the general public who attend the conference may have an opportunity to make a brief oral statement presenting their views on issues raised in the Rule Review. Oral statements of views by members of the general public will be limited to a few minutes in length. The time allotted for these statements will be determined on the basis of the time allotted for discussion of the issues by the selected parties, as well as by the number of persons who wish to make statements.

Written submissions of views, or any other written or visual materials, will not be accepted during the conference. The discussion will be transcribed and the transcription placed on the public record.

The conference will be held in the early fall over the course of two consecutive days. A forthcoming announcement will provide the exact dates and location. Parties interested in participating must notify Commission staff by August 11, 1995.

List of Subjects in 16 CFR Part 436

Advertising, Business and industry, Franchising, Trade practices.

Authority: 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 95–8619 Filed 4–6–95; 8:45 am]

BILLING CODE 6750–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Poison Prevention Packaging Requirements; Proposed Exemption of Certain Iron-Containing Dietary Supplement Powders

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to amend its regulations to exempt from child-resistant packaging requirements those dietary supplement powders that have no more than the equivalent of 0.12 percent weight-to-weight elemental iron. The Commission proposes this exemption because there are no known poisoning incidents with these products, and the dry powdered form deters children from ingesting them in harmful amounts.

DATES: Comments on the proposed rule must be received by the Commission no later than June 21, 1995.

ADDRESSES: Comments should be mailed, preferably in five (5) copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504–0470.

FOR FURTHER INFORMATION CONTACT: Jacqueline Ferrante, Ph.D., Project Manager, Directorate for Health Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0477.

SUPPLEMENTARY INFORMATION:

A. Background

Although iron is essential for good health, in large doses it can be toxic. For this reason, in 1978, the Consumer Product Safety Commission (''the Commission'') required child-resistant packaging (''CRP'') for drugs and dietary supplements that contain iron. 16 CFR 1700.14(a)(12) and (13). The Commission issued these rules under the Poison Prevention Packaging Act (''PPPA''), 15 U.S.C. 1471–1476, which authorizes the Commission to require CRP to protect children under 5 years of age from poisoning hazards posed by harmful household substances.

Specifically, CRP is required for dietary supplements ''that contain an equivalent of 250 milligrams or more of elemental iron, from any source, in a single package in concentrations of 0.025 percent or more on a weight-to-volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids.'' 16 CFR 1700.14(a)(13). This requirement does not apply if iron is present only as a colorant. *Id.*

On May 11, 1994, Nutritech, Inc., petitioned the Commission to exempt unflavored, unsweetened iron powders from CRP requirements for dietary supplements containing iron. Nutritech manufactures an unsweetened, unflavored vitamin, mineral, and amino acid powder intended to be mixed with fruit juice. The petitioner stated that CRP is unnecessary for this dietary supplement because: (i) The substance alone is unpalatable; (ii) due to the powder consistency of this substance, a child would not consume a toxic amount without gagging; and (iii) to Nutritech's knowledge, there have been no poisoning incidents involving this product in its 22 year history.(1) [1] The Commission published a notice in the **Federal Register** soliciting comments on the petition, 59 FR 39747, and has received no responses.

B. Toxicity Data

The minimum toxic and lethal doses of iron are not well defined. Generally, doses of elemental iron from 20 to 60 milligrams per kilogram of body weight (''mg/kg'') may produce mild symptoms of poisoning, 60 mg/kg is the minimal dose for serious toxicity, and approximately 180 to 250 mg/kg is considered a lethal dose. However, fatalities of young children have been reported at lower doses.(2)(3)

According to the relevant scientific and medical literature, where information on the formulation was available, the majority of pediatric poisoning incidents involved solid iron—in the form of tablets or capsules—with the remaining cases involving liquid preparations. Among the reported ingestion incidents, fatalities and serious cases of toxicity usually involve ingestion of adult preparations (such as prenatal vitamins) that contain 60 mg or more of elemental iron per tablet. The literature search did not identify a single case of pediatric poisoning involving powdered iron formulations.(2)(3)

Recently, the Food and Drug Administration (''FDA'') published proposed labeling and packaging requirements for iron-containing dietary supplements and drugs. 59 FR 51030 (October 6, 1994). Based on its review of iron poisonings involving children under 6 years of age, the FDA decided to limit its proposed rules to products in solid oral dosage forms (capsules and tablets) and not include liquid or powder products.(2)

The Commission's own 1994 study of pediatric iron poisonings and fatalities found that the majority of serious outcomes involved products in solid or capsule forms. The report showed that all 36 of the in-depth investigations of iron ingestion deaths of children under 5 years old occurring between 1986 and 1993 involved solid capsule or tablet formulations. In 1993, 57 hospital emergency room cases documented through NEISS involved ingestion of iron capsules or tablets by children under 5 years old, and one involved liquid iron. As noted, there were no known pediatric poisonings that involved powdered formulations. This study was based on data from the Commission's National Electronic Injury Surveillance System (''NEISS''), in-depth investigations, the National Center for Health Statistics (''NCHS'') and the American Association of Poison Control Centers (''AAPCC'').(2)

[1] Numbers in parentheses identify documents listed at the end of this notice.

Due to the subcategories that AAPCC uses to classify iron ingestion incidents, the data do not specifically address powdered iron-containing formulations. However, for these AAPCC cases, powdered formulations can be ruled out of all iron related fatalities involving children under 5 years old, and 98.4 percent of cases with serious symptoms, that were reported to the AAPCC between 1989 and 1992. (The remaining 1.2% of cases did not specify the physical form of the ingested product.) The formulations of the iron-containing products involved in pediatric deaths is unavailable from NCHS death certificate data.(2)

For powdered dietary supplements containing 18 mg of elemental iron per tablespoon (0.12% weight-to-weight), a 10 kg child would have to consume 11, 33, and 100 tablespoons to reach the respective minimal (20mg/kg), serious (60mg/kg), and lethal (180 mg/kg) toxicity levels. This assumes none of the product is spilled during consumption.(2)

C. Human Factors Data

Poisoning incidents involving ingestion of large amounts of any powdered substance are relatively rare. Rather, children are more likely to ingest large quantities in the form of liquids or solids, such as tablets and capsules. One reason for this distinction is the physical difficulty children have handling and swallowing powders. Eating a dry powder is difficult and time-consuming. Only small amounts can be eaten at a time to allow the powder to absorb sufficient saliva so the powder can be swallowed. Attempts to swallow too much at once or to swallow too soon will likely result in aspirating the powder and stimulate coughing, which would limit the amount ingested. Because of the time it takes to ingest a powder, it is questionable that a young child could eat a full tablespoon of powder at one time. The length of time required to successfully ingest powders may increase the opportunity for an adult to intervene.(2)(3)

Children's motivation is also a factor in poisoning incidents. Curiosity is the most common motivation among young children. Those less than 3 years old explore through manipulative and oral activity. The youngest at-risk children (less than 24 months) reportedly ingest substances like dirt or powdered detergent by grasping a handful of the substance and then opening their hands and using their palms to push the substance into their mouths. This often results in spilling much of the substance.(3)

Exploratory behavior among children 3 to 4 years old may be somewhat more controlled than for younger children. For example, in a study examining powdered aspirin, children 42 to 51 months of age had difficulty picking up the fine aspirin powder, and when asked to taste it, they did so by putting their fingers in the powder and licking their fingers or by licking the powder directly on the table. This behavior may tend to limit the amount ingested.(3)

In role-playing activities, children may use a powdered substance in imitation of adult behavior. They may mix it with a liquid and drink it or use the powder to substitute for some other food item (e.g., cake mix). However, incomplete mixing of the product will result in a grainy or lumpy mixture which may cause gagging. Repeated ingestion is unlikely following such an experience. It is unlikely that a child could effectively dissolve and ingest toxic amounts of powder with 0.12 percent weight-to-weight iron.(3)

Hunger is another potential motivation. The primary risk of poisoning from these iron-containing supplements would be to a starved, unattended child with no other available source of nutrition. However, it is unlikely that a child would have the time and perseverance to ingest a quantity of iron (11 tablespoons) that would be potentially toxic (20 mg/kg). This is especially true since these products are expensive, purchased by a select population of nutrition enthusiasts, and are probably stored near other foods that would be more appealing to children.(3)

The relative palatability of a substance may influence toxic ingestions. Although flavor plays little or no role in determining whether a product is ingested, it does influence the quantity ingested. The unpleasant taste of the petitioner's product may deter ingestion of toxic levels. Flavored products may pose a somewhat greater risk. However, the other factors discussed above would likely limit the toxic dose ingested of both flavored and unflavored powdered iron supplements.(3)

D. Economic Data

According to the Food and Drug Administration, a dietary supplement is ''a food, not in conventional form, that supplies a component to supplement the diet by increasing the total dietary intake of that component,'' Dietary Supplement Health and Education Act of 1994, Public Law 103–417. These are distinct from fortified foods, such as infant formulas and meal replacements, which are intended to serve as the sole item of a meal. The ingredients in dietary supplements and fortified foods may be similar, but the marketing emphasis and health claims are different.(4)

The petitioner markets two unsweetened, unflavored protein powder supplements that are sold in individual serving packets or in canisters. Each recommended serving of 1 tablespoon contains 18 mg of iron and is mixed with juice for consumption. The following table shows the available container sizes and the total iron content of each.

Size	Servings	Total iron content (mg)
5.29 oz.	10	180.
15.9 oz.	30	540.
2.2 lb.	66	1188.
25 packets	25	450 (18 mg per packet).

Sweetened or flavored supplements make up the major part of the powder dietary supplement market. Many are marketed as ''sports nutritionals'' for fitness enthusiasts. These products are packaged in cartons, canisters, packets, jugs, and pails in various sizes and strengths of iron. Unit and dollar sales of powdered nutritional products are not available. A spokesperson for the Council for Responsible Nutrition (''CRN''), an industry group, estimates the retail market for protein powders (including both supplements and fortified foods) at $2 billion. CRN attributes the larger market share (percent unknown) to flavored powders marketed as sports nutritionals and diet supplements.(4)

D. Action on the Petition

As discussed above, the relevant literature and data show no cases of child poisonings due to iron-containing powders. In addition, it is unlikely that young children would ingest toxic

amounts of iron-containing supplement powders which are difficult for children to handle without spilling or to swallow without gagging. A child would have to ingest approximately 11 tablespoons of petitioner's product (20 mg/kg in a 10 kg child) in order to produce a minimally toxic dose. Approximately 100 tablespoons would be required for a lethal dose. Most of the factors that make toxic ingestions of petitioner's unflavored product unlikely would also apply to flavored supplement powders.

After considering the available information, the Commission preliminarily concludes that the degree and nature of the hazard to children presented by the availability of dietary supplement powders with no more than the equivalent of 0.12 percent weight-to-weight elemental iron are such that special packaging is not required to protect children from serious personal injury or serious illness resulting from handling, or ingesting such substance. Accordingly, the Commission voted to grant the petition and proposes to amend 16 CFR 1700.14(a)(13) to exempt from requirements for child resistant packaging those dietary supplement powders with no more than the equivalent of 0.12 percent weight to-weight-elemental iron.

E. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (Public Law 96–354, 5 U.S.C. 601 *et seq.*), when an agency issues proposed and final rules, it must examine the rules' potential impact on small businesses. The Act requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis if a proposed rule would have a significant impact on a substantial number of small businesses, small organizations, and small governmental jurisdictions.

The exemption proposed below, to exempt powdered iron-containing dietary supplements from CRP requirements, will give manufacturers of these products the option of packaging products using any packaging they choose. As far as CPSC is aware, powdered iron-containing dietary supplements are not currently packaged in CRP. The Commission's Compliance staff is exercising its enforcement discretion regarding these products pending completion of this rulemaking. Thus, the proposed exemption will bring no change in the current packaging of products subject to the exemption. Accordingly, the Commission concludes that this exemption will not have any significant economic effect on a substantial number of small entities.

F. Environmental Considerations

The Commission's regulations at 16 CFR 1021.5(c)(3) state that rules exempting products from child-resistant packaging requirements under the PPPA normally have little or no potential for affecting the human environment. The Commission does not foresee any special or unusual circumstances surrounding this proposed rule. Therefore, exempting these products from the PPPA requirements will have little or no effect on the human environment. For this reason, the Commission concludes that no environmental assessment or impact statement is required in this proceeding.

G. Effective Date

Since the proposed rule provides for an exemption, no delay in the effective date is required. 5 U.S.C. 553(d)(1). Accordingly, the rule shall become effective upon publication of the final rule in the **Federal Register**.

List of Subjects in 16 CFR Part 1700

Consumer protection, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

Conclusion

For the reasons given above, the Commission amends Title 16 of the Code of Federal Regulations to read as follows:

PART 1700—[AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91–601, secs. 1–9, 84 Stat. 1670, 15 U.S.C. 1471–76, Secs. 1700.1 and 1700.14 also issued under Pub. L. 92–573, sec. 30(a), 88 Stat. 1231, 15 U.S.C. 2079(a).

2. Section 1700.14(a)(13) is revised to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) * * *

(13) *Dietary supplements containing iron.* Dietary supplements, as defined in § 1700.1(a)(3), that contain an equivalent of 250 mg or more of elemental iron, from any source, in a single package in concentrations of 0.025 percent or more on a weight-to-volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids (e.g., powders, granules, tablets, capsules, wafers, gels, viscous products, such as pastes and ointments, etc.) shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except for the following:

(i) Preparations in which iron is present solely as a colorant; and

(ii) Powdered preparations with no more than the equivalent of 0.12 percent weight-to-weight elemental iron.

* * * * *

Dated: April 3, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

Reference Documents

The following documents contain information relevant to this rulemaking proceeding and are available for inspection at the Office of the Secretary, Consumer Product Safety Commission, Washington, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814.

1. Briefing Memorandum with attached briefing package, March 14, 1995.

2. Memorandum from Sandra E. Inkster, Ph.D., HSPS, to Jacqueline N. Ferrante, Ph.D., HSPS, ''Review of Iron Toxicity: Relevance to a Petition Requesting Exemption for Powdered, Iron-Containing Dietary Supplements,'' February 15, 1995.

3. Memorandum from Catherine A. Sedney, EPHF, to Jacqueline N. Ferrante, Ph.D., HSPS, ''Petition to Exempt Iron-Containing Supplement Powders from PPPA Requirements,'' February 16, 1995.

4. Memorandum from Marcia P. Robins, EPSS, to Jacqueline N. Ferrante, Ph.D., HSPS, ''Preliminary Market Information: Petition for Exemption from Child-Resistant Packaging Requirements for Powdered Iron-Containing Dietary Supplements,'' March 10, 1995.

[FR Doc. 95–8522 Filed 4–6–95; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket Nos. RM95–8–000 and RM94–7–001]

Promoting Wholesale Competition Through Open Access Non-discriminatory Transmission Services by Public Utilities, Recovery of Stranded Costs by Public Utilities and Transmitting Utilities; Proposed Rulemaking and Supplemental Notice of Proposed Rulemaking

March 29, 1995.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed rulemaking and supplemental notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is proposing to require that public utilities owning and/or controlling facilities used for the transmission of electric energy in interstate commerce have on