cause a borrower to be in technical violation of its loan contract or mortgage. The paragraph would make it clear that if a borrower exceeded the 15 percent limit as a result of net profits earned on the aggregate of its investments, loans and guarantees during the past 10 years, the borrower would not be in default of its loan contract or mortgage. Net profit would be calculated by taking the sum of all profits earned on all transactions during the past 10 years (including interest earned on cash accounts, loans, and similar transactions), and subtracting all losses experienced on all transactions during the same period.

Also, under proposed paragraph (d) RUS would be willing to consider a borrower's request to exclude up to the amount of net profit earned on the borrower's investments, loans and guarantees during the past 10 years. Such exclusion by RUS may or may not reduce the borrower's aggregate investments, loans and guarantees to or below the 15 percent limit. If it does not, the borrower would be required to restructure or reduce its portfolio to come within the 15 percent level. Failure to do so within a timeframe set by RUS would result, upon written notice from RUS, in a default by the borrower.

Section 1717.657 Records, Reports and Audits

Paragraphs (a), (b) and (c) of proposed § 1717.657 are the same substantively as existing § 1717.655. Proposed paragraph (a) is the same substantively as existing paragraph (a) of § 1717.655, and proposed paragraph (c) is the same substantively as existing paragraph (b). Proposed paragraph (b) would combine existing paragraphs (c) and (d).

Proposed paragraph (d) would be a new provision. It would clarify that RUS monitoring of borrower compliance with this rule will be based primarily on the annual financial and statistical reports submitted by borrowers (i.e., the RUS Forms 7 and 12), and the annual auditor's report on borrower operations. While RUS would ordinarily rely primarily on these annual reports, all borrowers would continue to be obligated to comply with this rule throughout the entire year. For example, if a borrower was below the 15 percent level at the end of the preceding year, it could not exceed the 15 percent level during the current year without prior approval from RUS, unless of course it was exempt from approval under proposed § 1717.655.

Section 1717.658 Effect of Subpart on RUS Loan Contract and Mortgage

Section 1717.656 of the existing rule lists several specific provisions of the RUS mortgage that are not affected by the rule, as well as the fact that a supplemental lender's rights under the RUS mortgage regarding control of investments also are not affected by the rule. These specific provisions were listed for emphasis only; there being no intent to imply that other provisions of the mortgage are somehow affected by the rule on investment controls. Furthermore, section 1717.657 of the existing rule provides that the rule does not affect a supplemental lender's rights under its own loan documentation to control borrower investments.

Proposed § 1717.658 would combine and simplify the two existing sections. Rather than list, for emphasis, specific provisions of the RUS mortgage that are not affected by the rule, the proposed rule would make it clear that it does not 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 of investments, loans, and guarantees made by the borrower. Also, the proposed section would combine the provisions of the two existing sections regarding a supplemental lender's rights to control investments not being affected by the proposed rule.

Appendix A

Existing Appendix A to subpart N provides several examples of how certain types of investments, loans, and guarantees should be reported. In light of the clarification and additional guidance that would be provided in the main body of this proposed rule, as well as that provided annually in RUS Bulletins 1717B-2 and 1717B-3, it is proposed that Appendix A be dropped.

In summary, RUS believes the proposed changes to subpart N will clarify RUS's policies and requirements on investments, loans and guarantees, improve compliance, provide better service to our borrowers by reducing uncertainty as to what is expected of them, and improve the utilization of RUS staff resources.

List of Subject in 7 CFR Part 1717

Administrative practice and procedure, Electric power, Electric power rates, Electric utilities, Intergovernmental relations, Investments, Loan programs—energy, Reporting and recordkeeping requirements, Rural areas.

For the reasons stated, subpart N of 7 CFR 1717 is proposed to be revised as follows:

PART 1717—POST-LOAN POLICIES AND PROCEDURES COMMON TO INSURED AND GUARANTEED ELECTRIC LOANS

Subpart N—Investments, Loans, and Guarantees by Electric Borrowers

Sec.

- 1717.650 Purpose.
- 1717.651 Policy.
- 1717.652 Definitions.
- 1717.653 Transactions below the 15 percent level.
- 1717.654 Exclusion of certain investments, loans, and guarantees.
- 1717.655 Exemption of certain borrowers from controls.
- 1717.656 Investments, loans, and guarantees in excess of 15 percent of total utility plant.
- 1717.657 Records, reports and audits.
- 1717.658 Effect of this subpart on RUS loan contract and mortgage.

Subpart N—Investments, Loans, and Guarantees by Electric Borrowers

Authority: 7 U.S.C. 901–950b; Pub.L. 103–354, 108 Stat. 3178 (7 U.S.C. 6941 *et seq.*); Title I, Subtitle D, Pub.L. 100–203, 101 stat. 1330.

§ 1717.650 Purpose.

This subpart contains the general regulations of the Rural Utilities Service (RUS) for implementing and interpreting the provisions of the Rural Electrification Act of 1936, as amended, including section 312 (7 U.S.C. 901 *et seq.*) (RE Act), permitting, in certain circumstances, that borrowers of insured or guaranteed electric loans under the RE Act may, without restriction or prior approval of the Administrator of RUS, invest their own funds and make loans or guarantees.

§ 1717.651 Policy.

RUS electric borrowers are encouraged to utilize their own funds to participate in the economic development of rural areas, provided that such activity does not in any way put government funds at risk or impair a borrower's ability to repay its indebtedness to RUS and other lenders. In considering whether to make loans, investments, or guarantees, borrowers are expected to act in accordance with prudent business practices and in conformity with the laws of the jurisdictions in which they serve. RUS assumes that borrowers will use the latitude afforded them by section 312 of the RE Act primarily to make needed investments in rural community infrastructure projects (such as water and waste systems, garbage collection

services, etc.) and in job creation activities (such as providing technical, financial, managerial assistance) and other activities to promote business development and economic diversification in rural communities. Nonetheless, RUS believes that borrowers should continue to give primary consideration to safety and liquidity in the management of their funds.

§ 1717.652 Definitions.

As used in this subpart:

Borrower means any organization that has an outstanding loan made or guaranteed by RUS for rural electrification.

Cash-construction fund-trustee account means the account described in the Uniform System of Accounts as one to which funds are deposited for financing the construction or purchase of electric facilities.

Guarantee means to undertake collaterally to answer for the payment of another's debt or the performance of another's duty, liability, or obligation, including, without limitation, the obligations of subsidiaries. Some examples of such guarantees include guarantees of payment or collection on a note or other debt instrument (assuring returns on investments); issuing performance bonds or completion bonds; or cosigning leases or other obligations of third parties.

Equity means the Margins and Equities of the borrower as defined in the Uniform System of Accounts, less regulatory created assets.

Invest means to commit money in order to earn a financial return on assets, including, without limitation, all investments properly recorded on the borrower's books and records in investment accounts as those accounts are used in the Uniform System of Accounts for RUS Borrowers. Borrowers may submit any proposed transaction to RUS for an interpretation of whether the action is an investment for the purposes of this definition.

Make loans means to lend out money for temporary use on condition of repayment, usually with interest.

Mortgaged property means any asset of the borrower which is pledged in the RUS mortgage.

Natural gas distribution system means any system of community infrastructure that distributes natural gas and whose services are available by design to all or a substantial portion of the members of the community.

Operating DSC means Operating Debt Service Coverage (ODSC) calculated as:

$$\text{ODSC} = \frac{A + B + C}{D}$$

where:

A = Depreciation and Amortization Expense;

B = Interest on Long-term Debt, except that Interest on Long-term Debt shall be increased by $\frac{1}{3}$ of the amount, if any, by which the rentals of Restricted Property exceed 2 percent of Total Margins and Equities;

C = Patronage Capital & Operating Margins (distribution borrowers) or Operating Margins (power supply borrowers); and

D = Debt Service Billed (RUS + other) which equals all interest and principal billed during the calendar year plus $\frac{1}{3}$ of the amount, if any, by which the rentals of Restricted Property exceed 2 percent of Total Margins and Equities. Unless otherwise indicated, all terms used in defining ODSC and OTIER are as defined in RUS Bulletin 1717B-2 Instructions for the Preparation of the Financial and Statistical Report for Electric Distribution Borrowers, and RUS Bulletin 1717B-3 Instructions for the Preparation of the Operating Report for Power Supply Borrowers and for Distribution Borrowers with Generating Facilities, or the successors to these bulletins.

Operating TIER means Operating Times Interest Earned Ratio (OTIER) calculated as:

$$\text{OTIER} = \frac{A + B}{A}$$

where:

A = Interest on Long-term Debt, except that Interest on Long-term Debt shall be increased by $\frac{1}{3}$ of the amount, if any, by which the rentals of Restricted Property exceed 2 percent of Total Margins and Equities; and

B = Patronage Capital & Operating Margins (distribution borrowers) or Operating Margins (power supply borrowers).

Own funds means money belonging to the borrower other than the proceeds of loans made or guaranteed by RUS. Such proceeds include, but are not limited to, all funds on deposit in the cash-construction fund-trustee account.

Regulatory created assets means the sum of the amounts properly recordable in Account 182.2 Unrecovered Plant and Regulatory Study Costs, and Account 182.3 Other Regulatory Assets of the Uniform System of Accounts.

RUS means the Rural Utilities Service, an agency of the U.S.

Department of Agriculture established pursuant to Section 232 of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (Pub. L. 103-354, 108 Stat. 3178, 7 U.S.C. 6941 et seq.) and, for purposes of this subpart, includes its predecessor, the Rural Electrification Administration.

RUS mortgage means any and all instruments creating a lien on or security interest in the borrower's assets in connection with loans or guarantees under the RE Act.

RUS loan contract means the loan contract between the borrower and RUS.

Solid waste disposal system means any system of community infrastructure that provides collection and/or disposal of solid waste and whose services are available by design to all or a substantial portion of the members of the community.

Subsidiary means a company which is controlled by the borrower through ownership of voting stock, and is further defined in 7 CFR 1767.10.

Supplemental lender means a lender that has provided a supplemental source of financing that is secured by the RUS mortgage.

Telecommunication and other electronic communication system means any community infrastructure that provides telecommunication or other electronic communication services and whose services are available by design to all or a substantial portion of the members of the community.

Total assets means the total assets of the borrower as calculated according to the Uniform System of Accounts, less regulatory created assets.

Total utility plant means the sum of the borrower's Electric Plant Accounts and Construction Work in Progress—Electric Accounts, as such terms are used in the Uniform System of Accounts.

Uniform System of Accounts means the system of accounts prescribed for RUS borrowers in 7 CFR part 1767.

Water and waste disposal system means any system of community infrastructure that supplies water and/or collects and treats waste water and whose services are available by design to all or a substantial portion of the members of the community.

§ 1717.653 Transactions below the 15 percent level.

(a) A borrower in compliance with all provisions of its RUS mortgage, RUS loan contract, and any other agreement with RUS may, without prior written approval of the Administrator, invest its own funds or make loans or guarantees not in excess of 15 percent of its total utility plant without regard to any

provision contained in any RUS mortgage or RUS loan contract to the effect that the borrower must obtain prior approval from RUS. However, funds necessary to make timely payments of principal and interest on loans secured by the RUS mortgage remain subject to RUS controls on borrower investments, loans and guarantees.

(b) RUS will require that any electric loan made or guaranteed by RUS after [Date 30 days after the final rule is published in the **Federal Register**] shall be subject to a provision in the loan contract or mortgage restricting investments, loans and guarantees by the Borrower substantially as follows: The borrower may, to the extent permitted by this subpart, invest its own funds or make loans or guarantees not in excess of 15 percent of its total utility plant, as those terms are used in said subpart.

(c) RUS will not consider requests from borrowers to approve or exclude investments, loans, or guarantees made below the 15 percent level. (Categorical exclusions are set forth in 1717.654.)

§ 1717.654 Exclusion of certain investments, loans, and guarantees.

(a) In calculating the amount of investments, loans and guarantees permitted under this subpart, there is excluded from the computation any investment, loan or guarantee of the type which by the terms of the borrower's RUS mortgage or RUS loan contract the borrower may make in unlimited amounts without RUS approval.

(b) Furthermore, the borrower may make unlimited investments, without prior approval of the Administrator, in:

- (1) Securities or deposits issued, guaranteed or fully insured as to payment by the United States Government or any agency thereof;
- (2) Capital term certificates, bank stock, or other similar securities of the supplemental lender which have been purchased as a condition of membership in the supplemental lender, or as a condition of receiving financial assistance from such lender, as well as any other investment made in, or loans made to, the National Rural Utilities Cooperative Finance Corporation or the National Bank for Cooperatives;
- (3) Patronage capital allocated from a power supply cooperative of which the borrower is a member.

(c) Without prior approval of the Administrator, the borrower may also:

- (1) Invest or lend funds derived directly from grants received from, or loans made or guaranteed by, an agency of the U.S. Department of Agriculture

(USDA) for the purposes specifically authorized in such grants or loans;

(2) Make loans guaranteed by an agency of USDA, up to the amount of principal whose repayment, with interest, is fully guaranteed; and

(3)(i) Make unlimited investments in and unlimited loans to finance the following community infrastructure located within its service territory, and guarantee debt issued by such entities up to an aggregate amount of such guarantees not to exceed 20 percent of the borrower's equity:

(A) Water and waste disposal systems;

(B) Solid waste disposal systems;

(C) Telecommunication and other electronic communication systems; and

(D) Natural gas distribution systems.

(ii) In each of the four cases in paragraph (c)(3)(i) of this section, if the system is a component of a larger organization other than the borrower itself (e.g., if it is a component of a subsidiary of the borrower or a corporation independent of the borrower), to be eligible for the exemption the borrower must certify annually that either a majority of the assets of the larger organization were invested in said system at the end of the most recent fiscal year, or that a majority of the revenues of the larger organization came from said system during the most recent fiscal year.

(d) Also excluded from the calculation of investments, loans and guarantees made by the borrower are:

(1) Amounts properly recordable in Account 142 Customer Accounts Receivable, and Account 143 Other Accounts Receivable;

(2) Any investment, loan, or guarantee that the borrower is required to make by an agency of USDA, for example, as a condition of obtaining financial assistance for itself or any other person or organization;

(3) Investments included in an irrevocable trust for the purpose of funding post-retirement benefits of the borrower's employees; and

(4) Reserves required by a reserve bond agreement or other agreement legally binding on the borrower, that are dedicated to making required payments on debt secured under the RUS mortgage, not to exceed the amount of reserves specifically required by such agreements.

(e) Grandfathered exclusions. All amounts excluded by RUS from the calculation of the aggregate amount of investments, loans and guarantees as of February 16, 1995 shall remain excluded. Such exclusions must have been based on the RUS mortgage, RUS loan contract, regulations, bulletins, memoranda, or other written notice

from RUS. Profits, interest, and other returns earned (regardless of whether or not they are reinvested) on such investments, loans and guarantees after February 16, 1995 shall be excluded only if they are eligible for exclusion under paragraphs (a) through (d) of this section. Any new commitments of money to such investments, loans and guarantees shall likewise be excluded only if they are eligible under paragraphs (a) through (d) of this section.

(f) Any investment, loan or guarantee made by a borrower that is not excluded under this section or under § 1717.656(d) shall be included in the aggregate amount of investments, loans and guarantees made by the borrower, regardless of whether RUS has specifically approved the investment, loan or guarantee under § 1717.656(c), or has approved a related transaction (e.g., a related contract or lien accommodation).

§ 1717.655 Exemption of certain borrowers from controls.

(a) Any distribution or power supply borrower that meets all of the following criteria is exempted from the provisions of the RUS mortgage and loan contract that require RUS approval of investments, loans, and guarantees made by the borrower:

(1) The borrower is in compliance with all provisions of its RUS mortgage, RUS loan contract, and any other agreement with RUS;

(2) The average revenue per kWh for residential service received by the borrower during the two most recent calendar years does not exceed 130 percent of the average revenue per kWh for residential service during the same period for all residential consumers located in the state or states served by the borrower. This criterion applies only to distribution borrowers and does not apply to power supply borrowers. If a borrower serves customers in more than one state, the state average revenue per kWh will be based on a weighted average using the kWh sales by the borrower in each state as the weight. The calculation will be based on the two most recent calendar years for which both borrower and state-wide data are available. If a borrower fails to qualify for an exemption based solely on its failure to meet this criterion on rate disparity, at the borrower's request the Administrator may at his sole discretion exempt the borrower if he finds that the borrower's strengths with respect to the other criteria are sufficient to offset any weakness due to rate disparity;

(3) In the most recent calendar year for which data are available, the

borrower achieved an operating TIER of at least 1.0 and an operating DSC of at least 1.0, in each case based on the average of the two highest ratios achieved in the three most recent calendar years;

(4) The borrower's ratio of net utility plant to long-term debt is at least 1.1, based on year-end data for the most recent calendar year for which data are available; and

(5) The borrower's equity is equal to at least 27 percent of its total assets, based on year-end data for the most recent calendar year for which data are available.

(b) While borrowers meeting the criteria in paragraph (a) of this section are exempt from RUS approval of investments, loans and guarantees, they are nevertheless subject to the record-keeping, reporting, and other requirements of § 1717.657.

(c) Any borrower exempt under paragraph (a) of this section that ceases to meet the criteria for exemption shall, upon written notice from RUS, no longer be exempt and shall be subject to all provisions of this subpart applicable to non-exempt borrowers. A borrower may regain its exemption if it subsequently meets the criteria in paragraph (a) of this section, and is so notified in writing by RUS.

(d) If a borrower loses its exemption and the aggregate of investments, loans and guarantees of such borrower exceeds 15 percent of total utility plant, the borrower will be required to reduce or restructure its portfolio (e.g., divest or shift some investments to excluded investments) in order to come within the 15 percent level. (However, such borrower is eligible to ask RUS to exclude a portion of its investments under the conditions set forth in § 1717.656(d).) If the borrower does not come within the 15 percent level within a reasonable period of time determined by the Administrator, which shall not exceed 12 months from the date the borrower was notified of its loss of exemption, then, upon written notice from RUS, the borrower shall be in default of its RUS loan contract and/or RUS mortgage.

(e) By no later than May 1 of each year, RUS will provide written notice to any borrowers whose exemption status has changed as a result of more recent data being available for the qualification criteria set forth in paragraph (a) of this section, or as a result of other reasons, such as corrections in the available data. An explanation of the reasons for any changes in exemption status will also be provided to the borrowers affected.

§ 1717.656 Investments, loans, and guarantees in excess of 15 percent of total utility plant.

(a) *General.* This section applies only to borrowers that are subject to Administrator approval of investments, loans and guarantees made above the 15 percent limit, i.e., borrowers that do not meet the exemption criteria in § 1717.655(a).

(b) *Distribution borrowers.* Distribution borrowers subject to Administrator approval of investments, loans and guarantees will not be given approval to make investments, loans and guarantees in an aggregate amount in excess of 15 percent of total utility plant. Above the 15 percent level, such borrowers will be restricted to excluded investments, loans and guarantees as defined in § 1717.654. (However, they are eligible to ask RUS to exclude a portion of their investments under the conditions set forth in paragraph (d) of this section.)

(c) *Power supply borrowers.* (1) Power supply borrowers subject to Administrator approval of investments, loans and guarantees may request approval to exceed the 15 percent level if all of the following criteria are met:

(i) The borrower is in compliance with all provisions of its RUS mortgage, RUS loan contract, and any other agreement with RUS;

(ii) The borrower is not in financial workout and has not had its government debt restructured;

(iii) The borrower has equity equal to at least 5 percent of its total assets; and

(iv) After approval of the investment, loan or guarantee, the aggregate of the borrower's investments, loans and guarantees will not exceed 20 percent of the borrower's total utility plant.

(2) Borrower requests for approval to exceed the 15 percent level will be considered on a case by case basis. The requests must be made in writing.

(3) In considering borrower requests, the Administrator will take the following factors into consideration:

(i) The repayment of all loans secured under the RUS mortgage will continue to be assured, and loan security must continue to be reasonably adequate, even if the entire investment or loan is lost or the borrower is required to perform for the entire amount of the guarantee. These risks will be considered along with all other risks facing the borrower, whether or not related to the investment, loan or guarantee;

(ii) In the case of investments, the investment must be made in an entity separate from the borrower, such as a subsidiary, whereby the borrower is protected from any liabilities incurred

by the separate entity, unless the borrower demonstrates to the satisfaction of the Administrator that making the investment directly rather than through a separate entity will present no substantial risk to the borrower in addition to the possibility of losing all or part of the original investment;

(iii) The borrower must be economically and financially sound as indicated by its costs of operation, competitiveness, operating TIER and operating DSC, physical condition of the plant, ratio of equity to total assets, ratio of net utility plant to long-term debt, and other factors; and

(iv) Other factors affecting the security and repayment of government debt, as determined by the Administrator on a case by case basis.

(4) If the Administrator approves an investment, loan or guarantee, such investment, loan or guarantee will continue to be included when calculating the borrower's ratio of aggregate investments, loans and guarantees to total utility plant.

(d) *Distribution and power supply borrowers.* If the aggregate of the investments, loans and guarantees of a distribution or power supply borrower exceeds 15 percent of the borrower's total utility plant as a result of the cumulative profits or margins, net of losses, earned on said transactions over the past 10 calendar years (i.e., the sum of all profits earned during the 10 years on all transactions—including interest earned on cash accounts, loans, and similar transactions—less the sum of all losses experienced on all transactions during the 10 years) then:

(1) The borrower will not be in default of the RUS loan contract or RUS mortgage with respect to required approval of investments, loans and guarantees, provided that the borrower had not made additional net investments, loans or guarantees without approval after reaching the 15 percent level; and

(2) At the request of the borrower, the Administrator in his sole discretion may decide to exclude up to the amount of net profits or margins earned on the borrower's investments, loans and guarantees during the past 10 calendar years, if the Administrator determines that such exclusion will not increase loan security risks. The borrower must provide documentation satisfactory to the Administrator as to the current status of its investments, loans and guarantees and the net profits earned during the past 10 years. Any exclusion approved by the Administrator may or may not reduce the level of investments, loans and guarantees to or below the 15

percent level. If such exclusion does not reduce the level to or below the 15 percent level, RUS will notify the borrower in writing that it must reduce or restructure its investments, loans and guarantees to a level of not more than 15 percent of total utility plant. If the borrower does not come within the 15 percent level within a reasonable period of time determined by the Administrator, which shall not exceed 12 months from the date the borrower was notified of the required action, then, upon written notice from RUS, the borrower shall be in default of its RUS loan contract and mortgage.

§ 1717.657 Records, reports and audits.

(a) Every borrower shall maintain accurate records concerning all investments, loans and guarantees made by it. Such records shall be kept in a manner that will enable RUS to readily determine:

(1) The nature and source of all income, expenses and losses generated from the borrower's loans, guarantees and investments;

(2) The location, identity and lien priority of any loan collateral resulting from activities permitted by this subpart; and

(3) The effects, if any, which such activities may have on the feasibility of loans made, guaranteed or lien accommodated by RUS.

(b) In determining the aggregate amount of investments, loans and guarantees made by a borrower, the borrower shall use the recorded value of each investment, loan or guarantee as reflected on its books and records for the next preceding end-of-month, except for the end-of-year report which shall be based on December 31 information. Every borrower shall also report annually to RUS, in the manner and on the form specified by the Administrator, the current status of each investment, outstanding loan and outstanding guarantee which it has made pursuant to this subpart.

(c) The records of borrowers shall be subject to the auditing procedures prescribed in part 1773 of this chapter. RUS reserves the right to review the financial records of any subsidiaries of the borrower to determine if the borrower is in compliance with this subpart, and to ascertain if the debts, guarantees (as defined in this subpart), or other obligations of the subsidiaries could adversely affect the ability of the borrower to repay its debts to the Government.

(d) RUS will monitor borrower compliance with this subpart based primarily on the annual financial and statistical report submitted by the

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.

[FR Doc. 95-3665 Filed 2-15-95; 8:45 am]

BILLING CODE 3410-15-P

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.