

identifying number, or, under the direction of the inspector-in-charge, mark such marking device with a permanent identifying number.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015)

[50 FR 21423, May 24, 1985]

§ 381.132 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS Form, Application for Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in § 381.133(b) (2)-(9). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with subpart T of this part, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with subpart Q of this part. Such records shall be made available to any duly authorized representative of the Secretary upon request.

(b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in § 381.132(d), for all products, except as provided in § 381.133(b) (2)-(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.

(c) All labeling required to be submitted for approval as set forth in § 381.132(b) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate) for a product produced in other establishments that are owned by the corporation.

(d) "Sketch" labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in subpart N of this part. FSIS will accept sketches that are

hand drawn, computer generated or other reasonable facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 381.132(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 381.133(b)(9).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days under the following conditions:

(i) The proposed labeling would not misrepresent the product;

(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the Food Labeling Division, provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

[60 FR 67456, Dec. 29, 1995]

§ 381.133 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with subpart T of this part, is authorized to use generically approved labeling, as defined in paragraph (b) of this section,

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without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accord with this section and shows all mandatory features in a prominent manner as required in subpart N of this part, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with subpart T of this part, as required in § 381.132, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 381.233.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a product standard as specified in subpart 381 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;

(2) Labeling for single-ingredient products (such as chicken legs or turkey breasts) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 381.127;

(5) Labeling for products not intended for human food, provided they

comply with §§ 381.152(c) and 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with § 381.190(b);

(6) Poultry inspection legends, which comply with subpart M of this part;

(7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;

(8) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g., “lb.” for “pound,” or “oz.” for “ounce,” or of the word “pound” for “lb.” or “ounce” for “oz.”;

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words “prepared for” or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a

cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided that the size of the net weight statement complies with § 381.121;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

(xv) The deletion of the word “new” on new product labeling;

(xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 381.125(a);

(xvii) The addition of safe handling instructions as required by § 381.125(b);

(xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in § 381.147 and subpart P of this part;

(xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;

(xxi) The addition, deletion, or substitution of the official USDA poultry

grade shield; (xxii) A change in the establishment number by a corporation or parent company for an establishment under its ownership;

(xxiii) Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for services sizes, provided the nutrition labeling information maintains its accuracy and consistency;

(xxiv) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information;

(xxv) The addition or deletion of a direct translation of the English language into a foreign language for products marked “for export only”; and

(xxvi) The use of the descriptive term “fresh” in accordance with § 381.129(b)(6)(i) of this subchapter.

(xxvii) The use of the descriptive Term *frozen* as required by § 381.129(b)(6)(ii) of this subchapter.

[60 FR 67457, Dec. 29, 1995, as amended at 61 FR 66201, Dec. 17, 1996]

§ 381.134 Requirement of formulas.

Copies of each label submitted for approval, shall when the Administrator requires in any specific case, be accompanied by a statement showing, by their common or usual names, the kinds and percentages of the ingredients comprising the poultry product and by a statement indicating the method or preparation of the product with respect to which the label is to be used. Approximate percentages may be given in cases where the percentages of ingredients may vary from time to time, if the limits of variation are stated.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 59 FR 45196, Sept. 1, 1994. Redesignated at 60 FR 67457, Dec. 29, 1995]

§ 381.136 Affixing of official identification.

(a) No official inspection legend or any abbreviation or other simulation thereof may be affixed to or placed on or caused to be affixed to or placed on any poultry product or container thereof, except by an inspector or under the supervision of an inspector or other person authorized by the Administrator, and no container bearing