

IRON-CONTAINING SUPPLEMENTS AND DRUGS: LABEL WARNING STATEMENTS  
AND UNIT-DOSE PACKAGING REQUIREMENTS  
SMALL ENTITY COMPLIANCE GUIDE

The Food and Drug Administration (FDA) has prepared this guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121). This guidance document restates in plain language the legal requirements set forth in the current regulation for labeling and packaging of iron-containing supplements and drug products. Any statement in this guidance document that goes beyond merely restating the applicable legal requirements represents the agency's current thinking on this subject. The regulation is binding and has the force and effect of law; however, this guidance document does not, itself, 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 statute and regulations.

As stated in the final rule of January 15, 1997 (62 FR 2218) (the regulation), FDA is requiring that packages of iron-containing dietary supplement and drug products in solid dosage form (e.g., tablets, capsules or caplets) be labeled with warnings to prevent accidental, potentially fatal poisonings of children. The regulation requires the following warning statement:

Accidental overdose of 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.

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In addition, the regulation requires that those iron-containing products with 30 mg or more iron per dosage unit (tablet, capsule, caplet, etc.) be packaged in “unit-dose packaging” such as a “blister-pack,” pouch, or other nonreusable container.

The regulation temporarily exempts products that contain 30 mg or more of an elemental form of iron, which is called carbonyl iron, from the unit-dose packaging requirements. The reason for the temporary exemption is that preliminary data indicate that this form of iron may be so much less toxic than iron salts that accidental overdose of these products is unlikely to result in serious injury or death. If, during the one year temporary exemption period, FDA receives data that clearly establish that this is the case, FDA will consider permanently exempting carbonyl iron from the unit-dose packaging requirements of this regulation.

For low dose products (i.e., products with less than 30 mg of iron per dosage unit) that are not packaged in unit-dose packaging (e.g., for tablets packaged in a bottle), the regulation requires that the warning statement appear prominently and conspicuously on the information panel of the immediate container label (i.e., on the label of the bottle that holds the tablets). In instances when a bottle with an iron-containing product is placed within a separate box for retail sale, the regulation requires that the warning statement must appear prominently and conspicuously on the information panel of both the bottle label and the outer box label. In addition, the regulation requires that the warning statement must appear on any labeling (e.g., package inserts) that contains other product warnings. Furthermore, the regulation requires that

the warning statement that appears on the immediate container and outer box labels must be set off in a printed boxed area.

In the case of unit-dose packaging, if the “blister pack,” pouch, or other nonreusable container bears any printed material, the regulation requires that the warning statement must also appear prominently and conspicuously on this packaging. The regulation also requires that the warning statement must be placed on the unit-dose packaging in a way that maximizes the likelihood that it can be read until all the individual dosage units are used. For example, multiple copies of the warning statement may be printed on the unit-dose packaging to increase the chances that at least one complete warning statement will remain intact until all of the individual units are used.