applicable guidelines when adjusting a loss and we may consider any acreage and share of or reported by or for your spouse or child or any member of your household to be your bona fide share or the bona fide share of any other person having an interest therein.

18. Descriptive headings.

The descriptive headings of the various policy terms and conditions are formulated for convenience only and are not intended to affect the construction or meaning of any of the provisions of the contract.

Approved by the Board of Directors on February 23, 1983.

Dated: April 4, 1983.

Peter F. Cole,

Secretary, Federal Crop Insurance Corporation.

Approved by:

Merritt W. Sprague,

Manager.

[FR Doc. 83-9248 Filed 4-7-83; 8:45 am]

BILLING CODE 3410-08-M

Agricultural Marketing Service

7 CFR Part 910

[Lemon Reg. 406]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period April 10-16, 1983. Such action is needed to provide for orderly marketing of fresh lemons for the period due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: April 10, 1983.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202-447-5975.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Secretary's Memorandum 1512-1 and Executive Order 12291, and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities. This action is designed to promote orderly marketing of the California-Arizona lemon crop for the benefit of producers, and will not substantially affect costs for the directly regulated handlers.

This final rule is issued under Marketing Order No. 910, as amended (7 CFR Part 910; 47 FR 50196), regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Agreement Act of 1937, as amended (7 U.S.C. 601-674). The action is based upon recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy for 1982-83. The marketing policy was recommended by the committee following discussion at a public meeting on July 6, 1982. The committee met again publicly on April 5, 1983, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons is easier than that of the previous week.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared purposes of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910

Marketing agreements and orders, California, Arizona, Lemons.

PART 910—[AMENDED]

Section 910.706 is added as follows:

§ 910.706 Lemon regulation 406.

The quantity of lemons grown in California and Arizona which may be handled during the period April 10, 1983, through April 16, 1983, is established at 275,000 cartons.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Dated: April 7, 1983.

D. S. Kuryloski,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 83-9521 Filed 4-7-83; 12:08 pm]

BILLING CODE 3410-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 80N-0322]

Temporary Exemptions From Food Labeling Requirements for Conducting Authorized Food Labeling Experiments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing a procedure under which exemptions from certain food labeling requirements may be granted by FDA. This action is intended to encourage participation in authorized labeling experiments designed to provide FDA with pertinent food labeling data. These data are needed to supplement FDA's initiatives to provide consumers with more comprehensible and useful food labeling information.

EFFECTIVE DATE: April 8, 1983.

ADDRESS: Written proposals for labeling experiments should 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. Edward Scarbrough, Bureau of Foods (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3117.

SUPPLEMENTARY INFORMATION: FDA is encouraging industry to conduct voluntary experiments for testing different concepts of presenting nutrition information. Data generated by such experiments can be useful for evaluating whether changes in current food labeling requirements are warranted and for developing a nutrition labeling format that is more comprehensible and useful to consumers.

Under current FDA regulations (21 CFR 101.9) food labels are not required to bear nutrition information, except when nutrients are added to the food or when a nutrition claim is made on labeling or in advertising for the food.

Manufacturers may also voluntarily provide nutrition information. If nutrition information is provided on a food, it must conform to the provisions of § 101.9. As a result of the food labeling hearings announced in the Federal Register of June 9, 1978 (43 FR 25296) and subsequent related proceedings, FDA recognized the need for reviewing the nutrition labeling requirements and for permitting the industry to test market reasonable alternatives. Thus, FDA recognized that exemptions from some of the current food labeling requirements would be necessary. Therefore, in the Federal Register of September 5, 1980 (45 FR 58880), FDA published a proposal to establish a procedure for FDA to grant exemptions from the requirements of 21 CFR 101.9, 101.25, 105.66, 105.67, and 105.69 to allow for food labeling experiments.

Most of the comments on the proposal supported the concept of permitting food labeling experiments. Some requested a more detailed explanation of the information that should be submitted to FDA with exemption requests. Other comments expressed concern that the procedure outlined by the proposed regulation was too stringent and inflexible. A summary of the comments to the proposal and of FDA's responses follows:

1. Three comments requested more explicit guidance regarding the type of information that should be submitted in the exemption request. Two comments expressed the opinion that the requirements for evaluating the results of food labeling experiments were not adequately defined by the regulation.

These comments did not elaborate on the types of explicit guidance they desired from FDA. FDA proposed general guidance because more precisely defined and rigid guidance would reduce the flexibility for designing and conducting labeling experiments. Experiments should be designed to provide FDA with statistically valid data, and experimentors should collaborate with FDA to determine the appropriateness of the experimental design and of the proposed techniques for evaluating the results of the experiment.

2. Two comments were concerned that the proposal seemed to be confined to experimental programs offered on a limited basis in specific geographical locations. One comment contended that restricting experiments to a limited time would give no assurance that, if the experimental stage proved successful, the program could be continued. According to the comment, this would be unfair to consumers who rely on the program and would destroy incentive for the industry to commit resources to develop programs of excellence.

FDA proposed in § 101.108(b)(5) (21 CFR 101.108(b)(5)) to provide that a written proposal to undertake a labeling experiment include information on the geographic locale in which the experiment is to be conducted. No limitations on the size of the geographic area or on the size of the population to be tested were proposed. For clarification, the word "locale" in § 101.108(b)(5) has been replaced by the phrase "area or areas". Further § 101.108(b)(4) does not restrict the duration of the experiment. Parameters such as geographic area and duration should be defined in the written proposal submitted to FDA for review and should be selected to achieve the objectives of the experiment. The requirement of the regulation to provide information on these parameters is not directed toward limiting the scope of the experiment but is necessary for identifying the type of information FDA will use to evaluate the experiment. Experimentors are reminded, however, that the purpose of permitting food labeling experiments is to provide FDA with statistically valid data that can be used as a basis for developing food labeling policies. Therefore, FDA expects these parameters to be reasonable for obtaining sufficient, reliable data. FDA will not approve an experiment for which the parameters are so broad that the experiment appears to be designed primarily to circumvent currently established food labeling regulations and policies.

The comment is correct in contending that FDA has not provided assurance that a successful labeling concept could continue to be used beyond the experimental stage. FDA will need to evaluate the success of tested labeling concepts, taking into consideration the agency's over-all food labeling strategy and data from related labeling research, and determine whether a change in a food labeling policy appears warranted. Before implementing a change in food labeling regulations, FDA will publish the proposed change in the Federal Register and provide interested persons an opportunity to comment.

3. One comment contended that the scope of activity contemplated is too narrow, the time frame inappropriate, and the cost economically infeasible and, therefore, that the regulations would not encourage experimentation related to the dietary classification of foods in the supermarket.

FDA disagrees. The parameters of the activity contemplated are to be determined by the expefimentor and the rationale for the parameters should be discussed in the written proposal submitted to FDA. FDA recognizes that in some cases the period of time necessary for marketing a new labeling concept may be extensive in order to assess accurately consumer acceptability or comprehension of the labeling concept. FDA will not arbitrarily impose a shorter time frame for an experiment if the time frame proposed by the experimentor is reasonable for accomplishing the objectives of the experiment.

In addition, a few organizations are currently collaborating with FDA in developing experiments to test consumer acceptability of supermarket shelf labeling for highlighting various nutritional aspects of certain foods. For example, one supermarket chain is currently utilizing "shelf talkers" and in-store pamphlets to convey information relative to calorie, sodium, and fat/cholesterol content of specific foods. Ordinarily, conveyance of such nutrition information relative to calorie and fat and cholesterol content would trigger requirements for nutrition labeling according to the provisions of §§ 101.9, 101.25, and 105.66. However, FDA granted the supermarket chain an exemption relative to these nutrition labeling requirements, with the understanding that complete nutrition labeling information would be available to consumers. This exemption enabled the supermarket chain to test consumer response to point-of-purchase, off-label nutrition claims. In addition to this and other supermarket chains that have discussed with FDA alternative methods of conveying nutrition information to consumers, one trade association is currently collaborating with FDA on the concept of establishing flexible guidelines for point-of-purchase, off-label nutrition information. Thus, it appears that experiments related to the dietary classification of foods are economically feasible.

4. One comment requested that FDA clarify in the preamble to the final regulation that it also will consider approval of proposed experiments to test the effect of the deletion of information presently required on the label.

In reviewing current food labeling policies, FDA is evaluating whether certain information should be deleted from the food label. Certain labeling experiments for testing the effect of deleting some currently required nutrition information can provide useful information to the agency and, thus, will be considered for approval. However, any proposed deletions of information

must be consistent with public health needs and statutory requirements for labeling foods and should be directed toward improving the comprehensibility of the food label. Thus, experiments for testing consumer acceptance of the deletion of information should not be designed simply to determine whether consumers will purchase products that provide less information on the label. Rather, experiments should provide information regarding consumer comprehension of and the effectiveness and usefulness fo a particular format that does not include all of the information that is currently presented or that presents the information in a different manner. For example, an experiment to test the effect of totally eliminating nutrition labeling from foods on which nutrition labeling is currently required would not be approved. However, experiments to compare the comprehensibility of the current nutrition labeling format with a revised format would be considered for approval, even if some of the currently required nutrition information were deleted from the revised format. A thorough discussion of the rationale for suspecting that the information to be deleted is not useful to, used by, or needed by consumers should be included in the request for an exemption.

5. One comment suggested that shelf tags, booklets, posters, etc., providing consumers with required labeling information that has been exempted from appearing on the product label during an experiment (§ 101.108(b)(3) and (7)) should not be required as a prerequisite for approval of the proposed experiment. For example, to determine the effect of eliminating certain label information, it may not be desirable to present the information at all.

Shelf tags, booklets, and posters, per se, are not a prerequisite for approval of a proposed experiment to test the effect of deleting information from the label. However, experimentors should be prepared to provide the deleted information, rapidly and efficiently, to consumers who desire the information and should explain the exemption request the mechanism for doing so. In addition, the experiment should be carefully designed to measure the consumer's interest in the deleted information, rather than merely to determine whether consumers will buy products that do not provide the information. It cannot be assumed that consumers who purchase products from which information has been deleted do not need or would not use the information, particularly if there is no readily available mechanism by which the consumer may acquire the deleted information or by which they can inform the experimentor that the information is desired or needed.

6. One comment requested that the requirement of proposed § 101.108(b)(9) to report "promptly to FDA the results of labeling experiments" be revised to require that results be reported to FDA within a reasonable time, e.g., 60 to 120 days following conclusion of the experiment and the analysis of the experimental data.

The word "promptly" in proposed § 101.108(b)(9) should have been interpreted to mean as soon as possible after completion of the written report of the analysis of the experimental data. The projected dates for beginning and ending the experiment and for submitting the written report of analysis to FDA should be included in the proposal. The wording of proposed § 101.108(b)(4) has been revised to clarify this requirement, and proposed § 101.108(b)(9) has been deleted from this final rule.

7. One comment contended that the proposed regulation is too cumbersome and will lead to long delays in gaining FDA approval which will negate the ability to carry out some experiments. The comment suggested streamlining the requirements of § 101.108(b).

FDA does not agree with the comment. Anyone submitting proposed experiments can be assured that FDA will expedite the review and approval of plans for well-designed experimental studies related to food labeling issues on which the agency has requested additional data. However, they should also be aware that the agency has extremely limited resources for assisting in the development and implementation of such experiments and that poorly designed experimental plans may cause unavoidable delays in the review process. Expertise is available in the private sector for designing experiments that provide reliable, well-documented results. It is the responsibility of the experimentor to ensure that such expertise is used to the extent necessary for devising an experiment that will provide statistically valid results, and that information required by this final rule is thoroughly discussed in the written proposal submitted to FDA.

8. One comment supported the development of off-label nutrition information systems, but indicated that these systems must be implemented with more speed and flexibility than the proposal would permit.

FDA supports development of experiments to determine the usefulness of off-label nutrition information systems, and this final rule provides a mechanism for obtaining FDA approval of such experiments. FDA recognizes the necessity for expeditious approval of experiments that can provide valid, useful labeling information and will attempt to provide a timely review that will allow manufacturers to implement the experiment according to the time schedule in the written proposal. However, experimentors must remember that the time necessary for FDA to evaluate an experiment depends on the quality and completeness of the written proposal. Experimentors are encouraged to submit a thorough, well-explained proposal to FDA and to respond promptly to requests from FDA for clarification or for additional information that the agency considers necessary for prompt approval of the experiment.

9. One comment requested that proposed § 101.108(b)(8) be clarified by including the phrase "if such claim has not been previously approved by FDA" so that experimentors would not be required to repeat experiments to verify nutrition claims that previously have been approved by FDA.

Although FDA has defined, by regulation, some of the phrases and terms used to make nutrition claims, it is the responsibility of the food manufacturer to verify, by appropriate testing, that a nutrition claim is valid. FDA routinely examines foods to determine whether nutrition information on the label complies with regulatory requirements; however, FDA does not "approve" such claims, i.e., certify that a claim is accurate for each particular food. Therefore, the phrase suggested by the comment would not be an appropriate addition to § 101.108(b)(8). However, to alleviate some of the comment's concern regarding unnecessary repetition of tests to verify the accuracy of nutrition claims, FDA is revising § 101.108(b)(8) to clarify that the results of past tests performed by the manufacturer to determine nutritional characteristics of a particular product may be relied upon, provided they are still valid for the particular product.

10. One comment requested that the following criteria be included as requirements for proposed food labeling experiments: (a) Dates on which the experiment will begin and end together with a commitment to end the experiment on the termination date, and/or when FDA requires, upon showing that the program subject to experiment is deceiving or otherwise

misleading consumers, or upon passage of new food labeling legislation that affects the terms of this agreement; (b) a commitment to provide consumers with realistic and readily accessible methods of obtaining the required nutrition information that is exempted from nutrition labeling during the experiment; and (c) a commitment to place signs throughout the stores which define the terms being used on the shelf tags and inform consumers about how more complete nutrition information can be obtained.

FDA recognizes and shares the concerns expressed in the comments about ensuring that consumers are not misled by food labeling experiments. The agency will cautiously review proposed experiments to determine whether proposed labeling changes or omissions of information can be misleading. Because the points raised by the comment will be considered before approving an experiment, and the final rule already provides that the written proposal include information related to these points, the final rule had not been further revised.

11. One comment suggested developing detailed guidelines or regulations that define terms or classes of terms that can be used in labeling experiments, e.g., "low" and "reduced" sugar, fat, cholesterol and sodium, or "excellent source of " or "high in" for protein and other nutrients. The comment indicated that these terms should be used consistently.

A proposal setting forth definitions for "sodium free," "low sodium," "moderately low sodium," and "reduced sodium" was published by FDA in the **Federal Register** of June 18, 1982 (47 FR 26580). When such terms are defined by regulation, their consistent use on labels will be required. The provisions of § 101.9(c)(7)(v) are applicable when phrases are used indicating that a product is an "excellent source of" or "high in" a particular nutrient.

12. One comment suggested that FDA establish a formal application form that lists all the information it will require in approving experiments. The comment reasoned that a standardized form would minimize the frequency of requests for additional information, minimize review time and work, facilities comparison of experiments, lower the cost of broad evaluations, encourage experiments, and improve experiment proposals by promoting an exchange of useful success and failure data.

This final rule provides general guidance for the types of information FDA will need to evaluate proposed labeling experiments. The rationale for not providing more detailed guidance was previously discussed. The information required by the regulation must be submitted to FDA in writing and, for clarity, should be formatted using the nine information items in the regulation as general headings (§ 101.108(b) (1) through (9)). FDA does not anticipate that variations in format for the written proposal will present any particular problems for evaluating the proposal and, therefore, has not developed a standardized proposal application form. The extent of detail necessary to discuss thoroughly each of the information items will vary from one experiment to another and a few of the items may not be relevant to some experiments. For example, § 101.108(b)(2) would not be relevant for experiments that do not involve a segregation of foods into different categories based on nutrition or dietary claims. A brief statement in the written proposal indicating that the item is not relevant to the particular experiment would be adequate in such cases. Section 101.108(b) has been revised to clarify that the written proposal should include a thorough discussion of each of the nine information items that apply to the particular experiment.

13. One comment requested that notice of FDA-approved labeling experiments be published in the **Federal Register** and data relating to the experiment be readily accessible.

Following authorization by FDA of a proposed experiment, a copy of the proposal, FDA comments, correspondence, memoranda of meetings and telephone conversations concerning the proposal, and the agency's authorization letter will be made available to interested persons through FDA's Dockets Management Branch. When results from an approved experiment are used in the development of food labeling policies, data on the experimental results also will be filed with the Dockets Management Branch and will be publicly available. Although a **Federal Register** notice will not be published for each approved experiment, appropriate references to experimental data will be provided in **Federal Register** documents, if the data are used as support for the development of a particular regulation.

14. One comment requested that FDA establish a "logo" or "seal" or some other acceptable method to identify products that are being test marketed according to an FDA-approved labeling experiment. This would enable State regulatory officials and other food manufacturers to know which products are being marketed under an FDA-approved experiment.

FDA agrees that State regulatory officials should be notified of approved food labeling experiments so they will be aware of the types of labeling exemptions granted for the test products. FDA will use the National Regional State Telecommunications Exchange Network system to provide this information to State agencies. Food manufacturers or other interested persons may obtain information regarding FDA-approved labeling experiments by writing to the agency's Dockets Management Branch (address above). Therefore, a "logo" or "seal" is not necessary.

15. One comment requested that FDA clarify in the preamble to the final regulation that the program is strictly voluntary and that equal consideration will be given to future food labeling comments made by those who do not participate in a labeling experiment.

The development and administration of a labeling experiment is a voluntary activity. Any firm desiring to provide FDA with valid data that can be used for evaluating current or proposed food labeling policies may participate. However, failure to participate will have no negative impact on those who do not submit proposed experiments. Furthermore, voluntary participation in a labeling experiment will not provide the participant any additional advantage for influencing decisions regarding changes in foood labeling policies.

In addition to changes made in the regulation in response to comments, FDA has revised paragraphs (a), (b), (c), and (d) of § 101.108.

Proposed paragraph (a) has been editorially revised to remove the reference to the **Federal Register** document of December 21, 1979 (44 FR 75990).

Proposed paragraph (b) provided that an experimentor would agree "to conclude the experiment, if necessary, upon request by FDA following the passage of new food labeling legislation." This phrase has been removed because currently there is no pending food labeling legislation under active Congressional consideration, and it is generally understood that a change in a law may annul a food labeling experiment.

Proposed paragraph (c) provided that a written proposal to conduct a food labeling experiment requiring an exemption from current food labeling requirements be sent directly to FDA's Bureau of Foods. Paragraph (c) has been revised to clarify that a written proposal to conduct a food labeling experiment should be submitted as a citizen petition

under 21 CFR 10.30 and submitted for appropriate filing with the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Written proposals for labeling experiments requiring exemptions from current food labeling requirements that are received after April 8, 1983 will be filed as citizen petitions and assigned individual docket numbers. Written proposals received before April 8, 1983 and that were submitted to FDA's Bureau of Foods according to the provisions in the September 5, 1980 proposal will be filed with the Dockets Management Branch under Docket No. 80N–0322.

Paragraph (d) has been revised to clarify that "[a]pproval for food labeling experiments will be given by FDA in writing. Foods labeled in violation of existing regulations will be subject to regulatory action unless an FDA-approved exemption to the specific regulation has been granted for that specific product."

The agency has determined under 21 CFR 25.24(d)(13) (proposed December 11, 1979; 44 FR 71742), that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In accordance with Executive Order 12291, FDA has initially determined that this rule does not constitute a major rule as defined by that Order. The reasons underlying that determination are as follows:

1. The regulation will not have an annual effect on the economy of $100 million or more. The final rule provides guidance to manufacturers for requesting exemptions from the requirements of certain current food labeling regulations so they may conduct food labeling experiments. Participation in these experiments is strictly voluntary. Manufacturers are not likely to volunteer such participation if the costs for an experiment exceed the potential benefit that can be derived from the information resulting from the experiment. Further, because labeling experiments are likely to be of relatively short duration, the costs involved would not be incurred on an ongoing basis.

2. The regulation will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The decision by a manufacturer to conduct a labeling experiment is strictly voluntary, and it is not anticipated that manufacturers will volunteer to conduct experiments that would result in a major increase in their costs or in process changes for their products. Further, because a price differential could be a factor influencing the consumers' decisions about products that are the subject of an experiment and that are labeled differently from similar products, the agency expects that the price of the experimental product will not differ significantly from that of similar products.

3. The regulation will not have significant effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. Manufacturers are not likely to participate voluntarily in food labeling experiments that have an unfavorable impact on the marketing of their products. Further, because experiments will be of relatively short duration, any competitive advantage or disadvantage effects experienced by a manufacturer will likely be short lived.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

The reporting requirement contained in § 101.108(b) has been submitted to the Office of Management and Budget (OMB) under section 3507 of the Paperwork Reduction Act of 1980 and approved under OMB number 0910–0151.

List of Subjects in 21 CFR Part 101

Food labeling, Misbranding, Nutrition labeling, Warning statements.

PART 101—FOOD LABELING

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403, 701(a), 52 Stat. 1041 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a))) and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), Part 101 is amended by adding new § 101.108 to read as follows:

§ 101.108 Temporary exemptions for purposes of conducting authorized food labeling experiments.

(a) The food industry is encouraged to experiment voluntarily, under controlled conditions and in collaboration with the Food and Drug Administration, with graphics and other formats for presenting nutrition and other related food labeling information that is consistent with the current quantitative system in §§ 101.9 and 101.25 and with §§ 105.66, 105.67, and 105.69 of this chapter.

(b) Any firm that intends to undertake a labeling experiment that requires exemptions from certain requirements of §§ 101.9 and 101.25 and §§ 105.66, 105.67, and 105.69 of this chapter should submit a written proposal containing a thorough discussion of each of the following information items that apply to the particular experiment:

(1) A description of the labeling format to be tested;

(2) A statement of the criteria to be used in the experiment for assigning foods to categories, e.g., nutrient or other values defining "low" and "reduced";

(3) A draft of the material to be used in the store, e.g., shelf tags, booklets, posters, etc.;

(4) The dates on which the experiment will begin and end and on which a written report of analysis of the experimental data will be submitted to FDA, together with a commitment not to continue the experiment beyond the proposed ending date without FDA approval;

(5) The geographic area or areas in which the experiment is to be conducted;

(6) The mechanism to measure the effectiveness of the experiment;

(7) The method for conveying to consumers the required nutrition and other labeling information that is exempted from the label during the experiment;

(8) The method that will be or has been used to determine the actual nutritional characteristics of foods for which a claim is made; and

(9) A statement of the sections of the regulations for which an exemption is sought.

(c) The written proposal should be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. The proposal should be clearly identified as a request for a temporary exemption for purposes of conducting authorized food labeling experiments and submitted as a citizen petition under § 10.30 of this chapter.

(d) Approval for food labeling experiments will be given by FDA in writing. Foods labeled in violation of existing regulations will be subject to regulatory action unless an FDA-approved exemption to the specific regulation has been granted for that specific product.

(e) Reporting requirements contained in § 101.108(b) have been approved by this Office of Management and Budget and assigned number 0910–0151.

Effective date. This regulation is effective April 8, 1983.

(Secs. 201(n), 403, 701(a), 52 Stat. 1041 as amended, 1047–1048 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a)))

Dated: March 11, 1983.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 83-8947 Filed 4-7-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 155

[Docket No. 75P-0322]

Canned Peas and Canned Dry Peas; Standards of Identity

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standard of identity for canned peas to reinstate magnesium hydroxide, magnesium oxide, and magnesium carbonate as optional ingredients. FDA is also amending the standard of identity for canned dry peas to exclude, by cross-reference, these compounds. This action is based on a petition for reconsideration.

DATES: Effective May 10, 1983, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance may have begun August 31, 1982. Objections by May 9, 1983.

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 27, 1980 (45 FR 43394), FDA published a final regulation amending the U.S. standards of identity for canned peas (21 CFR 155.170) and canned dry peas (21 CFR 155.172) that removed magnesium hydroxide, magnesium oxide, and magnesium carbonate as optional ingredients. The confirmation of the effective date of July 1, 1981, was published in the **Federal Register** of April 10, 1981 (46 FR 21359). Before the effective date, a petition for reconsideration was filed on behalf of a company conducting research in food preservation and marketing requesting FDA to reconsider, under 21 CFR 10.33, its decision to remove these compounds from the standard of identity for canned peas and to stay the effective date of the final regulation with regard to these compounds. In the **Federal Register** of July 7, 1981 (46 FR 35086), FDA stayed the effective date of the amendment of the standard of identity that removed the magnesium compounds as optional ingredients. In the **Federal Register** of August 31, 1982 (47 FR 38346), FDA proposed to amend the standard of identity for canned peas to reinstate magnesium hydroxide, magnesium oxide, and magnesium carbonate as optional ingredients.

One comment was received in response to the proposal. The comment stated that preliminary research indicates that canned peas prepared under a new process involving magnesium compounds have strong consumer acceptance because of the resulting superior color retention and that the process is ready to be used in commercial production.

In consideration of the petition for reconsideration and other relevant information, FDA concludes that it will promote honesty and fair dealing in the interest of consumers to amend the standards of identity for canned peas and canned dry peas to reinstate the provision for the use of magnesium hydroxide, magnesium oxide, and magnesium carbonate as optional ingredients in canned peas.

In accordance with the Regulatory Flexibility Act, the agency has previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined and certified that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

List of Subjects in 21 CFR Part 155

Canned vegetables, Food standards, Vegetables.

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 5.10), Part 155 is amended as follows:

PART 155—CANNED VEGETABLES

1. In § 155.170, by redesignating paragraph (a)(2)(xii) as (a)(2)(xiii) and adding new paragraph (a)(2)(xii) to read as follows:

§ 155.170 Canned peas.

(a) * * *

(2) * * *

(xii) Magnesium hydroxide, magnesium oxide, magnesium carbonate, or any mixture or combination of these in such quantity that the pH of the finished canned peas is not more than 8, as determined by the glass electrode method for the hydrogen ion concentration.

* * * * *

2. In § 155.172, by redesignating paragraph (a)(2) as (a)(3) and by adding new paragraph (a)(2) to read as follows:

§ 155.172 Canned dry peas.

(a) * * *

(2) The optional ingredients specified in § 155.170(a)(2)(xii) shall not be used.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 9, 1983 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 and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after May 10, 1983 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: March 18, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-8948 Filed 4-7-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 177

[Docket No. 82F-0205]

Indirect Food Additives: Polymers; High-Temperature Laminates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of an aliphatic polyurethane laminating adhesive for fabricating retortable pouches and related high-temperature laminates for use in contact with food. This action is in response to a food additive petition filed by Morton Chemical, Division of Morton-Norwich Products, Inc.

DATES: Effective April 8, 1983. Objections by (May 9, 1983). The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 177.1390 effective on April 8, 1983.

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: Clyde A. Takeguchi, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 27, 1982 (47 FR 32480), FDA announced that a food additive petition (FAP OB3525) had been filed by Morton Chemical, Division of Morton-Norwich Products, Inc., 2 North Riverside Plaza, Chicago, IL 60606, proposing that § 177.1390 (21 CFR 177.1390) be amended to provide for the safe use of a polyurethane adhesive containing polyester-epoxy resins, and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanates as a cross-linking agent for fabricating high-temperature laminates. The actual cross-linking agent is the cyanurate trimer of the isocyanate (3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate cyanurate).

FDA has evaluated the data in the petition and other relevant material, and concludes that the proposed food additive use is safe and that the regulations should be amended as set forth below.

This amendment reflects the revision of § 177.1390(c)(2) and (3)(i) described in an earlier **Federal Register** document (47 FR 49638; November 2, 1982). In addition, FDA has revised § 177.1390(c)(3)(i)(*a*) to accommodate a new extraction requirement in paragraph (c)(3)(i)(*a*)(*2*), for laminates containing this newly petitioned adhesive. These are editorial changes that clarify the regulation, they do not change the substances or uses authorized.

The petition and the documents the FDA considered and relied upon in reaching its decision to approve the petition, in accordance with § 171.1(h) (21 CFR 171.1(h)), are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Incorporation by reference, Polymeric food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Foods (21 CFR 5.61 as revised February 4, 1983; 48 FR 5251), Part 177 is amended in § 177.1390 by adding new paragraph (c)(2)(v) and by revising paragraph (c)(3)(i)(*a*) to read as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

§ 177.1390 High-temperature laminates.

* * * * *

(c) * * *

(2) * * *

(v) Polyester-epoxy-urethane adhesives for use at temperatures not exceeding 121° C (250° F) and formulated from the following:

(*a*) Polyester resin formed by the reaction of polybasic acids and polyhydric alcohols listed in § 175.300(b)(3)(vii) of this chapter. Azelaic acid may also be used as a polybasic acid.

(*b*) Epoxy resin listed in § 175.300(b)(3)(viii)(*a*) of this chapter and comprising no more than 30 percent by weight of the cured adhesive.

(*c*) Urethane cross-linking agent comprising no more than 14 percent weight of the cured adhesive and formulated from 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate cyanurate (CAS Reg. No. 53880-05-0).

(3) * * *

(i) * * *

(*a*) For use at temperatures not to exceed 121° C (250° F): The container interior (food-contact side) shall be extracted with deionized distilled water at 121° C (250° F) for 2 hours.

(*1*) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2) (i), (ii), (iii), and (iv) of this section shall not exceed 0.0016 milligram per square centimeter (0.01 milligram per square inch) as determined by a method titled "Determination of Nonvolatile Chloroform Soluble Residues in Retort Pouch Water Extractives," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20404, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(*2*) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2)(v) of this section shall not exceed 0.016 milligram per square centimeter (0.10 milligram per square inch) as determined by a method titled "Determination of Nonvolatile Chloroform Soluble Residues in Retort Pouch Water Extractives," which is incorporated by reference in paragraph (c)(3)(i)(*a*)(*1*) of this section.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 9, 1983 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 indentified 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. This regulation shall become effective April 8, 1983.

(Secs. 201 (s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: March 15, 1983.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 83-8954 Filed 4-7-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Gentamicin Sulfate Oral Solution

Correction

In FR Doc. 83–6266, appearing on page 10301, in the issue of Friday, March 11, 1983, make the following corrections.

1. On page 10301, last column, line 2, correct "wanling" to "weanling".

2. On page 10302, first column correct the part heading for Part 520 to read:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

BILLING CODE 1505-01-M

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21 CFR Parts 520 AND 524

Oral, Ophthalmic, and Topical Dosage Form New Animal Drugs Not Subject to Certification; Ronnel Blocks, Tablets, and Emulsifiable Concentrate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to codify two previously approved new animal drug applications (NADA's) sponsored by Pitman-Moore, Inc. The NADA's provide for the treatment of dogs and cats for certain ectoparasites by oral (tablet), topical (solution), or combination administration of products containing the organophosphate pesticide ronnel. The regulations are also amended to indicate those conditions of use approved by FDA before October 10, 1962.

EFFECTIVE DATE: April 8, 1983.

FOR FURTHER INFORMATION CONTACT: Terence Harvey, Bureau of Veterinary Medicine (HFV–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3420.

SUPPLEMENTARY INFORMATION: Pitman-Moore, Inc., P.O. Box 344, Washington Crossing, NJ 08560, is sponsor of NADA's covering Ectoral Tablets (12–360) and Ectoral Emulsifiable Concentrate (12–361). The products contain the organophosphate pesticide ronnel. The tablets are administered orally to treat demodectic mange, ticks, fleas, and lice in dogs, and fleas in cats. The concentrate is diluted with water to prepare topical solutions used for treating those infestations, as well as sarcoptic mange in dogs and ear mites in dogs and cats. Topical application may be combined with oral treatment for enhanced results. These products were originally approved before the Drug Amendments of 1962 were enacted into law (October 10, 1962) by letters of May 16, 1961 (12–360) and June 2, 1961 (12–361).

In those letters, FDA concluded that the applications contained adequate data and information to demonstrate safety and effectiveness of the products. Accordingly, the regulations are amended to codify Pitman-Moore's approved NADA's and to specify the pre–1962 conditions of use.

Approvals at those times were not codified by publication in the Federal Register. This action codifies the previously approved NADA's but does not change the approved uses of the drugs. Because the applications were approved before July 1, 1975, the sponsor is not required to submit a summary of the safety and effectiveness data and information under the freedom of information provisions of the animal drug regulations in 21 CFR 514.11(e)(2).

In addition, the regulation for ronnel blocks is revised to reflect current format.

Since neither product was reviewed by the National Academy of Sciences/National Research Council (NAS/NRC), the Bureau of Veterinary Medicine conducted an effectiveness review and the referenced conditions of use are found effective. For identical or similar products having the same conditions of use, applications for use in non-food animals need not include effectiveness data as specified by § 514.1(b)(8)(ii) or 514.111(a)(5)(ii)(*a*)(*4*) (21 CFR 514.1(b)(8)(ii) or 514.111(a)(5)(ii)(*a*)(*4*)) of the animal drug regulations, but approval may require bioequivalency or similar data as suggested in the guidelines for submitting NADA's for NAS/NRC-reviewed generic drugs, available in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 520

Animal drugs, Oral use.

21 CFR Part 524

Animal drugs, Topical.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Parts 520 and 524 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. Part 520 is amended by redesignating § 520.2080 *Ronnel* as § 520.2080a *Ronnel blocks*, by revising its text, and by adding new §§ 520.2080 and 520.2080b to read as follows:

§ 520.2080 Ronnel oral dosage forms.

§ 520.2080a Ronnel blocks.

(a) *Specifications.* Each pound of block contains 25 grams of ronnel (5.5 percent).

(b) *Sponsor.* See 021930 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See 40 CFR 180.177.