

Proposed Rules

Federal Register

Vol. 60, No. 54

Tuesday, March 21, 1995

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 927

[Docket Nos. AO-99-A-6; FV-92-065]

Winter Pears Grown in Oregon, Washington, and California; Recommended Decision and Opportunity to File Written Exceptions to Proposed Further Amendment of Marketing Agreement and Order No. 927

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule and opportunity to file exceptions.

SUMMARY: This recommended decision invites written exceptions on proposed amendments to the marketing agreement and order for winter pears grown in the States of Oregon, Washington, and California. The proposed amendments would redefine "ship or handle" to include shipments of winter pears within the production area, update the definition of "export market" to recognize that there are now 50 states in the United States, authorize the Winter Pear Control Committee (WPCC) to accept voluntary contributions and how such funds may be used, and revise the authority for exempting certain shipments from regulation. These proposed amendments are designed to improve the administration, operation and functioning of the winter pear marketing order program.

DATES: Written exceptions must be filed by April 20, 1995.

ADDRESSES: Written exceptions should be filed with the Hearing Clerk, U.S. Department of Agriculture, room 1079-S, Washington, DC 20250-9200, Facsimile number (202) 720-9776. Four copies of all written exceptions should be submitted and they should reference the docket numbers and the date and page number of this issue of the **Federal Register**. Exceptions will be made available for public inspection in the

Office of the Hearing Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Kenneth Johnson or Britthany Beadle, Marketing Specialists, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, Room 2523-S, Washington, D.C. 20250-0200; telephone: (202) 720-5127; or Teresa Hutchinson, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, 1220 S.W. Third Avenue, Room 369, Portland, Oregon, 97204; telephone: (503) 326-2725.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of Hearing issued on November 16, 1992, and published in the November 20, 1992, issue of the **Federal Register** (57 FR 54728).

This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12866.

The amendments proposed herein have been reviewed under Executive Order 12778, Civil Justice Reform. They are not intended to have retroactive effect. If adopted, the proposed amendments would not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with the amendments.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and requesting a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Preliminary Statement

Notice is hereby given of the filing with the Hearing Clerk of this recommended decision with respect to the proposed further amendment of Marketing Agreement and Order No. 927, regulating the handling of winter pears grown in Oregon, Washington, and California, and the opportunity to file written exceptions thereto. Copies of this decision can be obtained from Kenneth G. Johnson, Britthany Beadle or Teresa Hutchinson whose addresses are listed above.

This action is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), hereinafter referred to as the "Act," and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR Part 900).

The proposed amendment of Marketing Agreement and Order No. 927 is based on the record of a public hearing held in Portland, Oregon, on December 2, 1992. Notice of this hearing was published in the **Federal Register** on November 20, 1992. The notice of hearing contained several proposals submitted by the WPCC, which locally administers the order.

The proposed amendments would: (1) Redefine "ship or handle" to include shipments of winter pears within the production area; (2) update the definition of "export market" to recognize that there are now 50 states in the United States; (3) authorize the WPCC to accept voluntary contributions and how such funds may be used; and (4) revise the authority for exempting certain shipments from regulation.

The notice of hearing also included proposals by the Fruit and Vegetable Division, Agricultural Marketing Service (AMS), U.S. Department of Agriculture (Department), to make such changes as are necessary to the order, if any or all of the above amendments are adopted, so that all of its provisions conform with the proposed amendment. The Department also proposed revising the language in several sections of the order.

Interested persons had until January 15, 1993, to file proposed findings and conclusions, and written arguments or briefs based on the evidence received at the hearing. No such documents were received.

Small Business Considerations

In accordance with the provisions of the Regulatory Flexibility Act (RFA), the Administrator of the AMS has determined that this action would not have a significant economic impact on a substantial number of small entities. Small agricultural producers have been defined by the Small Business Administration (SBA) (13 CFR 121.601) as those having annual receipts of less than \$500,000. Small agricultural service firms, which include handlers regulated under the order, are defined as those with annual receipts of less than \$5,000,000.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Interested persons were invited to present evidence at the hearing on the probable regulatory and informational impact of the proposed amendments on small businesses. The record indicates that handlers would not be unduly burdened by any additional regulatory requirements, including those pertaining to reporting and recordkeeping, that might result from this proceeding.

During the 1991-92 crop year, 88 handlers were regulated under Marketing Order No. 927. In addition, there were about 1,650 producers of winter pears in the production area. Marketing orders and amendments thereto are unique in that they are normally brought about through group action of essentially small entities for their own benefit. Thus, both the RFA and the Act are compatible with respect to small entities.

All of the changes in the amendments are designed to enhance the administration and functioning of the marketing agreement and order which would benefit the industry. If implemented, these amendments might impose some costs on affected handlers and producers. However, the added burden on small entities, if present at all, would not be significant because the benefits of the proposed amendments are expected to outweigh the costs.

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 35), any change in the reporting and recordkeeping provisions that may result from the proposed amendments would be submitted to the Office of Management and Budget (OMB). The provisions would not be effective until receiving OMB approval.

Material Issues

The material issues of record addressed in this decision are as

follows: (1) Whether to redefine "ship or handle" to include shipments of winter pears within the production area; (2) whether the definition of "export market" should be updated to recognize that there are now 50 states in the United States; (3) whether the WPCC should be authorized to accept voluntary contributions and how such funds may be used; and (4) whether to revise authority for exempting certain shipments from regulation.

Findings and Conclusions

The findings and conclusions on the material issues, all of which are based on evidence adduced at the hearing and the record thereof, are:

(1) Section 927.8, Ship or Handle, of the winter pear marketing order should be amended to cover shipments of winter pears within the production area, as well as interstate shipments.

Record evidence indicates that the intent of the proposal is to provide that shipments of winter pears within the production area be regulated the same as shipments marketed outside the production area. Currently, the order authorizes grade, size, and quality regulations and inspection and reporting requirements for fresh winter pears. While, no grade, quality or size requirements have been issued under the order since the 1979 marketing season, handlers who ship winter pears outside the production area are required to comply with reporting and recordkeeping requirements and pay assessments on those shipments. Handlers who ship winter pears within the production area are not required to comply with such requirements. The WPCC has considered reestablishing grade and size requirements for winter pear shipments in order to ensure the acceptability of such shipments. The WPCC recommended that winter pear shipments within the production area be regulated in the same manner as interstate shipments in order to improve the effectiveness of the marketing order. Regulation of winter pears within the marketing area will help to enhance the orderly marketing of winter pears. The record evidence supports this change in the definition of the term "ship or handle" to make shipments of winter pears within the production area subject to all order requirements.

In 1985, marketing order No. 927 was amended to provide for research and promotion activities, including paid advertising. Until then, the Oregon, Washington, California Pear Bureau (Bureau) represented the northwest winter pear industry in its market development and promotion and advertising programs throughout world

markets. The Bureau's purpose was to conduct those activities necessary to assure the continued success of the industry.

According to record evidence, the assessments to conduct these activities and membership in the Bureau were voluntary. These voluntary assessments were paid by handlers on winter pears marketed both within and outside of the production area.

The WPCC has the responsibility for collecting mandatory assessments on interstate winter pear shipments. The WPCC provides funds for its research and promotion activities and is responsible for oversight of such projects. Currently, the Bureau manages the WPCC's research and promotion activities. There is a contractual agreement between the WPCC and the Bureau for these purposes. The record indicates that this arrangement has proven beneficial, and the WPCC continues to utilize the Bureau which has over 60 years of experience in trade relations to conduct its marketing, promotion and advertising activities.

Other WPCC activities include collection of various statistical information, and post- and pre-harvest research programs to improve cultural practices. The statistical information collected is used by the WPCC to target potential markets to increase sales of winter pears. Research results to improve cultural and handling practices are distributed throughout the winter pear industry. Handlers pay assessments only on shipments of winter pears to destinations outside the production area, since the order currently provides no authority for assessments on shipments of winter pears within the production area. Currently, handlers of winter pears shipped within the production area may benefit from the WPCC's activities without absorbing any of the costs to conduct these programs. Handlers making shipments of winter pears within the production area are currently exempted from paying assessments.

According to record testimony, it is appropriate that assessments be paid on winter pear shipments within the production area to support production and marketing research and promotion projects. Approximately 15 percent (347,647 cartons out of 2,267,582 cartons for 1991) of the winter pears marketed within the production area are sold in the State in which they are grown.

Record evidence indicates that many of the pears initially shipped to intrastate destinations ultimately enter interstate commerce. According to record testimony, an estimated 70 to 80

percent of the pears sold at retail in Las Vegas, Nevada, and Arizona are moved there from distributors in southern California either by wholesalers or the retailer's own distribution system. Similar estimates are made for pears sold at retail in the Reno/Lake Tahoe area of central Nevada, with service from the Bay Area and/or Sacramento. Hawaii is also serviced by wholesalers in the California seaports. The WPCC believes and the evidence supports that many of these shipments originate from sources in the production area. Promotions paid for with mandatory assessments on interstate shipments are conducted in all of these production areas.

At the hearing, witnesses for the WPCC offered a modification of the proposal as it appeared in the hearing notice. These witnesses testified that the term "handle" should not include the transportation of winter pear shipments within the production area from the orchard where grown to a packing facility located within the production area for preparation for market. The intent of this proposal is that winter pears transported within the production area for purposes of preparation for market would not be subject to assessment or any other order requirements since they would not yet have been handled. All other winter pears placed in interstate commerce or marketed within the production area would be subject to regulation, unless otherwise exempt under other provisions of the order.

Record testimony also supported adding the definition of "consign" to the definition of "ship or handle". The record indicates that "consign" is defined as an agreement between a buyer and seller for the transport of product to be marketed with no previous determination of the return of the product. It is the responsibility of the buyer to market the product and return to the seller the proceeds. This should be included as "handling" because the "agent" or "handler" who receives the commodity is engaged in the buying, selling and distributing of the commodity for market. The record also indicates that the words "handle for shipment" should be deleted from the definition of the term "ship or handle" because they are redundant and not necessary.

Section 927.10, Production area, should be changed from "area" to "production area". This is a conforming amendment to clarify those areas that comprise the production area under the marketing order.

Section 927.41, Assessments, should be amended to remove any reference to

a specific State. Record testimony indicates that this is a conforming amendment to provide the necessary language to comply with the intent of the proposal to regulate winter pear shipments within and outside the production area. This section should also be amended to remove the words "upon billing". Record testimony indicates that current procedures to collect assessments do not entail billing. The WPCC does not bill handlers for assessments due. Rather, handlers pay their assessments every two weeks when they submit handler statements of winter pear shipments to the WPCC.

Section 927.52, Prerequisites to Control Committee recommendations, should be amended to provide conforming language updating the marketing order. Presently, the marketing order specifies a basis of one vote for each 25,000 boxes (except 2,500 boxes for Forelle and Seckel varieties) of the average quantity of such variety produced in the particular district and shipped therefrom during the immediately preceding three fiscal periods to destinations outside the State in which produced. As such, only interstate shipments of winter pears are used as a criteria to determine voting procedures. Record evidence supports the inclusion of shipments within the production area in the tonnage vote during WPCC meetings. This action is necessary to provide representation based on all winter pears handled, consistent with order provisions. The proposed amendment to the order has been modified for clarity.

(2) Section 927.12, Export Market, should be amended to update that provision of the marketing order. The marketing order currently provides that "export market" means any destination which is not within the 48 states, or the District of Columbia, of the United States. Record testimony indicates that this section of the marketing order should be updated to reflect that the United States is made up of 50 states.

(3) Section 927.45, Contributions, should be added to the marketing order to authorize the WPCC to receive voluntary contributions. Record evidence indicates that marketing promotion and research projects for winter pears should directly benefit growers of that commodity and secondarily benefit other groups and businesses whose interests are allied with the production and marketing of winter pears. These groups frequently desire to make contributions or donations to help defray the costs of such projects. Record testimony indicates that voluntary contributions could include money, information or

anything of value. Such contributions should be received by the WPCC free from any encumbrances by the donor and under the complete control of the WPCC. The WPCC should not receive a voluntary contribution from any person if that contribution could represent a conflict of interest. Handlers under the order would be allowed to make voluntary contributions to the WPCC.

Record testimony indicated that the provision to accept voluntary contributions as currently provided in the notice of hearing is too restrictive. According to the proposal included in the hearing notice, the WPCC would be prohibited from accepting funds for any purposes other than research and development. However, record testimony indicates that contributions might be provided for activities other than research and promotion projects including paid advertising. Record testimony indicates that the WPCC should be authorized to receive voluntary contributions for any purpose authorized under the order.

Witnesses testified at the hearing that a person making a voluntary contribution to the WPCC should be able to specify its use for a particular authorized activity. However, the WPCC should be free to receive and use such contributions, subject to the provisions of the order, without any encumbrances upon the donor. The acceptance of voluntary contributions with encumbrances by the donor could, at a minimum, give rise to the appearance of improprieties. Accordingly, this recommendation is not included in the proposed amendment.

Section 927.47, Research and Development, should be changed to include conforming language that provides for the acceptance and use of voluntary contributions. The marketing order currently provides that research and development projects shall be paid from funds collected pursuant to § 927.41. This proposed amendment would allow funds collected from voluntary contributions pursuant to § 927.45 to also pay for such projects.

(4) Section 927.65, Exemption from regulation, should be amended to include additional types of winter pear shipments that may be exempt from regulation under the marketing order. Record testimony suggested additional language should be added to the proposed order amendments to provide exemptions to allow the WPCC, with the approval of the Secretary, to establish regulations that exempt from any or all requirements pursuant to this part quantities of pears or of types of pear shipments that do not interfere with the objectives of the order. These proposed

provisions would be in addition to the proposed amendments in the notice of hearing. Record testimony indicates that the overall intent of this amendatory action is to enable the exemption of shipments that do not impact fresh commercial shipments. Record testimony indicated further that § 927.65, "Exemptions from regulation", would be reviewed by the WPCC annually, and that the WPCC would have the flexibility of including and or adjusting requirements, subject to the approval of the Secretary, depending on the circumstances of any given year.

Rulings on Briefs of Interested Persons

The presiding officer at the hearing set January 15, 1993, as the final date for filing briefs with respect to the evidence presented at the hearing and the conclusions which should be drawn therefrom. No briefs were received.

General Findings

(1) The findings hereinafter set forth are supplementary to the previous findings and determinations which were made in connection with the issuance of the marketing agreement and order and each previously issued amendment thereto. Except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein, all of the said prior findings and determinations are hereby ratified and affirmed;

(2) The marketing agreement and order, as amended, and as hereby proposed to be further amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(3) The marketing agreement and order, as amended, and as hereby proposed to be further amended, regulate the handling of winter pears grown in the production area in the same manner as, and are applicable only to, persons in the respective classes of commercial and industrial activity specified in the marketing agreement and order upon which a hearing has been held;

(4) The marketing agreement and order, as amended, and as hereby proposed to be further amended, are limited in their application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivision of the production area would not effectively carry out the declared policy of the Act; and

(5) All handling of winter pears grown in the production area as defined in the marketing agreement and order, as amended, and as hereby proposed to be

further amended, is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

Recommended Further Amendment of the Marketing Agreement and Order

The following amendment of the marketing agreement and order, both as amended, is recommended as the detailed means by which the foregoing conclusions may be carried out:

List of Subjects in 7 CFR Part 927

Marketing agreements, Pears, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the following provisions in Title 7, Part 927, are proposed to be amended as follows:

PART 927—WINTER PEARS GROWN IN OREGON, WASHINGTON, AND CALIFORNIA

1. The authority citation for 7 CFR Part 927 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 927.8 is revised to read as follows:

§ 927.8 Ship or handle.

Ship or handle means to sell, deliver, consign or transport pears, within the production area or between the production area and any point outside thereof: *Provided*, That the term "handle" shall not include the transportation of winter pear shipments within the production area from the orchard where grown to a packing facility located within the production area for preparation for market.

3. Section 927.10 is revised to read as follows:

§ 927.10 Production area.

Production area means and includes the States of Oregon, Washington, and California.

4. Section 927.12 is revised to read as follows:

§ 927.12 Export market.

Export market means any destination which is not within the 50 states, or the District of Columbia, of the United States.

5. In § 927.41, paragraph (a) is revised to read as follows:

§ 927.41 Assessments.

(a) Assessments will be levied only upon handlers who first handle pears. Each handler shall pay assessments on all pears handled by such handler as the pro rata share of the expenses which the Secretary finds are reasonable and likely

to be incurred by the Control Committee during a fiscal period. The payment of assessments for the maintenance and functioning of the Control Committee may be required under this part throughout the period such assessments are payable irrespective of whether particular provisions thereof are suspended or become inoperative.

* * * * *

6. Section 927.45 is added to read as follows:

§ 927.45 Contributions.

The Control Committee may accept voluntary contributions but these shall only be used to pay expenses incurred pursuant to § 927.47. Furthermore, such contributions shall be free from any encumbrances by the donor and the Control Committee shall retain complete control of their use.

7. Section 927.47 is revised to read as follows:

§ 927.47 Research and development.

The Control Committee, with the approval of the Secretary, may establish or provide for the establishment of production research, or marketing research and development projects designed to assist, improve, or promote the marketing, distribution, and consumption of pears. Such projects may provide for any form of marketing promotion, including paid advertising. The expense of such projects shall be paid from funds collected pursuant to §§ 927.41 and 927.45. Expenditures for a particular variety of pears shall approximate the amount of assessments and voluntary contributions collected for that variety of pears.

8. In § 927.52, paragraph (b)(1) is revised to read as follows:

§ 927.52 Prerequisites to Control Committee recommendations.

* * * * *

(b) * * *

(1) The basis of one vote for each 25,000 boxes (except 2,500 boxes for Forelle and Seckel varieties) of the average quantity of such variety produced in the particular district and shipped therefrom during the immediately preceding three fiscal periods; or

* * * * *

9. In § 927.65, paragraph (b) is revised to read as follows:

§ 927.65 Exemption from regulation.

* * * * *

(b) The Control Committee may prescribe rules and regulations, to become effective upon the approval of the Secretary, whereby quantities of pears or types of pear shipments may be

exempted from any or all provisions of this subpart.

* * * * *

Dated: March 15, 1995.

Lon Hatamiya,
Administrator.

[FR Doc. 95-6909 Filed 3-20-95; 8:45 am]

BILLING CODE 3410-02-P

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 LD₅₀ (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 LD₅₀ 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