milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* * * *

(d) *Other optional ingredients.* * * *

(e) *Methods of analysis.* * * *

(f) *Nomenclature.* * *

(1) * * *

(iii) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit".

* * * * *

(g) *Label declaration.* * * *

Any person who will be adversely affected by the foregoing amendments to the final regulation, published in the January 30, 1981 Federal Register (46 FR 9924), may at any time on or before October 21, 1982, submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to the amendment that may be stayed by the filing of proper objections, compliance with these amendments to the final regulations may begin November 22, 1982. The mandatory compliance date for the provisions that are revised in this document shall be July 1, 1985. Notice of the filing of objections or lack thereof will be published in the Federal Register. Accordingly, except as to those provisions being herein amended and the provisions listed above as stayed, the effective date of §§ 131.111, 131.112, 131.136, 131.138, 131.143, 131.144, 131.148, 131.170, 131.200, 131.203, and 131.206 as published in the Federal Register of January 30, 1981 (46 FR 9924) is confirmed as follows: Compliance with this regulation, including any required labeling changes, may have begun on March 31, 1981 and all affected products initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply.

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: September 14, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-25781 Filed 9-20-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 135

[Docket No. 79P-0441]

Frozen Desserts; Standards of Identity for Goat's Milk Ice Cream, Goat's Milk Frozen Custard, and Goat's Milk Ice Milk

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing standards of identity for goat's milk ice cream, goat's milk frozen custard, and goat's milk ice milk by cross-reference to the standards of identity for ice cream and frozen custard and for ice milk. This action will provide for the manufacture of ice cream, frozen custard, and ice milk from goat's milk, which consumers may use as alternatives to products made from cow's milk.

DATES: Effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance may begin November 22, 1982; objections by October 21, 1982.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 8, 1981 (46 FR 60007), FDA published a proposal to establish standards of identity for goat's milk ice cream and goat's milk frozen custard (21 CFR 135.115) and goat's milk ice milk (21 CFR 135.125) cross-referenced to the standards of identity for ice cream and frozen custard (21 CFR 135.110) and ice milk (21 CFR 135.120), respectively. The proposal allowed for the filing of comments by February 8, 1982.

Five comments were received in response to the proposal. The comments and the agency's response are discussed below.

1. Several comments requested that the concentrated and dry forms of goat's milk and goat's cream also be permitted in addition to the liquid form.

FDA advises that any of the dairy ingredients permitted in § 135.115(b) may be used in liquid, concentrated, or dry form. To clarify this issue, FDA is revising § 135.115(b) to read "The optional dairy ingredients referred to in paragraph (a) of this section are goat's skim milk, goat's milk, and goat's cream. These optional dairy ingredients may be used in liquid, concentrated, and/or dry form."

2. One comment suggested that goat's milk-derived ingredients, such as whey, caseinates, and coprecipitates of goat's milk protein, be added to the list of optional dairy ingredients that may be used. The comment stated that these ingredients are not now available, but providing for their use now will eliminate the need for amendments at a later date when the ingredients do become available.

FDA cannot approve the use of ingredients before they are actually developed because there are no data with which to establish whether they are safe and suitable. As new goat's milk-derived ingredients are developed and demonstrated to be suitable ingredients, interested persons may submit petitions to amend the standards of identity to provide for their use.

3. One comment suggested that the name of the food be changed from "goat's milk ice cream" to "goat ice cream" because inclusion of the word "milk" may mislead consumers about the nature of the product. The comment also stated that the proper designation should be "goat milk" rather than "goat's milk".

FDA believes the name "goat ice cream" is potentially more confusing than the name "goat's milk ice cream" and, therefore, is not making the suggested change. It is not clear to the agency how inclusion of the word "milk" in the name of the food could mislead consumers since the food is made from goat's milk and/or components of goat's milk. FDA also rejects the suggestion that "goat's milk" be referred to as "goat milk" instead, because the possessive form is the commonly recognized mode of

designating the source of various milks, e.g., cow's milk, sheep's milk.

4. One comment suggested permitting the use of 50 percent cow's milk and 50 percent goat's milk in the manufacture of ice cream. No data or information were submitted to indicate the use or need for such provisions.

In light of the fact that there are no data upon which to base this change, FDA is not providing for the use of combinations of goat's and cow's milks in the making of ice cream. Furthermore, one of the reasons given by the petitioner for establishing a standard for goat's milk ice cream was to increase the number of products available to consumers who are unable to tolerate products made with cow's milk and to do otherwise would defeat this purpose.

After considering the comments received, FDA concludes that it will promote honesty and fair dealing in the interests of consumers to establish standards of identity for goat's milk ice cream, goat's milk frozen custard, and goat's milk ice milk, as set forth below.

List of Subjects in 21 CFR Part 135

Food standards, Frozen desserts, Ice cream.

PART 135—FROZEN DESSERTS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 135 is amended by adding new §§ 135.115 and 135.125 to read as follows:

§ 135.115 Goat's milk ice cream.

(a) *Description.* Goat's milk ice cream is the food prepared in the same manner prescribed in § 135.110 for ice cream, and complies with all the provisions of § 135.110, except that the only optional dairy ingredients that may be used are those in paragraph (b) of this section; caseinates may not be used; and paragraphs (e)(1) and (f) of § 135.110 shall not apply.

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are goat's skim milk, goat's milk, and goat's cream. These optional dairy ingredients may be used in liquid, concentrated, and/or dry form.

(c) *Nomenclature.* The name of the food is "goat's milk ice cream" or, alternatively, "ice cream made with goat's milk", except that when the egg yolk solids content of the food is in excess of that specified for ice cream in paragraph (a) of § 135.110, the name of the food is "goat's milk frozen custard" or, alternatively, "frozen custard made with goat's milk", or "goat's milk french ice cream", or, alternatively, "french ice cream made with goat's milk", or "goat's milk french custard ice cream", or, alternatively, "french custard ice cream made with goat's milk".

(d) *Label declaration.* Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

§ 135.125 Goat's milk ice milk.

(a) *Description.* Goat's milk ice milk is the food prepared in the same manner prescribed in § 135.115 for goat's milk ice cream, except that paragraph (c) shall not apply, and which complies with all the requirements of § 135.120(a) (1), (2), (4), (5), (6), and (7) for ice milk.

(b) *Nomenclature.* The name of the food is "goat's milk ice milk" or, alternatively, "ice milk made with goat's milk".

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 21, 1982 submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the hearing of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date: Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin November 22, 1982, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985, shall fully comply. Notice of the filing of objections or lack thereof will be published in the **Federal Register.**

(Secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: September 13, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-25716 Filed 9-20-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR PART 145

[Docket No. 78N-0138]

Canned Pears; Standard of Quality

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standard of quality for canned pears in consideration of the quality provisions of the Recommended International Standard for Canned Pears developed by the Codex Alimentarius Commission and requests by the Canners League of California and the United States Department of Agriculture. This action will promote honesty and fair dealing in the interest of consumers and facilitate international trade.

DATES: Effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance may begin November 22, 1982. Objections by October 21, 1982.

ADDRESS: Written objections are to be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Bureau of Foods (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1164.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 25, 1978 (43 FR 32143), FDA published a proposal to amend the standard of quality for canned pears in § 145.175(b) (21 CFR 145.175(b)) in consideration of the quality provisions of the Recommended International Standard for Canned Pears (Codex standard) developed by the Codex Alimentarius Commission. The comment period was extended until January 23, 1979, in the **Federal Register** of January 9, 1979 (44 FR 1983).

Comments were received from two trade associations representing canners

of pears. The comments and FDA's responses are as follows:

1. One comment recommended eliminating the minimum size requirements for halves and quarters styles of canned pears because they are not in the Codex standard.

The basis for retaining the current minimum size requirements for canned pear halves and quarters was fully discussed in the preamble to the July 25, 1978 proposal. In response, no comments submitted information to show that the current U.S. minimum size requirements for canned pears are incompatible with the promotion of honesty and fair dealing in the interest of consumers. In the absence of such information, FDA concludes that the minimum size requirements for halves and quarters styles of canned pears are reasonable and retains them as part of the standard of quality for canned pears in § 145.175(b)(1)(ii).

2. Two comments characterized as "arbitrary" the agency's reliance upon certain of the more restrictive provisions of the Codex standard, the U.S. standard, or the U.S. Department of Agriculture (USDA) voluntary grade standards. The comments requested that the agency reconsider its position.

The agency has reconsidered its positions on the provisions at issue. With regard to the requirements for peel, FDA proposed adopting the Codex provision which allows an average of 10 square centimeters of peel, adhering to pears or loose in the container, per kilogram (1.6 square inches per 35.3 ounces) of net weight. FDA recognizes that the Codex provision for peel is more restrictive than the U.S. and USDA requirements which permit an average of 1 square inch of peel per 16 ounces (14 square centimeters per kilogram) of net contents. However, the Codex requirements reflect a minimum level of quality considered by the international community to be acceptable for canned pears. Comments have failed to submit any information that (1) shows that the Codex provisions being adopted are unreasonable or (2) supports the adoption of a requirement other than one based on the Codex. Therefore, FDA adopts the Codex provision for § 145.175(b)(1)(iv).

With regard to crushed or broken units, FDA proposed retaining the more restrictive U.S. requirement which states in § 145.175(b)(1)(vii) that, except in the case of mixed pieces of irregular sizes and shapes, not more than 10 percent by count of the units in containers of 10 or more units and not more than 1 unit in containers of less than 10 units are crushed or broken. The U.S. standard also provides that a unit which has lost its shape because of ripeness and bears no mark of crushing shall not be considered crushed or broken.

FDA is retaining the current U.S. provision for crushed or broken units because it reflects a level of quality consumers for many years have come to expect for canned pears in the United States.

The agency has also reassessed its position on the more restrictive proposed provisions for seeds and harmless plant materials. In both instances, FDA had proposed adopting the more restrictive USDA requirements. USDA allows an average of one loose seed per 10 ounces net contents (equivalent to an average of 3.5 seeds per 35.3 ounces (1 kilogram) of net weight or approximately 10.5 seeds in a No. 10 can). The more restrictive USDA standards are voluntary grade standards that are used for grading purposes at the request of industry. Based on this fact and comments received, FDA concludes that the Codex requirement for seeds more nearly reflects a level of quality acceptable to consumers in the United States as well as the rest of the world. Therefore, FDA is adopting the Codex requirement in § 145.175(b)(1)(x) for seeds which allows an average of 8 seeds per kilogram (35.3 ounces) of total contents, except in uncored pears. This is approximately 24 seeds in a No. 10 can.

For harmless plant materials, USDA allows one external pear stem per 100 ounces (2,857 grams of net weight which is approximately one stem per No. 10 can (3.09 kilograms or 109 ounces). Codex limits harmless plant material, including leaf or similar vegetable material and stems in styles in which the stem is customarily removed, to 0.2 percent by weight of total contents. This would allow approximately 10 stems, 3 to 4 centimeters long, in a No. 10 can of pears. FDA believes that the Codex provision permits excessive amounts of harmless plant materials in canned pears. In fact, the United States has proposed an amendment to the Codex standard to lower the limit for harmless plant material to the level provided for in the USDA voluntary grade standards. Under these circumstances, FDA believes that it is prudent to delay establishing a limit for harmless plant material until the Codex Alimentarius Commission has had an opportunity to consider and act on the proposed revision of the Codex standard. Therefore, FDA is not establishing a requirement for harmless plant material.

3. One comment stated that weight and diameter relationships on uniformity of size for halves and quarters styles of pears have been studied in the Northwestern States, and data collected indicate that the uniformity of size requirement should be based on diameter rather than weight. The comment added that supporting data will be submitted in conjunction with a petition to amend the uniformity of size requirement. A second comment also stated that work is being done on weight and diameter relationships for halves and quarters units. When this work is completed, submission of a petition will be considered.

FDA has obtained data only for the 1978 packing season in California on the diameter-weight relationships for uniformity of size for pear halves. In view of the limited data available at this time, the agency is not amending the standard of quality for canned pears to change the requirement for uniformity of size in whole, halves, and quarters styles from a weight to a diameter basis. The agency will review the need for and appropriateness of this and other such requirements when the regulation is subjected to the retrospective review mandated by the Regulatory Flexibility Act of 1980.

4. One comment suggested that § 145.175(b)(1)(vi) be clarified by adding the words "of the unit" to read as follows: "In the case of whole, halves, and quarters styles, all units are untrimmed or are so trimmed as to preserve normal shape of the unit."

FDA concurs, and the final regulation has been changed accordingly.

FDA notes that the current standard of quality for canned pears states in § 145.175(b)(3) that the alternative label statement of substandard quality, that is, "Not tender," "Blemished," etc., "shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name 'pears' and any words and statements required or authorized to appear with such name by paragraph (a)(2) of this section." This statement was omitted in the July 25, 1978 proposal. That the omission was inadvertent is obvious. Accordingly, in light of the fact that any prejudice caused by the omission is remote, the agency is including the statement in the final regulation in § 145.175(b)(4).

FDA is changing paragraph (b)(1)(iii) to (b)(1)(iii)(*a*) and (b)(4)(iii) to (b)(4)(iii)(*a*) to be consistent with the format of the final rule for "chunky" style pears which is published elsewhere in this issue of the **Federal Register**. Certain other editorial changes are also made for clarification in the final regulation.

In consideration of the quality aspects of the Codex standard, together with

comments received in response to the proposal, FDA concludes that it will promote honesty and fair dealing in the interest of consumers to amend the standard of quality for canned pears as set forth below.

List of Subjects in 21 CFR Part 145

Canned fruit, Canned pears, Food standards, Fruits.

PART 145—CANNED FRUITS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 361(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 145 is amended in § 145.175 by revising paragraph (b) to read as follows:

§ 145.175 Canned pears.

* * * * *

(b) *Quality.* (1) The standard of quality for canned pears is as follows:

(i) *Maturity.* All units tested in accordance with the method prescribed in paragraph (b)(2) of this section are pierced by a weight of not more than 300 grams (10.6 ounces).

(ii) *Minimum size.* In the case of halves and quarters styles, the weight of each unit is not less than 17 grams (0.6 ounce) and 8.5 grams (0.3 ounce), respectively.

(iii) *Uniformity of size—(a) Whole, halves, and quarters.* In the case of whole, halves, and quarters styles, among those units comprising 95 percent by count of those present in the container that are most uniform in size, the weight of the largest unit is not more than twice the weight of the smallest unit. In containers with fewer than 20 units, 1 unit may be disregarded in making the determination. Where a unit has broken in the container, reassemble the broken pieces to approximate a single unit of the appropriate style.

(*b*) [Reserved]

(iv) *Peel (except unpeeled style).* Not more than 10 square centimeters (1.6 square inches) of peel adhering to pears or loose in the container per kilogram (35.3 ounces) of net weight.

(v) *Blemished units.* Not more than 20 percent by count of the units in the container are blemished with scab, hail injury, discoloration, or other abnormality aggregating the area of a circle more than 6.5 millimeters (0.25 inch) in diameter; corky or hard spots on outer surfaces aggregating the area of a circle more than 13 millimeters (0.51 inch) in diameter; or dark brown areas aggregating the area of a circle less than 6.5 millimeters (0.25 inch) in diameter which penetrate into the flesh or affect the appearance of the unit.

(vi) *Trimmed units.* In the case of whole, halves, and quarters styles, all units are untrimmed or are so trimmed as to preserve normal shape of the unit.

(vii) *Crushed or broken units.* In the case of whole, halves, quarters, slices, and dice styles, not more than 10 percent by count of the units in containers of 10 or more units and not more than 1 unit in containers of less than 10 units are crushed or broken. A unit that has lost its normal shape because of ripeness and bears no mark of crushing shall not be considered to be crushed or broken.

(viii) *Loose core material in all styles except uncored whole style.* Not more than two units of loose core material per kilogram (35.3 ounces) of net weight. A unit of such material is defined as a portion of loose core, with or without seeds, aggregating approximately one-half of a pear core.

(ix) *Partially cored units in all styles except uncored whole style.* Not more than 40 percent by count partially cored units in halves, quarters, slices, and pieces or irregular pieces styles and not more than 5 percent by weight in dice style. A partially cored unit is a unit of pear that contains an attached portion of the seed cell cavity.

(x) *Seeds in all styles except whole uncored style.* Not more than 8 seeds or the equivalent in pieces of seeds per kilogram (35.3 ounces) of net weight. Seeds included as cored material in paragraph (b)(1) (viii) and (ix) of this section shall not be counted a second time.

(2) Canned pears shall be tested by the following method to determine whether they meet the requirements of paragraph (b)(1)(i) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of 28.6 millimeters (1.12 inches) inside diameter, with vertical sides; or rectangular in shape, 19 millimeters (0.75 inch) by 25.4 millimeters (1 inch) inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of 19 millimeters (0.75 inch). Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with rectangular peel surface at least 13 millimeters (0.51 inch) by 25.4 millimeters (1 inch) cannot be trimmed. Test the piece by means of a round metal rod 4 millimeters (0.16 inch) in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by the support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams (3.5 ounces). Set the receptacle so that the surface of the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams (0.42 ounce) per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(3) Determine compliance as specified in § 145.3(o) except that a lot shall be deemed to be in compliance for peel in all styles except unpeeled styles and seeds in all styles except whole uncored style based on the average of all samples analyzed according to the sampling plans set out in § 145.3(p).

(4) If the quality of canned pears falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned pears falls below standard with respect to only one of the factors of quality specified in paragraph (b)(1) (i) through (x) of this section, there may be substituted for the second line of such general statement of substandard quality ("Good Food—Not High Grade") a new line, as specified after the corresponding designation of paragraph (b)(1) of this section which the canned pears fail to meet, as follows:

(i) "Not tender";

(ii) "Small halves" or "small quarters", as the case may be;

(iii)(*a*) "Mixed sizes";

(*b*) [Reserved];

(iv) "Excessive peel";

(v) "Blemished";

(vi) "Unevenly trimmed";

(vii) "Partly crushed or broken";

(viii) "Excessive core";

(ix) "Excessive core";

(x) "Excessive seeds".

Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "pears" and any words and statements required or authorized to appear with such name by paragraph (a)(2) of this section.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 21, 1982 submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin November 22, 1982, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985, shall fully comply. Notice of the filing of objections or lack thereof will be published in the **Federal Register.**

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: September 14, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-25711 Filed 9-20-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 145

[Docket No. 78P-0147]

Canned Pears; Standards of Identity and Quality

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standards of identity and quality to provide for a new style of pears designated as "chunky" and to define the styles already provided for in the standard of identity. This action will promote honesty and fair dealing in the interest of consumers.

DATES: Effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance may begin November 22, 1982. Objections by October 21, 1982.

ADDRESS: Written objections are to be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Bureau of Foods (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1164.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 1, 1979 (44 FR 31669), FDA published a proposal to amend the standards of identity and quality for canned pears to provide for a new optional style of pears designated as "chunky". The proposal was based on a petition submitted by Libby, McNeill and Libby, Inc. The agency also proposed, on its own initiative, to define the styles already provided for in the standard of identity for canned pears, to be consistent with those currently provided for in the standard of identity for canned peaches in § 145.170 (21 CFR 145.170) and in the Recommended International Standards (Codex standards) for canned pears and for other canned fruits.

Three letters, each containing one or more comments, were received in response to the proposal. One comment supported the proposal. The remaining comments and FDA's responses are as follows:

1. Two comments recommended eliminating the dimension requirements from the definition of "chunky" style pears. One comment suggested that the style be defined as "consisting of peeled pears, with cores removed, and cut into random size pieces." The comment added that this would make clear the distinction between "chunky" style and other styles. A second comment recommended defining chunky style pears as "consisting of peeled pears, with cores removed, and cut into pieces, other than provided in paragraphs (ii), (iii), (iv), and (v) of this section, which may or may not be symmetrical or uniform in shape and size, and conforms to § 145.175(b)(1)(viii)." Paragraph (a)(2)(ii), (iii), (iv), and (v) refers to halves, quarters, slices, and dice styles, respectively. The comment asserts that this is intended for clarification and to provide a definition of the style "chunky" which conforms to the generic-type definition of the other styles of canned pears. The comment also stated the purpose of referencing the styles halves, quarters, slices, and dice is to distinguish clearly "chunky" from the more uniform styles.

FDA does not agree with these suggested changes. FDA advises that establishing dimension requirement in the definition of "chunky" style pears is consistent with a comparable style, "chunks", provided for in the standard of identity for canned pineapple (21 CFR 145.180(a)). FDA believes that the style "chunky" pears would not be clearly defined in relation to the style "pieces or irregular pieces" as provided for in § 145.175(a)(2)(vi) without size specifications. The generic-type definition referred to in the comments seems applicable only to such clearly identifiable styles as halves, quarters, slices, and dice. Therefore, FDA concludes that the proposed dimension requirements are reasonable and is so providing in § 145.175(a)(2)(vii).

2. Two comments recommended that the regulation state that not more than 25 percent of the drained weight of the contents of the container consists of units that will pass through an opening 13 millimeters (0.51 inch) wide or that are more than 44 millimeters (1.75 inches) along the longest cut edge. The purpose of this suggested change is to base compliance on the weighing of units that will pass through a one-half inch wide linear opening "when presented to the opening from all possible orientations or profiles."

FDA agrees with this suggestion and has incorporated the recommended change in § 145.175(b)(1)(iii)(*b*).

FDA is renumbering proposed paragraphs (b)(1)(viii) and (b)(3)(viii) to provide for "chunky" style pears in (b)(1)(iii)(*b*) and (b)(4)(iii)(*b*), respectively. This action will incorporate "chunky" pears into the format of a final regulation considering the quality provisions of the Recommended International Standard