products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1981 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: June 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-19080 Filed 6-26-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 146

[Docket No. 78P-0039]

Canned Fruit Juices; Lemon Juice; Standards of Identity and Fill of Containers; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Confirmation of effective date.

SUMMARY: This document confirms the effective date for compliance with the standards of identity and fill of container for lemon juice that were published in the **Federal Register** of February 5, 1980 (45 FR 7784).

DATES: Effective July 1, 1981 for all affected products initially introduced into interstate commerce on or after that date. Voluntary compliance may have begun March 7, 1980.

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: A final regulation establishing standards of identity and fill of container for lemon juice (21 CFR 146.114) was published in the **Federal Register** of February 5, 1980 (45 FR 7784). The final regulation provided that any person who would be adversely affected could at any time, on or before March 6, 1980, file written objections to the final regulation and request a hearing on the specific provisions to which there were objections. No objections have been filed.

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 5.1), notice is given that § 146.114 *Lemon juice* (21 CFR 146.114) as promulgated in the **Federal Register** of February 5, 1980 (45 FR 7784) will become effective July 1, 1981. Voluntary compliance may have begun March 7, 1980.

Dated: June 20, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-19324 Filed 6-26-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 155

[Docket No. 75P-0322]

Canned Peas and Canned Dry Peas; Standards of Identity, Quality, and Fill of Container

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the standards of identity, quality, and fill of container for canned peas and, by cross-reference, for canned dry peas by, among other things, (1) providing for specified nutritive carbohydrate sweeteners; (2) providing for garnishes of other vegetables; (3) continuing to permit artificial color to be used, but requiring declaration as part of the name of the food instead of a label statement of substandard quality; (4) establishing a limit for blond and yellow peas; and (5) employing statistical sampling plans as a basis for determining compliance with quality and fill requirements. This action is for the purpose of promoting honesty and fair dealing in the interest of consumers and facilitating international trade.

DATES: Effective July 1, 1981 for all affected products intially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance: August 26, 1980. Objections by: July 28, 1980.

ADDRESS: Written objections to the Hearing Clerk (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: The Food and Drug Administration (FDA) published a proposal in the **Federal Register** of June 7, 1977 (42 FR 29014) to amend the U.S. standards of identity, quality, and fill of container for canned peas (21 CFR 155.170) and canned dry peas (21 CFR 155.172), to adopt, insofar as practicable, both the Recommended International Standards for Canned Green Peas (Codex standard) and a proposal by the Corn Refiners Association, 1001 Connecticut Ave. NW., Washington, DC 20036. The agency also proposed a definition section (21 CFR 155.3) setting out a sampling and acceptance procedure for canned vegetables. Further, the agency proposed editorial amendments to the standards of quality for canned green beans and canned wax beans (21 CFR 155.120), and standards of quality and fill of container for canned corn (21 CFR 155.130) and canned tomatoes (21 CFR 155.190) to delete the sampling and acceptance procedure appearing in each of those standards and to reference the sampling and acceptance procedure proposed for the definition section for Part 155—Canned Vegetables.

Comments were received from six consumers, an association representing consumers, two canners, two trade associations representing canners of canned peas, and a food chain. No adverse comments were received concerning the proposed editorial amendments regarding canned green beans and canned wax beans, canned corn, and canned tomatoes. The comments and the agency's responses are given below:

Percentage Labeling of Ingredients

1. One comment favored label declaration of the percentage of ingredients, especially salt and sugar, because of a personal problem with hypoglycemia (low blood sugar).

FDA, the U.S. Department of Agriculture (USDA), and the Bureau of Consumer Protection of the Federal Trade Commission (FTC) held a series of five public hearings between August 1978 and October 1978 to discuss various food labeling issues. FDA also sponsored in 1978 a survey of food shoppers to obtain information on their views of certain aspects of food labeling. On the basis of the information obtained and their review of current regulatory laws and policies, the agencies have developed tentative positions on various food labeling issues including percentage ingredient labeling that were set out in a notice published in the **Federal Register** of December 21, 1979 (44 FR 75990). For this reason, it is premature to provide for percentage ingredient labeling in the regulations set out below.

Flavorings and Flavor Enhancers

2. One comment opposed the provisions for the optional addition of salt, monosodium glutamate, disodium inosinate, disodium guanylate, hydrolyzed vegetable protein, autolyzed yeast extract, spice, and natural flavorings to canned peas. It stated that the only purpose of the ingredients is to

disguise the "true flavor" of the peas, and consumers who want flavored canned peas can add the flavors. The addition of "sodium ingredients," the comment stated, "is contrary to medically sound policy and may contribute to hypertension."

FDA notes that these ingredients are already provided for in the present standard of identity for canned peas and, when used, the label statement of ingredients alerts consumers that such ingredients are present. The agency further notes that canned peas without such added ingredients are available in the so-called "dietetic" sections of food stoes. Therefore, FDA concludes that the standards for canned peas and canned dry peas should continue to provide for these ingredients and has so provided in the regulations as set out below in 21 CFR 155.170(a)(2) and, by cross-reference, in 21 CFR 155.172(a).

Nutritive Carbohydrates Sweeteners

3. One comment said that the amendment to provide for the optional use of any safe and suitable nutritive carbohydrate sweetener in lieu of specifying a limited number of specific sweeteners is against the "stated wishes of consumers." A second comment urged that the standard permit no added sweeteners on the basis that wrinkled peas have a natural sweetness and early, June, or early June peas are not particularly sweet but have a unique flavor of their own. The comment believed that the added sweetener gives the consumer a product other than the natural product. The comment further stated that since the peas may absorb some of the added sweetener, the caloric content of the peas may be increased. However, the comment continued, should FDA decide to permit added sweetener, the standard should specify the particular sweeteners that may be used. A third comment said corn sweeteners are a good, inexpensive product; but amendment of the standard to allow the optional use of such sweeteners could cause a dramatic upheaval in the sugar market and force the government to purchase tremendous amounts of sugar as price supports. This would not happen "just from peas but surely other vegetables would not be far behind."

The comment referring to the proposed provision for the optional use of safe and suitable nutritive carbohydrate sweeteners as being against the "stated wishes of consumers" was unsupported by documentation or data. The agency agrees that consumers generally are opposed to unnecessary added ingredients. However, it is not aware that consumers consider as unnecessary the use of nutritive carbohydrate sweeteners in the amounts generally added by manufacturers to canned peas. The agency notes that sweeteners have long been considered to be suitable ingredients for canned peas and other canned vegetables and have not been limited to any maximum amount. Further, it notes that the standards of identity for canned green beans and canned wax beans (21 CFR 155.120(a)) and canned corn (21 CFR 155.130(a)) provides for the use of safe and suitable nutritive carbohydrate sweeteners while the standard for "certain other canned vegetables" (21 CFR 155.200(a)) provides for the use of corn sweeteners in addition to sucrose. Therefore, FDA concludes that it is reasonable to provide for nutritive carbohydrate sweeteners. The agency maintains that food standards should provide, whenever possible, for classes of permitted functional optional ingredients so that manufacturers will have flexibility in the selection of specific ingredients used in foods. If the ingredient is unsafe, it may not be used. However, based on information resulting from the series of public hearings held between August 1978 and October 1978, it now appears that consumers desire a specific listing, by name, in food standards of those ingredients which characterize the food rather than simply a general provision for the use of "safe and suitable" ingredients. A notice requesting public comment on a tentative proposed revision of the agency's policy regarding the use of "safe and suitable" provisions in food standards was published in the **Federal Register** of December 21, 1979 (44 FR 75990). Consistent with consumer desire, FDA is therefore listing in the final regulations set out below the individual nutritive carbohydrate sweeteners that may be used. The agency requests comments about the completeness of the list. Comments should be submitted to the Hearing Clerk during the period for objections. If any commonly used nutritive carbohydrate sweeteners have been omitted, they will be included in the notice confirming the effective date of the final regulation.

The agency is aware that some individuals may prefer unsweetened canned peas. However, it points out that whenever a sweetener is used, it must be declared in the ingredient statement by its common or usual name, thus alerting consumers to its presence. Concerning the comment about an increase in the caloric content of canned peas resulting from added sweetener, the agency points out that the sweetener is not added in sufficient amount to decrease the nutritional value or to significantly increase the caloric content since such an amount would produce a product not organoleptically acceptable to the consumer. However, those who wish to avoid high calorie foods may do so by seeking out foods which bear nutritional labeling and/or foods to which no sweetener has been added. Concerning the comment about the possible increase in price supports in the sugar market resulting from providing for the optional addition of corn sweeteners to canned peas, the agency has not been provided with data on the costs involved. In any event, it has no authority to prohibit a safe and suitable ingredient simply because it has a price advantage over a competing ingredient.

Color Additives

4. Three comments favored and four comments opposed the proposal to delete the requirement that artificially colored peas be labeled "Below standard in quality artificially colored" and to require that, if any color additive has been added, the name of the food shall include the term "artificially colored." One comment stated that the provision to allow the addition of added artificial colors is against the "stated wishes of consumers." A second comment stated that the only purpose for artificially coloring peas is to deceive consumers as to the quality of the peas since off-color is considered a defect by the U.S. and Codex standards. There is no assurance, the comment stated, that the proposal will inform consumers that artificially colored canned peas are below standard in quality. A third comment stated that consumer acceptance of canned peas may be affected by "unusual color hues" produced by the coloring agents. The comment did not define the term "unusual color hues."

The agency points out that the present standard of identity for canned peas provides for the use of artificial color, and the only change proposed was to delete the provision in the standard of quality which requires that when artificial color is present, the label shall bear the statement "Below standard in quality artificially colored," and instead require that when artificial color is used the name of the food shall include the term "artificially colored." Such labeling is a more direct method of informing the consumer that color has been added. Further, canned peas, regardless of whether they would be artifically colored, are required to comply with the standard of quality. The comment referring to the provision to allow the

addition of artificial color as being against the "stated wishes of consumers" was unsupported by documentation or data. As stated in comment 3 above, the agency agrees that consumers generally are opposed to unnecessary added ingredients. However, the agency is unaware that consumers consider as unnecessary the use of color additives in the amounts generally added by manufacturers to canned peas. The agency is of the opinion that the use of suitable artificial colors would not mask off-color peas and would not produce "unusual color hues" in artificially colored canned peas. FDA concludes that color additivies are suitable ingredients of canned peas and canned dry peas and has so provided in 21 CFR 155.170 (a)(2)(x) and, by cross-reference, in 21 CFR 155.172(a) of the regulations as set out below.

Calcium Salts

5. One comment stated that allowing the addition of calcium salts is against the "stated wishes of consumers."

The agency notes that the comment was unsupported by documentation or data. As stated in comment 3 above, the agency agrees that consumers generally are opposed to unnecessary added ingredients. However, the agency is unaware that consumers consider as unnecessary the use of calcium salts in the amounts that would be generally added by manufacturers to canned peas. The agency proposed to provide for the optional use of any safe and suitable calcium salts as firming agents on the basis that in the occasional instances where very soft water is used for washing, blanching, and processing, the peas may become somewhat mushy unless firming agents are used. The agency believes that there is a technologically valid use for calcium salts as firming agents in canned peas under the conditions described. The agency points out that when a calcium salt is used, it must be declared on the label by its common or usual name, thus alerting the consumer to its presence. FDA concludes that calcium salts are suitable ingredients for use in canned peas and, therefore, has so provided in 21 CFR 155.170(a)(2)(xi) and, by cross-reference, in 21 CFR 155.172(a) of the regulations as set out below.

Seasonings and Garnishes

6. One comment stated that the provision allowing the addition of garnishes is against the "stated wishes of consumers." A second comment stated that a regulation should be written to assure Grade A products and to assure that the market is not flooded with canned peas containing low quality mixtures of granishes.

The comment referring to the provision to allow the addition of garnishes as being against the "stated wishes of consumers" was unsupported by documentation or data. As stated in comment 3 above, the agency agrees that consumers generally are opposed to unnecessary added ingredients. However, the agency is unaware that consumers consider as unnecessary the use of garnishes in the amount that generally would be added by manufacturers to canned peas. The agency notes that the present standard of identity for canned peas provides for green or red peppers, onions, garlic, and horseradish as seasonings. As stated in the preamble to the proposal, the agency is of the opinion that providing for suitable seasoning agents and garnishes in reasonable proportions as provided for by the Codex standard will afford the consumers a wider choice of products in the marketplace. Further, the proposed regulations would require the declaration, as part of the name or in close proximity to the name of the food, of any seasoning or garnishing that characterizes the food. Therefore, FDA concludes that it is reasonable to provide for seasonings and garnishes as proposed and has so provided in 21 CFR 155.170(a)(2)(xii) and, by cross-reference, in 21 CFR 155.172(a) of the regulations as set out below. The agency points out that authority under the Federal Food, Drug, and Cosmetic Act is limited to establishing minimum standards of quality and that voluntary grade standards which would identify Grade A products are established by the U.S. Department of Agriculture.

Designation of Sweet Peas as "Green"

7. One comment from a trade association stated that there is substantial consensus among its member companies opposing the use of the term "green" for label designation to distinguish sweet-type peas from Alaska-type peas.

The agency has reconsidered its proposal to restrict use of the term "green" to the sweet wrinkled varieties. FDA concludes that the word "green" is descriptive of both the the sweet wrinkled varieties and smooth-skin varieties, or hybrids thereof, and, therefore, has provided for such optional use in 21 CFR 155.170(a)(3)(i) of the regulation as set out below.

Petit Pois

8. Three comments opposed the provision that the term "petit pois" may be used when an average of 80 percent or more of the peas will pass through a circular opening of a diameter of 8.75 millimeters (0.34 inch) for sweet green wrinkled peas and 8.2 millimeters (0.32 inch) for smooth-skin or substantially smooth-skin peas, such as Alaska-type peas. One comment said the term "petit pois" should continue to be permitted in the labeling of peas that will pass through a circular opening with a diameter of 7.1 millimeters (0.28 inch) (commonly referred to as a No. 1 sieve) in that consumers recognize the term as meaning very small peas. A second comment stated that, in a survey, four companies favored the proposal, 14 opposed it, and one had no opinion. The comment said there is a difference of opinion whether the term should be limited to peas that will pass through a No. 1 sieve or to peas that will pass through both No. 1 and No. 2 sieves. The comment concluded, however, that there is no justification for allowing "petit pois" to be used for larger size peas of one varietal type than another. The third comment said the majority of the industry favors restricting the use of the term "petit pois" to peas that will pass through a No. 1 sieve with an allowance for peas of the No. 2 sieve size.

The agency has reconsidered its proposal and concludes that the term "petit pois" may be used in conjunction with the product name only when an average of 80 percent or more of the peas will pass through a circular opening of 7.1 millimeters (0.28 inch). FDA has so provided in the regulation as set out below (21 CFR 155.170(a)(3)(i)).

Quality Standard

9. Four comments were concerned with the 12-percent total defect limitation for "defective" peas in canned peas. One of these comments expressed concern that the proposal would lower the quality of canned peas and stated that there should be no allowance for defective peas. Two of the comments were concerned that the proposal provided for an increase in defective peas.

It was the intent of the agency in the June 7, 1977 proposal to adopt the most stringent, reasonable criteria for ensuring the quality of canned peas. The agency recognizes that it is impractical to produce canned peas completely free of defects such as blond and yellow peas, blemishes, pea fragments, and extraneous vegetable material (vine, leaf or pod material). Therefore, both the existing standard and the proposed amendment set out maximum levels for specific defects. In addition, the proposed amendment provides for a total maximum defect level of 12 percent if the specific defect levels are not

exceeded. It is the agency's opinion that this 12-percent defect level will result in higher quality canned peas than required by the present standard, which does not provide for a cumulative maximum defect level. When any of the defect levels are exceeded, the standard (21 CFR 155.170(b)(3)) requires that the label show that the product is below standard in quality. FDA concludes that the limitation of 12 percent for total defects including blond and yellow peas, blemishes, pea fragments, and extraneous vegetable material is in the interest of consumers and has so provided in 21 CFR 155.170(b)(1)(vii) of the regulation as set out below.

Blond and Yellow Peas

10. Three comments opposed the provision that not more than 2 percent of the drained weight may be blond peas, i.e., yellow or white edible peas. One comment stated that blond peas do not detract from the wholesomeness of the product. A second comment said that in a survey, five companies favored the proposal, 12 opposed it, and two had no opinion. Included in the comment was a statement that "Blond peas, as we know them, (strictly as color mutations) are entirely different from yellow peas found in foreign canned peas." The agency understands from subsequent conversations related to this comment, copies of memoranda of which are on file with the Hearing Clerk, that blond peas have not been a problem to the extent that they would exceed the proposed 2-percent limitation. However, it was stated that a potential problem may exist where there is heavy vine growth which tends to prevent the pods from receiving adequate sunlight. As a result, there is a greater chance of the pods containing some blond peas, i.e., peas without sufficient chlorophyll. The second comment further questioned why there should be any limitation on blond peas and stated that the 2-percent limitation should be for yellow mature (not succulent) peas. The third comment suggested that 21 CFR 155.170(b)(1)(i) should be revised to make it consistent with the Codex standard. It stated that, in industry, blond peas lack chlorophyll, and are generally young peas with typical flavor that result from uncontrollable growing conditions and are impractical to remove in the canning process. However, yellow peas, the comment continued, can be considered "a true defect" since they are overmature peas of yellow seeded varieties. This difference between blond and yellow peas, the comment concluded, had been argued at the Codex Alimentarius meetings with the result that the Codex standard considers yellow peas (overmature peas) as defects but excludes blond peas as defective peas.

The agency notes that the proposed quality provision restricting "blond" peas (i.e., yellow or white but edible peas) to not more than 2 percent was based on color and not on whether or not canned peas are succulent. FDA agrees that blond peas do not affect the wholesomeness of the food. However, FDA is of the opinion that when consumers purchase canned peas they expect the peas to be green in color as indicated elsewhere in this preamble. The agency recognizes that a limitation based on color that includes blond peas will be a deviation from the Codex standard, but FDA believes that it is in the consumers' interest to establish such a limitation. Therefore, FDA concludes that such a limitation is reasonable and is requiring in 21 CFR 155.170(b)(1)(i) of the regulation as set out below that not more than 2 percent of the drained weight is blond and/or yellow peas, i.e., yellow or white but edible peas.

Maturity

11. One comment said that a majority of the canners who responded to its questionnaire desired the maximum alcohol-insoluble solids (AIS) for Alaska or other smooth-skin varieties to remain at 23.5 percent since there are times when growing conditions may cause difficulties in meeting the proposed 21-percent AIS. A second comment said that a 21-percent requirement is too restrictive to include all types of peas, that is, the Alaska-type. A third comment said that in a survey, six companies favored the proposal, eight opposed it, and five had no opinion. This comment favored use of the tenderometer rather than AIS as a measure of pea maturity.

The agency noted in the proposal that the higher AIS (23.5 percent) was established because of the growing conditions in certain eastern areas of the U.S. but that the amount of Alaska-type peas now grown in these areas has decreased to the point that it may be feasible to pack such peas before they develop an AIS above 21 percent. The comments reveal, however, that Alaska-type peas grown in other areas of the U.S. may at times not meet the 21-percent AIS. Therefore, FDA concludes that a maximum 23.5-percent AIS for smooth-skin peas, such as Alaska-type peas or hybrids having similar characteristics, is reasonable and has so provided in 21 CFR 155.170(b)(1)(vi) of the regulation as set out below. The agency recognizes that the tenderometer is widely used to measure the maturity of fresh peas, but usually prior to size and maturity separations. In the absence of data on the basis of which to establish maximum levels of maturity using the tenderometer, the test based on AIS in 21 CFR 155.170(b)(1)(vi) of the regulation as set out below has been retained.

Extraneous Matter and Filth

12. One comment urged that the standard of identity include a defect action level for extraneous matter and filth. No data or information were submitted in support of the comment.

The agency notes that the standard of quality set out in 21 CFR 155.170(b)(1)(v) provides for a limitation for extraneous vegetable material. The presence of other extraneous material and filth in canned peas, however, constitutes adulteration which is not considered a part of food standards but is dealt with under other sections of the act. The agency advises that no defect action levels have been established for canned peas since it is not aware of a demonstrated problem in this regard. However, anyone who has data demonstrating that a need exists should submit such data and request that an appropriate defect action level be provided for under 21 CFR 110.99.

Drained Weight

13. One comment urged that a minimum drained weight provision be included in the standard of identity, as is included in the standards of identity for various other canned vegetables. No data or information were submitted in support of the comment.

The agency notes that minimum drained weight requirements are established in fill-of-container standards and not standards of identity. A proposal was published in the **Federal Register** of December 9, 1977 (42 FR 62282), to amend or establish standards of fill of container to require minimum drained weights for certain canned foods but not including canned peas. As discussed in the June 7, 1977 proposal, the agency is now in the process of obtaining data to support specific drained weight requirements for canned peas.

Therefore, FDA concludes that it is inappropriate to consider establishing a minimum drained weight requirement for canned peas in this final regulation. The proposed fill of container procedure in 21 CFR 155.170(c)(2) has been editorially amended to delete reference to drained weight in the regulation as set out below.

In consideration of the comments received and other relevant information, FDA concludes that it will promote honesty and fair dealing in the interest

of consumers to establish a definition section; to amend the standards of identity, quality, and fill of container for canned peas and canned dry peas; to amend the standards of quality for canned green beans and canned wax beans; and to amend the standards of quality and fill of container for canned corn and canned tomatoes as set forth below. Amendments to the standards of identity, quality, and fill of container for canned peas as set out below are also applicable, by cross reference, to canned dry peas unless otherwise noted in the latter regulation.

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, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Chapter I of Title 21, Part 155 is amended as follows:

1. In Subpart A by adding a new subpart heading and new § 155.3 to read as follows:

Subpart A—General Provisions

§ 155.3 Definitions.

For the purposes of this part:

(a) The procedure for determining drained weight is set forth in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980,[1] section 32.001–32.003, which is incorporated by reference.

(b) Compliance means the following: Unless otherwise provided in a standard, a lot of canned vegetables shall be deemed in compliance for the following factors, to be determined by the sampling and acceptance procedure as provided in paragraph (c) of this section, namely:

(1) *Quality.* The quality of a lot shall be considered acceptable when the number of defectives does not exceed the acceptance number (c) in the sampling plans.

(2) *Fill of container.* A lot shall be deemed to be in compliance for fill of container (packing medium and vegetable ingredient) when the number of defectives does not exceed the acceptance number (c) in the sampling plans.

(3) *Drained weight.* A lot shall be deemed to be in compliance for drained weight based on the average value of all samples analyzed according to the sampling plans.

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the Office of the Federal Register Library.

(c) The sampling and acceptance procedure means the following:

(1) *Definitions*—(i) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(ii) *Lot size.* The number of primary containers or units in the lot.

(iii) *Sample size.* The total number of sample units drawn for examination from a lot.

(iv) *Sample unit.* A container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit. For fill of container, the sample unit shall be the entire contents of the container.

(v) *Defective.* Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(vi) *Acceptance number (c).* The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(vii) *Acceptable quality level (AQL).* The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(2) *Sampling plans.*

Lot size (primary containers)	Size of container	
	n[1]	*c*[2]
Net weight equal to or less than 1 kg (2.2 lb):		
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb):		
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to120,000	126	13
Over 120,000	200	19
Net weight greater than 4.5 kg (10 lb):		
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

[1] *n* = number of primary containers in sample.
[2] *c* = acceptance number.

2. By revising § 155.120(b)(3) to read as follows:

§ 155.120 Canned green beans and canned wax beans.

* * * * *

(b) * * *

(3) Determine compliance as specified in § 155.3(b) except that a lot shall be deemed to be in compliance for extraneous plant material based on an average of all containers examined.

* * * * *

3. By revising § 155.130 (b)(4) and (c)(2) to read as follows:

§ 155.130 Canned corn.

* * * * *

(b) * * *

(4) Determine compliance as specified in § 155.3(b).

* * * * *

(c) * * *

(2) Determine compliance as specified in § 155.3(b).

* * * * *

4. By revising § 155.170 to read as follows:

§ 155.170 Canned peas.

(a) *Identity*—(1) *Definition.* Canned peas is the food prepared from fresh or frozen succulent seeds of the pea plant of the species *Pisum sativum* L. but excluding the subspecies *macrocarpum.* Only sweet wrinkled varieties, smooth-skin varieties, or hybrids thereof may be used. The product is packed with water or other suitable aqueous liquid medium to which may be added one or more of the other optional ingredients set forth in paragraph (a)(2) of this section. Such food is sealed in a container and, before or after sealing, is so processed by heat as to prevent spoilage.

(2) *Optional ingredients.* In addition to the optional packing media provided for in paragraph (a)(1) of this section, the following safe and suitable optional ingredients may be used:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate.

(iv) Disodium guanylate.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(vii) One or any combination of two or more of the dry or liquid forms of sugar, invert sugar sirup, dextrose, glucose sirup, and fructose.

(viii) Spice.

(ix) Flavoring (except artificial).

(x) Color additives.

(xi) Calcium salts, the total amount of which added to firm the peas shall not result in more than 350 milligrams/kilogram (0.01 ounce/2.2 pounds) of calcium in the finished food.

(xii) Seasonings and garnishes:

(*a*) Pieces of green or red peppers or mixtures of both, either of which may be dried, or other vegetables not exceeding in total 15 percent of the drained weight of the finished food.

(*b*) Lemon juice or concentrated lemon juice.

(*c*) Mint leaves.

(*d*) Butter or margarine in a quantity not less that 3 percent by weight of the finished food, or other vegetable or animal fats or oils in a quantity not less than 2.4 percent by weight of the finished foods. When butter, margarine, or other vegetable or animal fats or oils are added, emulsifiers or stabilizers or both may be added, but no color, spice, or flavoring simulating the color or flavor imparted by butter or margarine may be used.

(3) *Labeling.* (i) The name of the food is "peas" and may include the designation "green." The term "early," "June," or "early June" shall precede or follow the name in the case of smooth-skin peas or substantially smooth-skin peas, such as Alaska-type peas or hybrids having similar characteristics. Where the peas are of sweet green wrinkled varieties or hybrids having similar characteristics, the name may include the designation "sweet," "wrinkled," or any combination thereof. The term "petit pois" may be used in conjunction with the name of the food when an average of 80 percent or more of the peas will pass through a circular opening of a diameter of 7.1 millimeters (0.28 inch). If any color additive has been added, the name of the food shall include the term "artificially colored."

(ii) The following shall be included as part of the name or in close proximity to the name of the food:

(*a*) A declaration of any flavoring that characterizes the food, as specified in § 101.22 of this chapter.

(*b*) A declaration of any spice, seasoning, or garnishing that characterizes the product, e.g., "seasoned with green peppers", "seasoned with butter", "seasoned with ——— oil", the blank to be filled in with the common or usual name of the oil, "with added spice", or, in lieu of the word spice, the common or usual name of the spice.

(*c*) The words "vacuum pack" or "vacuum packed" when the weight of the liquid in the container, as determined by the method prescribed in § 155.3(a) is not more than 20 percent of the net weight, and the container is closed under conditions creating a high vacuum in the container.

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

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

(i) *Blond and yellow peas.* Not more than 2 percent of the drained weight is blond and/or yellow peas, i.e., white or yellow but edible peas.

(ii) *Blemished peas.* Not more than 5 percent of the drained weight is blemished peas, i.e., slightly stained or spotted peas.

(iii) *Seriously blemished peas.* Not more than 1 percent of the drained weight is seriously blemished peas, i.e., peas that are hard, shrivelled, spotted, discolored, or otherwise blemished to an extent that the appearance or eating quality is seriously affected.

(iv) *Pea fragments.* Not more than 10 percent of the drained weight is pea fragments, i.e., portions of peas, separated or individual cotyledons, crushed, partial or broken cotyledons, and loose skins, but excluding entire intact peas with skins detached.

(v) *Extraneous vegetable material.* Not more than 0.5 percent of the drained weight is extraneous vegetable material, i.e., vine or leaf or pod material from the pea plant or other such material.

(vi) *Alcohol-insoluble solids.* The alcohol-insoluble solids of smooth-skin or substantially smooth-skin peas, such as Alaska-type peas or hybrids having similar characteristics, may not be more than 23.5 percent and, of sweet green wrinkled varieties or hybrids having similar characteristics, not more than 21 percent based on the procedure set forth in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980,[1] section 32.012, which is incorporated by reference.

(vii) *Limitation.* The sum of the pea material described in paragraph (b)(1) (i), (ii), (iii), (iv), and (v) of this section shall not exceed 12 percent.

(2) Determine compliance as specified in § 155.3(b).

(3) If the quality of canned peas 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; but in lieu of such general statement of substandard quality when the quality of canned peas falls below the standard in only one respect, the label may bear the alternative statement, "Below standard in quality ", the blank to be filled in with the words specified after the corresponding paragraph under paragraph (b)(1) of this section which such canned peas fail to meet, as follows: (i) "Excessive blond and/or yellow peas"; (ii) "Excessive blemished peas"; (iii) "Excessive seriously blemished peas"; (iv) "Excessive pea fragments"; (v) "Excessive vegetable material"; (vi) "Excessive mealy". Such alternative statement shall immediately and conspicuously precede or follow without intervening written, printed, or graphic matter, the name "peas" and any words and statements required or authorized to appear with such name by paragraph (a)(3) of this section.

(c) *Fill of container.* (1) Except in the case of vacuum pack peas, the fill of pea ingredient and packing medium, as determined by the general method for fill of container prescribed in § 130.12(b) of this chapter, is not less than 90 percent of the total capacity of the container.

(2) When the peas and liquid are removed from the container and returned thereto, the leveled peas (irrespective of the quantity of the liquid), 15 seconds after they are so returned, completely fill the container. A container with lid attached by double seam shall be considered to be completely filled when it is filled to 5 millimeters (0.2 inch) vertical distance below the top of the double seam; and a glass container shall be considered to be completely filled when it is filled to 13 millimeters (0.5 inch) vertical distance below the top of the container.

(3) Determine compliance for fill of container as specified in § 155.3(b).

(4) If canned peas fall below the standard of fill of container prescribed in paragraph (c)(1) and/or (2) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

5. By revising § 155.172 to read as follows:

§ 155.172 Canned dry peas.

(a) *Identity.* Canned dry peas conforms to the definition and standard of identity, and is subject to requirements for label statement of optional ingredients prescribed for canned peas by § 155.170(a), except that:

(1) The optional pea ingredient is the dry seeds of the pea plant of the species *Pisum sativum* L. but excluding the subspecies *macrocarpum*.

(2) The name of the food is "cooked dry peas" or "soaked dry peas". The optional terms specified by § 155.170(a)(3), "early", "June", "sweet", "green", "wrinkled", or any combination thereof, shall not be used on the labels.

(b) *Quality.* (1) The standard of quality for canned dry peas is that specified for canned peas by § 155.170(b) except that:

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the Office of the Federal Register Library.

(i) The alcohol-insoluble solids maximums specified in § 155.170(b)(1)(vi) do not apply.

(ii) The skins of not more than 25 percent by count of the peas in the container are ruptured to a width of 1.6 millimeters (0.06 inch) or more.

(2) If the quality of canned dry peas falls below the standard of quality prescribed by paragraph (b)(1) of this section, the label shall bear the statement of substandard quality in the manner and form specified in § 155.170(b)(3) for canned peas, except that the words "Excessively mealy" shall not be used.

(c) *Fill of container.* (1) The standard of fill of container for canned dry peas is that prescribed for canned peas by § 155.170(c).

(2) If canned dry peas fall below the standard of fill of container prescribed by paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

6. By revising § 155.190(b)(3) and by redesignating § 155.190(c)(2) as (c)(3) and adding a new paragraph (c)(2) to read as follows:

§ 155.190 Canned tomatoes.

* * * * *

(b) * * *

(3) Determine compliance as specified in § 155.3(b).

* * * * *

(c) * * *

(2) Determine compliance as specified in § 155.3(b).

(3) If canned tomatoes fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

Any person who will be adversely affected by the foregoing regulation may at any time on or before July 28, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 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 August 26, 1980, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1981 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: June 20, 1980.

Note.—Incorporation by reference approved by the Director of the Office of the Federal Register on March 11, 1976, and is on file in the Federal Register Library.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-19369 6-26-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 310

[Docket No. 79N-0177]

New Drugs; Sweet Spirits of Nitre Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document contains the final decision that any drug product containing sweet spirits of nitre is not generally recognized as safe effective and is misbranded for over-the counter (OTC) human use. Any sweet spirits of nitre drug product marketed for OTC use will be subject to regulatory action unless it is the subject of an approved new drug application. The Food and Drug Administration (FDA) is taking this action after considering all the available evidence which was set forth in the preamble to the proposal published in the **Federal Register** of February 22, 1980 (45 FR 11846). This final rule is part of FDA's ongoing review of OTC drug products.

EFFECTIVE DATE: June 26, 1980.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 22, 1980, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), FDA issued a proposal to establish a regulation for OTC sweet spirits of nitre drug products, together with the conclusions and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products.

In accordance with § 330.10(a)(2) (21 CFR 330.10(a)(2)), the data and information considered by the Panel were put on display in the Hearing Clerk's office, Food and Drug Administration (FDA), Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, after deletion of small amounts of information considered confidential.

In the preamble to the proposed regulation, FDA advised that it would not follow the full OTC rulemaking procedure set forth in § 330.10 (21 CFR 330.10) because the agency determined that use of any drug product containing sweet spirits of nitre for any purpose is contrary to the public interest and that action to remove all products containing sweet spirits of nitre from the market should be implemented expeditiously. The agency also advised that a final rule under the proposal would become effective on the date of publication in the **Federal Register.** Interested persons were invited to file, on or before March 24, 1980, written comments regarding the proposed rule. No comments were received. Because of the risk to the public health involved in the use of sweet spirits of nitre drug products, the Commissioner has found that there is good cause to have this final rule become effective on the date of publication, as authorized by 5 U.S.C. 553(d)(3) and by 21 CFR 10.40(c)(4)(ii). This final rule contains the agency's final decision on OTC sweet spirits of nitre drug products and is effective immediately.

Sweet spirits of nitre contains between 3.5 and 4.5 percent of ethyl nitrite in alcohol and is also known as spirit of nitre, spirit of nitrous ether, and ethyl nitrite spirit. It has been marketed OTC for use as a diaphoretic to reduce fevers in children, as a diuretic, and as an intestinal antispasmodic for the treatment of flatulent colic in infants. It has also been used topically for cold sores and fever blisters. The agency has

reviewed the available data and information on sweet spirits of nitre and is aware of no scientific evidence to support its effectiveness for any use. There is evidence that severe and/or fatal methemoglobinemia may ensue if sweet spirits of nitre is ingested. The risk of poisoning for infants due to some undeveloped enzyme systems and to the increased level of fetal hemoglobin (Ref. 1) are major factors in the agency's assessment that sweet spirits of nitre is not safe for OTC use.

Based on the available evidence, the agency is making a final determination that sweet spirits of nitre cannot be generally recognized as safe and effective for any OTC use. If the labeling of any drug product represents or suggests it to contain sweet spirits of nitre for any OTC use, that product will be considered misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) and a new drug within the meaning of section 201(p) of the act (21 U.S.C. 321(p)) for which an approved new drug application, under section 505 of the act (21 U.S.C. 355) and Part 314 of the regulations (21 CFR Part 314), is required for marketing. In the absence of an approved new drug application, any such drug product in interstate commerce after the effective date of this final rule will be subject to regulatory action. The agency is unaware of any sweet spirits of nitre drug product that is the subject of an approved new drug application.

In addition, because of the risk associated with the use of sweet spirits of nitre, the agency intends to request firms to recall to the retail level all drug products containing sweet spirits of nitre.

Reference

(1) Chilcote, R. R., et al., "Sudden Death of an Infant from Methemoglobinemia After Administration of 'Sweet Spirits of Nitre'," *Pediatrics*, 59:280–282, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended in Part 310 by adding new § 310.525, to read as follows:

§ 310.525 Sweet spirits of nitre drug products.

(a) Historically, sweet spirits of nitre has been present as an ingredient in over-the-counter (OTC) drug products for various uses. Based upon the lack of adequate data to establish effectiveness for any use and the adverse benefit-to-risk ratio, sweet spirits of nitre drug products cannot be considered generally recognized as safe and effective. The benefit from using sweet spirits of nitre for any use is insignificant when compared to the risk.

(b) Any drug product containing sweet spirits of nitre is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and is a new drug within the meaning of section 201(p) of the act for which an approved new drug application under section 505 of the act and Part 314 of this chapter is required for marketing.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" (Form FDA–1571), as set forth in § 312.1 of this chapter, is required to cover clinical investigations designed to obtain evidence that any preparation containing sweet spirits of nitre for any use is safe and effective for the purpose intended.

(d) Any drug product containing sweet spirits of nitre in interstate commerce after June 27, 1980, that is not in compliance with this section is subject to regulatory action.

Effective date. This rule shall be effective on June 27, 1980.

(Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371); secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704))

Dated: June 20, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–19323 Filed 6–26–80; 8:45 am]

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21 CFR Part 522

Disophenol Sodium; Implantation or Injectable Dosage Form; New Animal Drugs Not Subject to Certification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the regulation for disophenol sodium injection to indicate those conditions of use for which applications for approval of identical products need not include certain types of effectiveness data. These conditions of use were classified as effective as a result of a National Academy of Sciences/National Research Council, Drug Efficacy Study Group (NAS/NRC) evaluation of the product. In lieu of certain effectiveness data, approval may require submission of bioequivalence or similar data. A previous **Federal Register** publication has reflected that this product is in compliance with the conclusions of the review.

EFFECTIVE DATE: June 27, 1980.

FOR FURTHER INFORMATION CONTACT: Henry C. Hewitt, Bureau of Veterinary Medicine (HFV–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3430.

SUPPLEMENTARY INFORMATION: The NAS/NRC review of this product was published in the **Federal Register** of February 1, 1969 (34 FR 1610). In that document, the Academy concluded, and FDA concurred, that the product was effective for the removal of certain hookworms from dogs.

That announcement was issued to inform holders of new animal drug applications (NADA's) of the findings of the Academy and the agency, and to inform all interested persons that such articles could be marketed if they were the subject of approved NADA's and otherwise complied with the requirements of the Federal Food, Drug, and Cosmetic Act.

American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540, responded to the notice by submitting a supplemental NADA (12–598V) providing current information covering manufacturing and controls and revising the labeling for the safe and effective use of the product for treating dogs infested with certain hookworms. The supplemental application was approved by a regulation published in the **Federal Register** of October 13, 1972 (37 FR 21632). The regulation reflecting this approval established a new section for the drug (21 CFR 135b.71, recodified as 21 CFR 522.740). The new section did not specify those conditions of use that were NAS/NRC approved.

This document amends the regulation to indicate those conditions of use for which approval for identical products in dogs need not include certain types of efficacy data required for approval by § 514.111(a)(5)(vi) of the new animal drug regulations. In lieu of those data, approval of such products may be obtained if bioequivalency or similar data are submitted as suggested in the guideline for submitting NADA's for generic drugs reviewed by the NAS/NRC. The presently approved use of the product in cats is based on effectiveness data which is proprietary, and new