exempted from any or all provisions of this subpart.

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Dated: March 15, 1995.

Lon Hatamiya,

Administrator.

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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]

Acute Toxicity of Elemental (Reduced, Metallic Powder) Forms of Iron Relative to That of Iron Salts; Notice of a Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on the acute toxicity of elemental (reduced, metallic powder) forms of iron. The purpose of this workshop is to solicit scientific data and information from interested persons about the acute toxicity of elemental forms of iron with regard to whether such forms are sufficiently safe in dietary supplement and drug products to warrant exemption from the special packaging and labeling requirements that FDA has proposed for products containing iron salts.

DATES: The public workshop will be held on April 20, 1995, 8:30 a.m. to 5 p.m. Submit written comments by April 20, 1995.

ADDRESSES: The public workshop will be held at the Parklawn Bldg., conference room G, 5600 Fishers Lane, Rockville, MD 20857. Written comments regarding the workshop may be submitted 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: In the **Federal Register** of October 6, 1994 (59 FR 51030), FDA issued a proposal (the initial proposal) on actions that it tentatively concluded were necessary to stem the recent epidemic of pediatric poisonings from over-consuming iron-containing products. In the **Federal Register** of February 16, 1995 (60 FR 8989), the agency issued a supplementary proposal to clarify changes in its legal authority with the passage of the Dietary Supplement Health and Education Act (Pub. L. 103–417).

In the initial proposal, FDA briefly described the three basic types of elemental iron powders that are marketed for use in foods. The three types are reduced iron, electrolytic iron, and carbonyl iron. The term ''carbonyl'' refers to the production process, not the composition of the product. The bioavailability of these various elemental iron sources is dependent primarily on their physical characteristics, which in turn depend on the manufacturing method. For example, higher relative bioavailabilities of elemental iron are obtained with smaller particle sizes.

Some evidence suggests that carbonyl iron may be a useful substitute for the more commonly used chemical compounds of iron in reducing the risk of accidental iron poisonings. Data from studies in animals suggest that carbonyl iron may be only 1/100th as toxic as ferrous sulfate in single doses, i.e., the LD_{50} (lethal dose for 50 percent of the test group) of ferrous sulfate is approximately 0.30 gram ferrous per kilogram (g Fe/kg) (*The Merck Index*, 11th ed., p. 635 (1989)), and the LD_{50} for carbonyl iron is approximately 30.0 g Fe/kg body weight. At the same time, data from human subjects indicate that the overall bioavailability of carbonyl iron in supporting the nutritional functions of iron is about 70 percent that of ferrous sulfate. Thus, carbonyl iron, in comparison with ferrous sulfate, appears to have a much larger margin of safety between the level that would provide adequate iron nutrition and the level that causes acute toxicity. Consequently, carbonyl iron may be inherently safer to use, and its use may help to reduce the risk of iron poisoning in children, than ferrous sulfate.

In the initial proposal, FDA expressed interest in receiving data on the potential of elemental iron to have acute toxicity in humans, and particularly in children, and stated that the agency would carefully consider any information that it received on this subject. FDA stated that, if the information it received was persuasive in establishing that the use of elemental iron would substantially decrease the risk of pediatric poisoning while allowing for effective dietary iron supplementation, FDA would consider exempting iron-containing products that incorporate elemental iron from any regulations that result from this rulemaking.

In response to this request for information, FDA received several comments that supplied information on this topic. Some of the comments included citations to scientific literature or copies of scientific articles. The comments argued that the information supports an exemption of products formulated with elemental iron from the labeling and packaging requirements applied to products containing iron salts. These comments have convinced FDA that the issues and data that they have presented should be discussed in a public workshop.

The purpose of the workshop on the acute toxicity of elemental iron is to:

1. Identify data that objectively describe the acute toxicity of elemental iron.
2. Identify the market uses of elemental iron and any adverse reaction reporting systems or processes used by manufacturers and vendors.
3. Identify any data on acute, accidental exposure of children or adults to products containing elemental iron.
4. Discuss a possible conceptual framework for evaluation of the effects of elemental forms of iron upon acute exposure.
5. Discuss the validity, and limitations, of acute toxicity data in experimental animals in predicting the risk in young children.

Specific topics that may be relevant and on which discussion is invited include:

1. Physiological factors that influence acute toxicity of elemental forms of iron, in comparison with those for iron salts.
2. The quality, results, and relevance of animal studies on acute toxicity of elemental iron and iron salts.
3. The quality and results of human studies for evaluating the effects of elemental iron.
4. Factors influencing the validity of extrapolation of experimental animal data on acute toxicity of various forms of iron for predicting the risk in young children.
5. Current uses of elemental iron in dietary supplements and drugs and the data available on potential adverse effects.

Discussion of these topics will be considered by FDA in the development of any final rule on the packaging and labeling of products containing iron salts. In conjunction with the workshop, FDA specifically requests comments on the appropriateness of elemental iron as a source of iron in drugs and dietary supplements. The comments should focus on whether the use of elemental

iron in iron-containing products will decrease the risk of pediatric poisonings, while providing desirable iron nutrition to those who need iron supplementation, and on whether an exemption for products that contain elemental iron from any packaging and labeling requirements that result from the underlying rulemaking is appropriate.

Interested persons may on or before April 20, 1995, submit to the Dockets Management Branch (address above) comments on the workshop. Additional written comments may be submitted for 30 days after the date of this workshop. Two copies of any comments are to be submitted, except that individuals may submit one copy. Written comments and submitted documents are to be identified with the docket numbers found in brackets in the heading of this document. Received comments and the transcript of the discussion identified with the same docket numbers may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 16, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–6919 Filed 3–20–95; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD 6010.8–R]

RIN 0720–AA26

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Six Separate Changes

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule addresses six separate changes to comply with new statutory provisions affecting CHAMPUS. These changes will update this part to include as a benefit, a screen to check for the level of lead in the blood of an infant; eliminate the implied statement that ambulance services are covered only to and from hospitals; include other forms of prescribed contraceptives by eliminating the reference that limits prescribed contraceptives only to those taken orally; recognize chemical aversion therapy as a treatment modality for alcoholism by eliminating the exclusionary language in the current regulation; identify three additional Gulf Conflict groups eligible for the delay in the increased deductible; and to establish lower limits on the fiscal year catastrophic cap from $10,000 to $7,500 for all eligibles except dependents of active duty personnel, whose limit remains at $1,000.

DATES: Written comments, whether from the general public or from other governmental agencies, must be received on or before May 22, 1995.

ADDRESSES: Office of the Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), Program Development Branch, Aurora, Co 80045–6900.

FOR FURTHER INFORMATION CONTACT: Mr. A. Chris Armijo, Program Development Branch, OCHAMPUS, telephone (303) 361–1120.

SUPPLEMENTARY INFORMATION: 32 CFR 199.4 lists Basic Program benefits including exclusions and limitations. Paragraph (c) defines, in general terms, the scope of reimbursable services provided by physicians and other authorized individual professional providers; paragraph (e) extends benefits under certain circumstances, to conditions and limitations that are subject to applicable definitions, conditions, or exclusions that are set forth in this or other sections of this regulation; paragraph (f) identifies the liabilities, in the form of cost-shares and deductibles, to be paid by beneficiaries or sponsors.

Well-Baby Care: Paragraph (c)(3)(xi), provides for certain well-baby care services for infants up to the age of two years. A paragraph (6) will be added under paragraph (xi)(A) to list blood lead level screening for infants as a benefit.

Ambulance Service: Ambulance services are covered between points deemed to be medically necessary for the covered medical condition, therefore, the restrictive language, ''to, from, and between hospitals'' will be removed from paragraph (d)(3)(v).

Family Planning: Paragraph (e)(3) provides for a family planning benefit. Paragraph (e)(3)(i)(A)(3) of this Section allows benefits for prescribed oral contraceptives. With the development of new methods of contraception, prescribed contraceptives are no longer limited to those taken orally. We are, therefore, amending that paragraph by removing the word ''oral'' to expand the coverage accordingly.

Treatment for Alcoholism: Paragraph (e)(4)(iii)(A) of § 199.4, has historically excluded benefits for aversion therapy as a treatment modality for alcoholism. At the request of OCHAMPUS, the Office of Health Technology Assessment (OHTA) of the Public Health Service (PHS) conducted an assessment of the safety and efficacy of chemical aversion conditioning for the treatment of alcoholism. On the basis of the OHTA assessment, it was determined that chemical aversion conditioning is no less effective than other therapies for alcoholism when it is provided following the failure of less intrusive therapies. This rule proposes to remove paragraph (e)(4)(iii)(A) in its entirety to remove exclusionary language, to reserve that paragraph for future use, and to revise paragraph (4)(ii), to include coverage of chemical aversion therapy as a treatment modality.

Financial Liability-Deductibles: Under paragraph (f) of section 199.4, CHAMPUS beneficiaries and sponsors have some financial responsibility when medical care is received from civilian sources. Financial liability is imposed in order to encourage use of the Uniformed Services direct medical care system whenever facilities and services are available. Beneficiaries are responsible for payment of certain deductible and cost-sharing amounts in connection with otherwise covered services and supplies. The cost-share and deductible amounts are controlled by statute and subject to change by Congressional action. Previous legislation had deferred a statutory increase in the deductible amount from April 1, 1991, to October 1, 1991, for dependents of active duty members who served in the Gulf Conflict. The National Defense Authorization Act for Fiscal Year 1993 contains language which prompts a revision of paragraph (f)(2)(i)(G) of this section to identify three new groups of Gulf Conflict beneficiaries, besides the dependents of active duty members, eligible for the delay in the increased deductibles, and to allow credit or reimbursement of excess amounts inadvertently paid by those groups subject to availability of appropriated funds.

Catastrophic Loss: The National Defense Authorization Act for Fiscal Years 1988 and 1989 (P.L. 100–180) amended Title 10, United States Code and established catastrophic loss protection for CHAMPUS beneficiaries on a government fiscal year basis. The law placed fiscal year limits or, catastrophic caps, on beneficiary liability for cost-shares and deductibles under the CHAMPUS Basic Program. After the fiscal year cap is met by the beneficiary, the CHAMPUS determined allowable amounts for all covered services or supplies received under the Basic Program are to be paid in full by CHAMPUS.

For dependents of active duty members, the maximum family liability