

under § 316.301. Service under the employee's excepted appointment counts against the maximum limit for the term appointment.

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FEDERAL TRADE COMMISSION

16 CFR Part 436

Request for Comments Concerning Trade Regulation Rule on Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures

AGENCY: Federal Trade Commission.

ACTION: Request for public comments.

SUMMARY: The Federal Trade Commission (the "Commission") is requesting public comments on its Trade Regulation Rule on Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures ("the Franchise Rule" or "the Rule"). The Commission is requesting comments about the overall costs and benefits of the Rule and its overall regulatory and economic impact as a part of its systematic review of all current Commission regulations and guides. The Commission also is requesting comment on whether the Rule should be modified to: Replace the Rule's disclosure requirements with those set forth in the revised Uniform Franchise Offering Circular Guidelines, approved by the Commission on December 30, 1993; modify the scope of disclosure requirements for business opportunity ventures; clarify the applicability of the Rule to trade show promoters; and require the disclosure of earnings information. All interested persons are hereby given notice of the opportunity to submit written data, views, and arguments concerning the Rule.

DATES: Written comments will be accepted on or before August 11, 1995.

ADDRESSES: Comments should be directed to: Secretary, Federal Trade Commission, Room H-159, Sixth and Pennsylvania Ave., NW., Washington, DC 20580. Comments about the Franchise Rule should be identified as "16 CFR Part 436—Comment."

Notification of interest in the Public Workshop-Conference should be submitted in writing to Myra Howard, Division of Marketing Practices, Federal Trade Commission, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Steven Toporoff, (202) 326-3135, or

Myra Howard, (202) 326-2047, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The Commission has determined, as part of its oversight responsibilities, to review Rules and guides periodically. These reviews seek information about the costs and benefits of the Commission's Rules and guides and their regulatory and economic impact. The information obtained assists the Commission in identifying Rules and guides that warrant modification or rescission.

The Commission is currently seeking comment on several issues specific to the Franchise Rule. The Commission recognizes that there have been changes in the franchise industry since the Rule was promulgated in 1978. Among these changes is the modification of the Uniform Franchise Offering Circular ("UFOC") Guidelines by the North American Securities Administrators Association ("NASAA"). In 1986, NASAA revised Item 19 of the Guidelines to require franchisors who make earnings claims to have a reasonable basis for such claims. On April 25, 1993, NASAA revised the entire UFOC Guidelines. The Commission approved the revised UFOC Guidelines on December 30, 1993. The Commission now seeks comment on the desirability of replacing the current Rule disclosure requirements with those set forth in the revised UFOC Guidelines. The Commission also seeks comment on the desirability of modifying the scope of the Rule as it pertains to the sale of business opportunities. In addition, the Commission seeks comment on whether it should revoke the current conditional exemption for trade show promoters and whether it should modify the Rule to add specific disclosure requirements or prohibitions concerning trade show promoters. Finally, there has been considerable discussion in the franchise industry and among franchise regulators about requiring the disclosure of earnings information to prospective investors. The Commission solicits comment on the desirability of modifying the Rule to require the disclosure of earnings information, and if so, what form those disclosures should take.

A. Background

The Franchise Rule was promulgated by the Commission on December 21, 1978. 43 Fed. Reg. 59,614. The Rule makes it an unfair or deceptive act or practice for franchisors and franchise brokers to fail to disclose to prospective

franchisees specific information about the franchisor, franchise business, and terms of the franchise agreement. Franchisors and franchise brokers must disclose additional information if they make any claim about actual or potential earnings to prospective franchisees or to the media. The Rule sets forth both the form and content of the required disclosures. Franchisors must provide prospective franchisees with the required disclosures before any sale is made.

B. Issues for Comment

1. The Revised UFOC

The Franchise Rule sets forth the content and form of the required disclosures. 16 CFR 436.1(a)-(e). In lieu of the Rule's format, the Commission has accepted the UFOC Guidelines originally adopted by the Midwest Securities Commissioners Association on September 5, 1975. 44 FR 49,966, 49,970, and as subsequently amended by NASAA on November 27, 1986. 52 FR 22,686. Most recently, NASAA petitioned the Commission to approve new amendments to the UFOC Guidelines, which NASAA adopted on April 25, 1993. See Extra Edition, Bus. Fran. Guide (CCH), Rpt. No. 161 (May 25, 1993). The Commission approved the use of the new UFOC on December 30, 1993. 58 FR 69,224. The new amendments are the product of a comprehensive revision of the UFOC Guidelines. The Commission is concerned about costs and other potential disadvantages to franchisors and franchisees that may result from a lack of uniformity between federal and state regulations. Accordingly, the Commission solicits comments on whether it is desirable to revise the Rule by replacing the current Rule disclosure requirements with those set forth in the revised UFOC Guidelines.

2. The Application of the Franchise Rule to Business Opportunities

The Franchise Rule applies to both franchises and business opportunities. The Rule currently does not provide a specific definition of the term "business opportunity." Rather, the Rule's definition of the term "franchise" includes some forms of business opportunities. Specifically, if the following three conditions are met, a business opportunity will be deemed a franchise:

(A) A person (hereinafter "franchisee") offers, sells, or distributes to any person other than a "franchisor" (as hereinafter defined), goods, commodities, or services which are:

- (1) Supplied by another person (hereinafter "franchisor"), or
- (2) Supplied by a third person (e.g., a supplier) with whom the franchisee is directly or indirectly required to do business by another person (hereinafter "franchisor"); or
- (3) Supplied by a third person (e.g., a supplier) with whom the franchisee is directly or indirectly advised to do business by another person (hereinafter "franchisor") where such third person is affiliated with the franchisor; and

(B) The franchisor:

- (1) Secures for the franchisee retail outlets or accounts for said goods, commodities, or services; or
- (2) Secures for the franchisee locations or sites for vending machines, rack displays, or any other product sales display used by the franchisee in the offering, sale, or distribution of said goods, commodities, or services; or
- (3) Provides to the franchisee the services of a person able to secure the retail outlets, accounts, sites or locations * * *; and

(C) The franchisee is required as a condition of obtaining or commencing the franchise operation to make a payment or a commitment to pay [at least \$500 within the first six months of operation] to the franchisor, or to a person affiliated with the franchisor. 16 CFR 436.2(a)(1)(ii)(A)-(B) and (a)(2).

Accordingly, the Commission seeks comment on the desirability of modifying the Rule to include a specific definition of the term "business opportunity." The Commission also seeks comment on whether such a definition should include other business opportunity formats that are currently not covered by the Rule, such as multi-level marketing, seller assisted market plans, work-at-home plans, and certain distributorships and licenses.

The Commission is also concerned that the Rule's disclosure requirements may not be well suited to the sale of business opportunities and may impose unnecessary costs on both business opportunity sellers and buyers. Accordingly, the Commission seeks comment on whether to modify the Rule to require different disclosures for the sale of business opportunities. Specifically, the Commission seeks comment on what disclosures are most relevant to business opportunity purchasers. The Commission asks whether certain Rule disclosures should be eliminated and if any additional disclosures should be required.

3. Trade Show Promoter Liability

The Franchise Rule applies to franchisors and franchise brokers.

Franchise brokers are jointly and severally liable for violations of the Franchise Rule. 16 CFR 436.1, 436.2(j). In 1981, the Commission advised trade show promoters that they would be exempt from Rule coverage as brokers if they provided trade show attendees with a specific consumer education notice. The notice advises consumers that the Commission's Franchise Rule grants them rights to receive certain information about a franchise investment prior to signing agreements. See 46 FR 52327 (October 27, 1981). The exemption requires trade show promoters to give trade show attendees the required notice upon their first entry to the show. Trade show promoters who fail to distribute the required consumer education notice may be held jointly and severally liable for all participating franchisors' Rule violations that may occur at the shows.

Since the Commission issued this conditional exemption in 1981, the sale of franchises and business opportunities at trade shows has increased significantly. In 1994, the Commission settled charges of Rule violations against two trade show promoters who allegedly failed to provide the required consumer education notices at their respective shows. The Commission solicits comments on the desirability of revoking the conditional exemption for trade show promoters. In addition, the Commission seeks comment on whether the Rule should be revised to provide separate disclosure requirements and prohibitions for trade show promoters.

4. Earnings Disclosure Requirements

Franchisors making claims about actual or potential sales, profits, or earnings must provide detailed disclosures mandated by § 436.1(b)-(e) of the Rule. Section 436.1(b) enumerates the substantiation requirements for claims based on projections or forecasts; § 436.1(c), for claims based on actual operating results; and § 436.1(e), for claims that appear in media advertising. The franchisor must have a "reasonable basis" for all such claims; they must be "geographically relevant" to the potential franchisee's market area; and, if they are based on operating results, must be prepared in accordance with generally accepted accounting principles.

The franchisor must also give a separate earnings claim disclosure document to any potential investor to whom such a claim is made. The earnings claim document must contain a cover page specified by § 436.1(d); a full statement of the basis and assumptions for the claim; prescribed cautionary language; a notice that

substantiating material is available for inspection by investors; a disclosure of the number and percentage of the franchisor's outlets that have achieved the same or better results; and various additional information, depending on the type of claim made.

The Franchise Rule does not mandate the disclosure of actual or projected earnings information. The NASAA Franchise Committee and some members of its Industry Advisory Committee, however, have proposed that franchisors and promoters of business opportunities be required to disclose and provide substantiation for some form of earnings information to potential investors. They are concerned that, in the absence of required earnings disclosures, prospective investors seeking information about potential earnings may receive unsubstantiated, misleading, deceptive, and possibly false earnings information. The Commission shares this concern. Over the past five years, allegations of false and deceptive earnings claims have been the most common allegation set forth in Commission complaints filed against franchisors and business opportunity promoters. Therefore, the Commission seeks comments on the desirability of modifying the Rule to include a mandatory earnings disclosure. In particular, the Commission seeks comments on the specific benefits of such disclosures to prospective investors as well as the potential for mandated earnings disclosures to mislead prospective investors. In addition, the Commission requests comment on potential burdens and compliance costs that such Rule modification might impose on prospective franchisees and franchisors. The Commission specifically requests commentors to submit statistical information, including survey data, or other report materials, in support of their comments.

C. Request for Comment

At this time, the Commission solicits written public comments on the following questions:

- (1) Is there a continuing need for the Rule?
- (a) To what extent do franchisors use the Commission's Franchise Rule format?
- (b) What benefits has the Rule provided to purchasers of franchises and business opportunities?
- (c) Has the Rule imposed costs on purchasers? Explain.
- (2) What changes, if any, should be made to the Rule to increase the benefit of the Rule to purchasers?

(a) How would these changes affect the costs the Rule imposes on firms subject to its requirements?

(3) What significant burdens or costs has the Rule imposed on firms subject to its requirements?

(a) Has the Rule provided benefits to such firms? Explain.

(4) What changes, if any, should be made to the Rule to reduce the burdens or costs imposed on firms subject to its requirements?

(a) How would these changes affect the benefits provided by the Rule?

(5) Does the Rule overlap or conflict with other Federal, state, or local laws or regulations?

(6) Since the Rule was issued, what effects, if any, have changes in relevant technology, economic conditions, and industry practices had on the Rule?

The Revised UFOC Guidelines

(7) Would it be in the public interest for the Commission to establish one national franchise disclosure standard?

(8) Should the Commission revise the Rule by replacing the Rule's required disclosures with those set forth in the revised UFOC Guidelines, approved by the Commission on December 31, 1993? Explain.

(a) What would be the costs and benefits of such a revised Rule on sellers of franchises and business opportunities?

(b) What would be the costs and benefits of such a revised Rule on purchasers of franchises and business opportunities?

The Applicability of the Rule to Business Opportunities

(9) To what extent do business opportunity sellers currently comply with the Rule?

(10) What are the costs and benefits of the Rule to business opportunity sellers subject to the Rule's disclosure requirements?

(11) What are the costs and benefits of the Rule to prospective purchasers of business opportunities?

(12) To what extent do purchasers of business opportunities obtain relevant and material information from the required disclosures? Explain.

(13) Should the Commission clarify the Rule by adding a separate definition of the term "business opportunity"? Explain.

(a) Should such a definition of "business opportunity" be expanded beyond the current definition of a "business opportunity" franchise? Explain.

(b) Should such a definition include the sale of other business arrangements such as multi-level marketing, seller

assisted marketing plans, work-at-home plans, and certain distributorships and licenses? Explain.

(14) Should the Commission revise the Rule's disclosure requirements for sellers of business opportunities? Explain.

(a) Should the Commission require a different disclosure document for business opportunities?

(b) What information do purchasers of business opportunities need that is not currently required by the Rule?

(c) What disclosures currently required by the Rule should be eliminated?

(15) What would be the costs and benefits to firms that would be subject to such revised disclosure requirements?

(16) What would be the costs and benefits of such revised disclosure requirements to purchasers of business opportunities?

Trade Show Promoter Liability

(17) Should the Commission revoke the current conditional exemption to the Rule for trade show promoters? Explain.

(a) To what extent do consumers purchase franchises or business opportunities as a result of attending franchise trade shows?

(b) To what extent do exhibitors at trade shows violate the Rule in their presentations to consumers? What is the nature of any such violations?

(c) What would be the costs and benefits of revoking the conditional exemption to the Rule?

(18) Should the Commission revise the Rule to include separate disclosures and prohibitions for trade show promoters? Explain.

(a) What disclosures should trade show promoters be required to make to show attendees?

(b) What conduct should the Rule prohibit trade show promoters from engaging in?

(c) What would be the costs and benefits of such a revised Rule?

Earnings Information

Background

(19) To what extent do prospective franchisees want information about (a) actual earnings and (b) projected earnings?

(20) To what extent do prospective franchisees receive pre-sale written or oral earnings information?

(a) To what extent do franchisees receive historical earnings information?

(b) To what extent do franchisees receive earnings projections or other earnings claims?

(c) To what extent do franchisees receive substantiation for such earnings information or earnings projections?

(21) To what extent do franchisors currently provide earnings disclosures to prospective franchisees?

(a) To what extent do franchisors provide historical earnings information?

(b) To what extent do franchisors provide earnings projections or other earnings claims?

(c) To what extent do franchisors substantiate such earnings information or earnings projections?

(22) For those franchisors that do provide earnings information:

(a) In what industries are these franchisors engaged?

(b) What is their size (e.g., number of franchisees and gross revenues of the franchise system)?

(c) Does the franchisor use the UFOC or FTC disclosure document format?

(23) To what extent do (a) the Rule requirements and (b) the UFOC requirements inhibit franchisors from providing historical earnings information or earnings projections to prospective franchisees? Explain.

(24) In the absence of earnings disclosures under the Rule or UFOC, is earnings information available to prospective franchisees from other sources? Explain.

(a) What are the costs to prospective franchisees to obtain such information?

(b) To what extent is such information accurate and reliable?

Financial Data Currently Available to Franchisors

(25) To what extent do franchisors routinely receive financial and/or other operating performance information from franchisees?

(a) What types of information do franchisors receive?

(b) Do franchisees give the information voluntarily or by contractual requirements?

(c) How often do franchisors receive such information?

(d) How long is such information retained by franchisors?

(26) Are the financial data currently submitted by franchisees sufficient to enable franchisors to provide prospective franchisees with an accurate appraisal of the financial risks of investing in a franchise? Explain.

(a) If the data are insufficient to provide such information, what additional information would correct the deficiency?

(b) What would be the additional costs and benefits of obtaining and providing this additional information to prospective franchisees?

(27) To what extent do franchisors conduct periodic audits of franchisee financial operations? Explain.

(28) To what extent do franchisors require franchisees to use particular accounting formats? Explain.

Possible Required Earnings Disclosures

(29) Would it be in the public interest for the Commission to establish one national earnings claims disclosure requirement? Explain.

(30) What types of earnings data, or other measures of franchisee operating performance, would be most useful to prospective franchisees (e.g., revenues, royalties, net income before income taxes, break-even sales volume, time to reach a break-even point, return on investment)? Describe.

(31) Are there industries for which traditional financial measures of operating performance are either irrelevant or inadequate to provide prospective franchisees with useful earnings information?

(a) What are these industries?

(b) What supplemental information could these industry franchisors provide to ensure that prospective franchisees receive useful earnings information?

(32) Should the Rule be revised to require franchisors to disclose information about franchisee success rates? If so, which measure of success (e.g., failures, turnover, or longevity in a franchise system) would most help franchisees gauge the financial success of the system? Explain.

(a) How should a franchisee failure be defined? Explain.

(b) What type of franchisee failure data (number of failures, failure rates, or longevity of franchisees who fail) would be most useful to prospective franchisees?

(c) How should franchisee turnover be defined? Explain.

(d) What type of franchisee turnover data (number of failures, terminations, cancellations, or transfers) would be most useful to prospective franchisees?

(e) Should information about franchisee longevity in a franchise system, regardless of reasons for departure, be disclosed to prospective franchisees? Explain.

(f) What are the costs and benefits of requiring franchisors to disclose information about franchisee failures, turnover, or longevity in a franchise system?

(33) Is it possible to have a uniform earnings disclosure requirement for all franchise systems? Explain.

(34) How can an earnings disclosure requirement be configured to assure relevancy to the market location being considered? What types of earnings information would be relevant? Explain.

(35) How can an earnings disclosure requirement be configured to reflect differences in the length of franchisees' operating experience? Explain.

(36) How frequently should earnings disclosures be updated?

(37) How long should prospective franchisees be given to review required earnings disclosures before signing a contract? Is the Rule's ten-day minimum review period sufficient? Explain.

(38) If the Commission requires earnings disclosures, should franchisors be prohibited from making earnings disclosures other than those mandated by the revised Rule? Explain.

(39) In what ways might a mandatory earnings disclosure be misleading or deceptive to prospective franchisees? Explain the specific form of earnings disclosure (e.g., gross sales, profit and loss statements, average net income) and why it may be misleading or deceptive.

Possible Exemptions and Special Circumstances

(40) What kind of meaningful earnings information can new franchise systems provide to prospective franchisees? Explain.

(a) Should a new franchise system be exempt from an earnings disclosure requirement?

(b) What would be an appropriate exemption period?

(c) Should a new franchisor be required to provide a negative disclosure cautioning prospective franchisees that its franchise system has not been in business long enough to provide an accurate earnings history?

(41) What kind of meaningful earnings information can a small franchise system provide to prospective franchisees? Explain.

(a) How should the term "small franchise system" be defined?

(b) Would compliance with an earnings disclosure requirement impose significant burdens and costs on small franchise systems?

(c) Should a small franchise system be exempt from an earnings disclosure requirement? If so, should a qualifying small franchise system be required to provide a negative disclosure cautioning prospective franchisees that its franchise system cannot provide accurate and reliable earnings information?

(42) Should the Commission consider exemptions to an earnings disclosure requirement for other circumstances? Explain.

Additional Considerations

(43) What concerns do franchisors have about being required to provide earnings information to prospective

franchise purchasers? How can the Commission address these concerns?

(44) If the Commission adopts a mandatory earnings disclosure requirement, franchisors might be compelled to collect financial data from franchisees. What concerns do franchisees have about: (a) revealing financial data to their franchisors; and (b) franchisors' use of their financial data to comply with an earnings disclosure requirement? How can the Commission address these concerns?

(45) To what extent do franchisors' contractual agreements with franchisees prevent franchisees from disclosing information about their own operating performance to prospective franchisees? How should the Commission address this concern?

D. Invitation to Comment

In reviewing the Franchise Rule, Commission staff will consider all comments submitted by August 11, 1995. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552) and Commission regulations, on normal business days between the hours of 8:30 a.m. and 5 p.m. at the Public Reference Section, Room 130, Federal Trade Commission, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580.

E. Public Workshop Conference

The FTC staff will conduct a Public Workshop Conference to discuss written comments received in response to this Request for Comments. The purpose of the conference is to afford Commission staff and interested parties a further opportunity to openly discuss and explore issues raised during the rule review, and, in particular, to examine publicly any areas of significant controversy or divergent opinions that are raised in the written comments. Commission staff will consider the views and suggestions made during the conference, in conjunction with the written comments, in formulating its final recommendation to the Commission concerning the review of the Franchise Rule.

Commission staff will select a limited number of parties, from among those who submit written comments, to represent the significant interests affected by the Rule Review. These parties will participate in an open discussion of the issues. It is contemplated that the selected parties might ask and answer questions based on their respective comments.

In addition, the conference will be open to the general public. Members of

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.

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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

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

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)