2. *General Software Note.* General License GTDR, without written assurance, is available to all destinations, except Country Groups S and Z, Iran, and Syria, for release of software that is generally available to the public by being:

* * * * *

Supplement No. 1 to § 799.2 [Amended]

3. In Supplement No. 1 to § 799.2 (Interpretations), interpretations Nos. 24, 25, and 26 are removed.

Dated: October 12, 1995.

Sue E. Eckert,

Assistant Secretary for Export Administration.

[FR Doc. 95–25742 Filed 10–16–95; 8:45 am]

BILLING CODE 3510–DT–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

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

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending 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 issues 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: The exemption is effective on October 17, 1995.

FOR FURTHER INFORMATION CONTACT: Michael Bogumill, Division of Regulatory Management, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0400 ext. 1368.

SUPPLEMENTARY INFORMATION:

A. Background

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. (''Nutritech''), 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 several reasons why CRP is unnecessary for this dietary supplement. (1) [1] The Commission published a notice in the Federal Register on August 4, 1994, soliciting comments on the petition, 59 FR 39747, and received no responses.

B. Proposed Rule and Comment

On April 7, 1995, the Commission published a notice granting Nutritech's petition to initiate rulemaking and proposing to exempt certain powdered iron-containing dietary supplements from CRP requirements. 60 FR 17660. The Commission proposed that the exemption would apply to dietary supplement powders, both flavored and unflavored, with no more than the equivalent of 0.12 percent w/w elemental iron.

In response to the proposed rule, the Commission received one comment. The comment, submitted on behalf of an organization called SI Metric, objected that the proposed regulation did not use proper SI metric terminology. The Commission has considered the comment and has made some changes in the preamble to ensure that measurements are presented in metric terminology. However, the Commission declines to make some changes suggested by the commenter—for example, using the term mass rather than weight. The Commission also believes that its expression of the percentage of concentration of iron for liquids and non-liquids as weight-to-volume (''w/v'') or weight-to-weight (''w/w'') measurements is appropriate. Based on the United States Pharmacopeia guidelines, the percent w/v refers to the number of grams of a constituent in 100 milliliters of solution, and the percent w/w is the number of grams of a constituent in 100 grams of solution or mixture. The Commission believes that its use of terminology is consistent with use throughout the Federal government. Moreover, the terminology is consistent with other regulations under the PPPA.

C. 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)(5)

When 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), it decided to limit the 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

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

Surveillance System (''NEISS''), in-depth investigations, the National Center for Health Statistics (''NCHS'') and the American Association of Poison Control Centers (''AAPCC''). (2)(5)

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 (20 mg/kg), serious (60 mg/kg), and lethal (180 mg/kg) toxicity levels. This assumes none of the product is spilled during consumption. (2)(5)

D. Human Factors Data

Poisoning incidents involving ingestion of large amounts of any powdered substance are relatively rare. 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)(5)

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)

E. 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, P.L. 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)
150 g	10	180
450 g	30	540
1 kg .	66	1188
354 g	25	450 (18 mg per packet)

Sweetened or flavored supplements make up the major part of the powdered 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)

F. Action on the Petition

As discussed above and in the notice of proposed rulemaking, 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.

The Commission preliminarily concluded 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 proposed 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. 60 FR 17660 (April 7, 1995).

After considering all available and relevant information, the Commission determines to issue the proposed exemption on a final basis.

G. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (Pub. L. 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.

When the Commission proposed to exempt powdered iron-containing dietary supplements from CRP requirements, it found that the exemption would not have any significant economic impact on a substantial number of small entities. The exemption 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 exemption will bring no change in the current packaging of products subject to the exemption. The Commission is not aware of any information that would alter its conclusion that this exemption will not have any significant economic effect on a substantial number of small entities.

H. 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 did not foresee any special or unusual circumstances surrounding the proposed rule and found that exempting these products from the PPPA requirements would have little or no effect on the human environment. For this reason, when the Commission issued the proposed exemption, it concluded that no environmental assessment or impact statement is required in this proceeding. That conclusion remains unchanged.

I. Effective Date

Because this 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: 15 U.S.C. 1471–1476. Secs. 1700.1 and 1700.14 also issued under 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: October 6, 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.
5. Briefing Memorandum with attached briefing package, September 19, 1995.
6. Memorandum from Marcia P. Robins, EPSS, to Jacqueline N. Ferrante, Ph.D., HSPS, Final Regulatory Flexibility Act Issues: Petition for Exemption from Child-Resistant Packaging Requirements for Powdered Iron-Containing Dietary Supplements,'' July 5, 1995.

[FR Doc. 95–25322 Filed 10–16–95; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Decoquinate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Rhone-Poulenc, Inc. The supplemental NADA provides for use of decoquinate Type A medicated articles to make Type C medicated feeds for young sheep for the prevention of certain forms of coccidiosis.

EFFECTIVE DATE: October 17, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary