(3) If any article of labeling (other than a label) contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on such article of labeling.

§ 101.17 Food labeling warning, notice, and safe handling statements.

(a) *Self-pressurized containers.* (1) The label of a food packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning:

WARNING—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 °F. Keep out of reach of children.

(2) In the case of products intended for use by children, the phrase ''except under adult supervision'' may be added at the end of the last sentence in the warning required by paragraph (a)(1) of this section.

(3) In the case of products packaged in glass containers, the word ''break'' may be substituted for the word ''puncture'' in the warning required by paragraph (a)(1) of this section.

(4) The words ''Avoid spraying in eyes'' may be deleted from the warning required by paragraph (a)(1) of this section in the case of a product not expelled as a spray.

(b) *Self-pressurized containers with halocarbon or hydrocarbon propellants.* (1) In addition to the warning required by paragraph (a) of this section, the label of a food packaged in a self-pressurized container in which the propellant consists in whole or in part of a halocarbon or a hydrocarbon shall bear the following warning:

WARNING—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

(2) The warning required by paragraph (b)(1) of this section is not required for the following products:

(i) Products expelled in the form of a foam or cream, which contain less than 10 percent propellant in the container.

(ii) Products in a container with a physical barrier that prevents escape of the propellant at the time of use.

(iii) Products of a net quantity of contents of less than 2 ounces that are designed to release a measured amount of product with each valve actuation.

(iv) Products of a net quantity of contents of less than one-half ounce.

(c) *Food containing or manufactured with a chlorofluorocarbon or other ozone-depleting substance.* Labeling requirements for foods that contain or are manufactured with a chlorofluorocarbon or other ozone-depleting substance designated by the Environmental Protection Agency (EPA) are set forth in 40 CFR part 82.

(d) *Protein products.* (1) The label and labeling of any food product in liquid, powdered, tablet, capsule, or similar forms that derives more than 50 percent of its total caloric value from either whole protein, protein hydrolysates, amino acid mixtures, or a combination of these, and that is represented for use in reducing weight shall bear the following warning:

WARNING: Very low calorie protein diets (below 400 Calories per day) may cause serious illness or death. Do Not Use for Weight Reduction in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women.

(2) Products described in paragraph (d)(1) of this section are exempt from the labeling requirements of that paragraph if the protein products are represented as part of a nutritionally balanced diet plan providing 400 or more Calories (kilocalories) per day and the label or labeling of the product specifies the diet plan in detail or provides a brief description of that diet plan and adequate information describing where the detailed diet plan may be obtained and the label and labeling bear the following statement:

NOTICE: For weight reduction, use only as directed in the accompanying diet plan (the name and specific location in labeling of the diet plan may be included in this statement in place of ''accompanying diet plan''). Do not use in diets supplying less than 400 Calories per day without medical supervision.

(3) The label and labeling of food products represented or intended for dietery (food) supplementation that derive more than 50 percent of their total caloric value from either whole protein, protein hydrolysates, amino acid mixtures, or a combination of these,

that are represented specifically for purposes other than weight reduction; and that are not covered by the requirements of paragraph (d) (1) and (2) of this section; shall bear the following statement:

NOTICE: Use this product as a food supplement only. Do not use for weight reduction.

(4) The provisions of this paragraph are separate from and in addition to any labeling requirements promulgated by the Federal Trade Commission for protein supplements.

(5) Protein products shipped in bulk form for use solely in the manufacture of other foods and not for distribution to consumers in such container are exempt from the labeling requirements of this paragraph.

(6) The warning and notice statements required by paragraphs (d) (1), (2), and (3) of this section shall appear prominently and conspicuously on the principal display panel of the package label and any other labeling.

(e) *Dietary supplements containing iron or iron salts.* (1) The labeling of any dietary supplement in solid oral dosage form (e.g., tablets or capsules) that contains iron or iron salts for use as an iron source shall bear the following statement:

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

(2)(i) The warning statement required by paragraph (e)(1) of this section shall appear prominently and conspicuously on the information panel of the immediate container label.

(ii) If a product is packaged in unit-dose packaging, and if the immediate container bears labeling but not a label, the warning statement required by paragraph (e)(1) of this section shall appear prominently and conspicuously on the immediate container labeling in a way that maximizes the likelihood that the warning is intact until all of the dosage units to which it applies are used.

(3) Where the immediate container is not the retail package, the warning statement required by paragraph (e)(1) of this section shall also appear prominently and conspicuously on the information panel of the retail package label.

(4) The warning statement shall appear on any labeling that contains warnings.

(5) The warning statement required by paragraph (e)(1) of this section shall be set off in a box by use of hairlines.

(f) *Foods containing psyllium husk.* (1) Foods containing dry or incompletely hydrated psyllium husk, also known as psyllium seed husk, and bearing a health claim on the association between soluble fiber from psyllium husk and reduced risk of coronary heart disease, shall bear a label statement informing consumers that the appropriate use of such foods requires consumption with adequate amounts of fluids, alerting them of potential consequences of failing to follow usage recommendations, and informing persons with swallowing difficulties to avoid consumption of the product (e.g., ''NOTICE: This food should be eaten with at least a full glass of liquid. Eating this product without enough liquid may cause choking. Do not eat this product if you have difficulty in swallowing.''). However, a product in conventional food form may be exempt from this requirement if a viscous adhesive mass is not formed when the food is exposed to fluids.

(2) The statement shall appear prominently and conspicuously on the information panel or principal display panel of the package label and any other labeling to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The statement shall be preceded by the word ''NOTICE'' in capital letters.

(g) *Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens.* (1) For purposes of this paragraph (g), ''juice'' means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrate of such liquid or puree.

(2) The label of:

(i) Any juice that has not been processed in the manner described in paragraph (g)(7) of this section; or

(ii) Any beverage containing juice where neither the juice ingredient nor the beverage has been processed in the manner described in paragraph (g)(7) of this section, shall bear the following warning statement:

WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

(3) The warning statement required by this paragraph (g) shall not apply to juice that is not for distribution to retail consumers in the form shipped and that is for use solely in the manufacture of other foods or that is to be processed, labeled, or repacked at a site other than originally processed, provided that for juice that has not been processed in the manner described in paragraph (g)(7) of this section, the lack of such processing is disclosed in documents accompanying the juice, in accordance with the practice of the trade.

(4) The warning statement required by paragraph (g)(2) of this section shall appear prominently and conspicuously on the information panel or on the principal display panel of the label of the container.

(5) The word ''WARNING'' shall be capitalized and shall appear in bold type.

(6) The warning statement required by paragraph (g)(2) of this section, when on a label, shall be set off in a box by use of hairlines.

(7)(i) The requirements in this paragraph (g) shall not apply to a juice that has been processed in a manner that will produce, at a minimum, a reduction in the pertinent microorganism for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, of the following magnitude:

(A) A 5-log (i.e., 100,000-fold) reduction; or

(B) A reduction that is equal to, or greater than, the criterion established for process controls by any final regulation requiring the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of juice.

(ii) For the purposes of this paragraph (g), the ''pertinent microorganism'' is the most resistant microorganism of public health significance that is likely to occur in the juice.

(h) *Shell eggs.* (1) The label of all shell eggs, whether in intrastate or interstate commerce, shall bear the following statement:

SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.

(2) The label statement required by paragraph (h)(1) of this section shall appear prominently and conspicuously, with the words ''SAFE HANDLING INSTRUCTIONS'' in bold type, on the information panel or principal display panel of the container.

(3) The label statement required by paragraph (h)(1) of this section shall be set off in a box by use of hairlines.

(4) Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (h) of this section.

(5) The safe handling statement for shell eggs that are not for direct sale to consumers, e.g., those that are to be repacked or labeled at a site other than where originally processed, or are sold for use in food service establishments, may be provided on cartons or in labeling, e.g., invoices or bills of lading in accordance with the practice of the trade.

(6) Under sections 311 and 361 of the Public Health Service Act (PHS Act), any State or locality that is willing and able to assist the agency in the enforcement of paragraphs (h)(1) through (h)(5) of this section, and is authorized to inspect or regulate establishments handling packed shell eggs, may in its own jurisdiction, enforce paragraphs (h)(1) through (h)(5) of this section through inspections under paragraph (h)(8) of this section and through administrative enforcement remedies identified in paragraph (h)(7) of this section until FDA notifies the State or locality in writing that such assistance is no longer needed. When providing such assistance, a State or locality may follow the hearing procedures set out in paragraphs (h)(7)(ii)(C) through (h)(7)(ii)(D) of this section, substituting, where necessary, appropriate

State or local officials for designated FDA officials or may utilize State or local hearing procedures if such procedures satisfy due process.

(7) This paragraph (h) is established under authority of both the Federal Food, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the food misbranding provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U.S.C. 264 provides for the issuance of implementing enforcement regulations; therefore, FDA has established the following administrative enforcement procedures for the relabeling, diversion, or destruction of shell eggs and informal hearings under the PHS Act:

(i) Upon finding that any shell eggs are in violation of this section an authorized FDA representative or State or local representative in accordance with paragraph (h)(6) of this section may order such eggs to be relabeled under the supervision of said representative, diverted, under the supervision of said representative for processing in accordance with the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*), or destroyed by or under the supervision of an officer or employee of the FDA, or, if applicable, of the State or locality, in accordance with the following procedures:

(A) *Order for relabeling, diversion, or destruction under the PHS Act.* Any district office of the FDA or any State or locality acting under paragraph (h)(6) of this section, upon finding shell eggs held in violation of this regulation, may serve upon the person in whose possession such eggs are found a written order that such eggs be relabeled with the required statement in paragraph (h)(1) of this section before further distribution. If the person chooses not to relabel, the district office of the FDA or, if applicable, the appropriate State or local agency may serve upon the person a written order that such eggs be diverted (from direct consumer sale, e.g., to food service) under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or destroyed by or under the supervision of the issuing entity, within 10-working days from the date of receipt of the order.

(B) *Issuance of order.* The order shall include the following information:

(*1*) A statement that the shell eggs identified in the order are subject to relabeling, diversion for processing in accordance with the EPIA, or destruction;

(*2*) A detailed description of the facts that justify the issuance of the order;

(*3*) The location of the eggs;

(*4*) A statement that these eggs shall not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (h)(7)(i)(E) of this section;

(*5*) Identification or description of the eggs;

(*6*) The order number;

(*7*) The date of the order;

(*8*) The text of this entire section;

(*9*) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(*10*) The name and phone number of the person issuing the order; and

(*11*) The location and telephone number of the responsible office or agency and the name of its director.

(C) *Approval of director.* An order, before issuance, shall be approved by the director of the office or agency issuing the order. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum as soon as possible.

(D) *Labeling or marking of shell eggs under order.* An FDA, State, or local representative issuing an order under paragraph (h)(7)(i)(A) of this section shall label or mark the shell eggs with official tags that include the following information:

(*1*) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(*2*) A statement that the shell eggs shall not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*i*) Relabel, divert them for processing in accordance with the EPIA, or destroy them, or

(*ii*) Move them to another location for holding pending appeal.

(*3*) A statement that the violation of the order or the removal or alteration

of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act, 42 U.S.C. 271).

(*4*) The order number and the date of the order, and the name of the government representative who issued the order.

(E) *Sale or other disposition of shell eggs under order*. After service of the order, the person in possession of the shell eggs that are the subject of the order shall not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until the notice is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local agency in writing, to:

(*1*) Relabel, divert, or destroy them as specified in paragraph (h)(7)(i) of this section, or

(*2*) Move them to another location for holding pending appeal.

(ii) The person on whom the order for relabeling, diversion, or destruction is served may either comply with the order or appeal the order to the FDA Regional Food and Drug Director.

(A) *Appeal of a detention order*. Any appeal shall be submitted in writing to the FDA District Director in whose district the shell eggs are located within 5-working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing shall be held within 5-working days after the appeal is filed or, if requested by the appellant, at a later date, which shall not be later than 20-calendar days after the issuance of the order. The order may also be appealed within the same period of 5-working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order shall state the ownership or proprietary interest the appellant has in the shell eggs.

(B) *Summary decision*. A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the FDA Regional Food and Drug Director or his or her designee determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the FDA Regional Food and Drug Director determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(C) *Informal hearing*. Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing shall be conducted by the FDA Regional Food and Drug Director or his designee, and a written summary of the proceedings shall be prepared by the FDA Regional Food and Drug Director.

(*1*) The FDA Regional Food and Drug Director may direct that the hearing be conducted in any suitable manner permitted by law and this section. The FDA Regional Food and Drug Director has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(*2*) Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(*3*) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(*4*) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the FDA Regional Food and Drug Director's report of the hearing.

(*5*) The FDA Regional Food and Drug Director shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time

permits, the FDA Regional Food and Drug Director may give the parties the opportunity to review and comment on the report of the hearing.

(*6*) The FDA Regional Food and Drug Director shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons.

(D) *Written appeal*. If the appellant appeals the detention order but does not request a hearing, the FDA Regional Food and Drug Director shall render a decision on the appeal affirming or revoking the detention within 5-working days after the receipt of the appeal.

(E) *Regional Food and Drug Director decision*. If, based on the evidence presented at the hearing or by the appellant in a written appeal, the FDA Regional Food and Drug Director finds that the shell eggs were held in violation of this section, he shall affirm the order that they be relabeled, diverted under the supervision of an officer or employee of the FDA for processing under the EPIA, or destroyed by or under the supervision of an officer or employee of the FDA; otherwise, the FDA Regional Food and Drug Director shall issue a written notice that the prior order is withdrawn. If the FDA Regional Food and Drug Director affirms the order he shall order that the relabeling, diversion, or destruction be accomplished within 10-working days from the date of the issuance of his decision. The FDA Regional Food and Drug Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the FDA Regional Food and Drug Director shall constitute final agency action, reviewable in the courts.

(F) *No appeal*. If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to relabel, divert, or destroy them within 10-working days, or if the demand is affirmed by the FDA Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to relabel, divert, or destroy them within 10-working days, the FDA district office, or, if applicable, the State or local agency may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(8) Persons engaged in handling or storing packed shell eggs for retail distribution shall permit authorized representatives of FDA to make at any reasonable time such inspection of the establishment in which shell eggs are being held, including inspection and sampling of the labeling of such eggs as may be necessary in the judgment of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(9) No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement requiring safe handling instructions on unpasteurized shell eggs that are less stringent than those required in paragraphs (h)(1) through (h)(5) of this section.

[42 FR 14308, Mar. 15, 1977, as amended at 42 FR 22033, Apr. 29, 1977; 49 FR 13690, Apr. 6, 1984; 49 FR 28548, July 13, 1984; 61 FR 20100, May 3, 1996; 62 FR 2249, Jan. 15, 1997; 63 FR 8118, Feb. 18, 1998; 63 FR 37055, July 8, 1998; 63 FR 63982, Nov. 18, 1998; 66 FR 17358, Mar. 30, 2001; 65 FR 76111, Dec. 5, 2000]

§ 101.18 Misbranding of food.

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(c) Among representations in the labeling of a food which render such food misbranded is any representation that expresses or implies a geographical origin of the food or any ingredient of the