the DSHEA. Moreover, the DSHEA does not bear on how drugs are regulated. Thus, the proposed requirements for iron-containing drugs are also unaffected by the new law. Even with the DSHEA, however, FDA continues to have authority to require that dietary supplements that contain 30 mg or more of iron per dosage unit be unit-dose packed.

III. Discussion

A. Effect of Section 201(s)(6) of the Act

In the proposal, FDA explained the basis for its tentative conclusion that it had authority to impose packaging requirements on iron-containing dietary supplements, FDA stated:

> Should FDA determine that a particular type of packaging is necessary to ensure the safe use of iron substances in dietary supplements, either as GRAS substances or as listed food additives, then any use of iron substances in dietary supplements that does not involve use of that type of packaging would constitute a use of an unapproved food additive and render the dietary supplements adulterated under the act.

See 59 FR 51047.

This argument is deprived of its legal validity by new section 201(s)(6) of the act. The use of iron ingredients in dietary supplements is not subject to section 409 of the act, even if the conditions of use of the iron ingredients are not those that are GRAS. Thus, FDA cannot rely on section 409 of the act for authority to require unit-dose packaging of dietary supplements.

B. Effect of Section 402(g) of the Act

While, on the one hand, the DSHEA deprives the agency of the authority that it relied on in the proposal to require unit-dose packaging, on the other it added a new provision to the act that gives the agency authority to establish such a requirement.

Section 402(g)(2) of the act provides that CGMP's for dietary supplements shall be modeled after the CGMP's for food. The current food CGMP regulations provide that food is to be packaged in a way that ensures that it is safe and sanitary (§§ 110.5(a)(2) and 110.80(b)(13)). As explained in the preamble to the October 6, 1994, proposal, FDA has tentatively concluded that unit-dose packaging is necessary to ensure the safety of dietary supplements that contain 30 mg or more of iron per dosage unit.

As discussed in the proposal, the recent data available to FDA demonstrate that iron-containing products with 30 mg or more iron per dosage unit are associated with a significant number of pediatric illnesses and deaths. As FDA stated with respect to drugs in the proposal, to ensure that these products are safe, CGMP requires that manufacturers respond to this new information, and take advantage of advances in technology, to alter, adapt, or change their manufacturing processes to ensure that all possible measures have been taken to eliminate known dangers from their products.

Existing technology permits safeguards, specifically unit-dose packaging, to be used for iron-containing products, including dietary supplements. Unit-dose packaging limits a child's ability to gain access to enough dosage units to provide a harmful amount of iron. Given the known dangers posed by dietary supplements that contain 30 mg or more iron per dosage unit, and the ability to minimize or eliminate such dangers through the use of unit-dose packaging, FDA tentatively concludes that the CGMP dictates that unit-dose packaging be used for these products.

Thus, FDA tentatively concludes that, to ensure that dietary supplements that contain 30 mg of iron or more per dosage unit are safe, CGMP requires that they be packaged in unit-dose packaging.

The agency will consider conducting a more complete rulemaking on what CGMP requirements for dietary supplements under section 402(g) of the act are. However, considering the hazard presented to young children by iron-containing products, FDA tentatively concludes that it is appropriate to effect this aspect of its CGMP authority in advance of any broader rulemaking.

To reflect the shift in the agency's authority with respect to packaging of dietary supplements, FDA is codifying the proposed CGMP requirements for iron-containing dietary supplements in new part 111, rather than in part 170 (21 CFR part 170). Proposed § 170.55 is being removed in this supplemental proposal and replaced by § 111.1. The agency is also making conforming amendments to part 101 to reflect new part 111 rather than part 170. For the convenience of the reader, FDA is republishing the amendments to parts 101 and 310 in their entirety. Thus, the codified portion of this document will also reflect the changes proposed in the October 6, 1994, proposed rule and thereby supersedes that codified material.

In proposing the unit-dose packaging requirement under new part 111, the agency is removing the provision from the packaging regulation in the original proposal that also would have required the proposed warning labels as a condition of safe use (i.e., as food additives or GRAS ingredients) for iron and iron salts in iron-containing supplements. The authority for this requirement was also derived from section 409 of the act, which permits the agency to consider any necessary labeling requirements in establishing conditions of safe use for a food additive. New section 201(s)(6) of the act also invalidates the legal authority that FDA relied upon for this proposed provision because the use of iron ingredients in dietary supplements is no longer subject to section 409 of the act.

IV. Comments

Because of the change in the law and issuance of this supplemental proposal, FDA will allow an additional 60 days for comment on the entire proposed action. This additional time will provide an opportunity for the submission of all views on the issues in the rulemaking.

Interested persons may, on or before April 17, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

V. Environmental Impact

The agency previously considered the environmental effects of its action to require unit-dose packaging for iron-containing products, in the proposed rule that was published in the **Federal Register** of October 6, 1994 (59 FR 51030). The changes in legal authority being proposed in this document will not affect the agency's previously proposed requirement for unit-dose packaging for iron-containing products and, therefore, will not affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Analysis of Impacts

FDA previously examined the impact of the proposed rule as published in the **Federal Register** of October 6, 1994 (59 FR 51030), in accordance with Executive Order 12866 and the Regulatory Flexibility Act, and determined that it is not an economically significant rule. The discussion of the legal authority contained in this supplemental proposed rule does not alter the