

SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT, THE POULTRY PROD- UCTS INSPECTION ACT, AND THE EGG PRODUCTS IN- SPECTION ACT

PART 412—LABEL APPROVAL

Sec.

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AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 78 FR 66838, Nov. 7, 2013, unless otherwise noted.

§ 412.1 Label approval.

(a) No final label may be used on any product unless the label has been submitted for approval to the FSIS Labeling and Program Delivery Staff, accompanied by FSIS Form 7234–1, Application for Approval of Labels, Marking, and Devices, and approved by such staff, except for generically approved labels authorized for use in § 412.2. The management of the official establishment or establishment certified under a foreign inspection system, in accordance with parts 327 and 381, subpart T, must maintain a copy of all labels used, in accordance with parts 320 and 381, subpart Q, of this chapter. Such records must be made available to any duly authorized representative of the Secretary upon request.

(b) All labels required to be submitted for approval as set forth in paragraph (a) of this section will be submitted to the FSIS Labeling and Program Delivery Staff. A parent company for a corporation may submit only one label application for a product produced in other establishments that are owned by the corporation.

(c) The Food Safety and Inspection Service requires the submission of labeling applications for the following:

(1) Sketch labels as defined in paragraph (d) of this section for products which are produced under a religious exemption;

(2) [Reserved]

(3) Special statements and claims as defined in paragraph (e) of this section

and presented in the context of a final label.

(4) Requests for the temporary use of final labels as prescribed in paragraph (f) of this section.

(d) A “sketch” label is the concept of a label. It may be a printer’s proof or equivalent that is sufficiently legible to clearly show all labeling features, size, and location. The Food Safety and Inspection Service will accept sketches that are hand drawn or computer generated, or other reasonable facsimiles that clearly reflect and project the final version of the label.

(e) “Special statements and claims” are statements, claims, logos, trademarks, and other symbols on labels as defined in this paragraph (e).

(1) The following are considered special statements and claims:

(i) Those not defined in the Federal meat and poultry products inspection regulations or the Food Standards and Labeling Policy Book;

(ii) “Natural” claims, regardless of whether they are defined in the Food Standards and Labeling Policy Book; and

(iii) Health claims (including graphic representations of hearts), ingredient and processing method claims (*e.g.*, high-pressure processing), structure-function claims, claims regarding the raising of animals (*e.g.*, “no antibiotics administered”), products labeled as organic (except for those where only individual ingredients are labeled as organic), and instructional or disclaimer statements concerning pathogens (*e.g.*, “for cooking only” or “not tested for *E. coli* O157:H7”).

(2) The following are not considered special statements and claims:

(i) Allergen statements (*e.g.*, “contains soy”) applied in accordance with the Food Allergen Labeling and Consumer Protection Act;

(ii) Negative claims regarding ingredients not listed in the ingredients statement (*e.g.*, “No MSG Added,”

“Preservative Free,” “No Milk,” “No Pork,” or “Made Without Soy”);

(iii) Statements that characterize a product’s nutrient content in compliance with Title 9 of the CFR, such as “low fat”; and

(iv) Claims related to geographical significance, such as “German Brand Made in the US,” or those that make a country of origin statement on the label of any meat or poultry product “covered commodity,”¹ or displays of geographic landmarks, such as a foreign country’s flag, monument, or map.

(f)(1) Temporary approval for the use of a final label that may be deemed deficient in some particular may be granted by the FSIS Labeling and Program Delivery Staff. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:

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

(ii) The use of the label 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 FSIS Labeling and Program Delivery Staff provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

[78 FR 66838, Nov. 7, 2013, as amended at 88 FR 2811, Jan. 18, 2023]

§ 412.2 Approval of generic labels.

(a)(1) An official establishment, or an establishment certified under a foreign inspection system in accordance with part 327, or part 381, subpart T of this chapter, is authorized to use generically approved labels, as defined in paragraph (b) of this section, and thus is free to use such labels without submitting them to the Food Safety and Inspection Service for approval, provided the label, in accordance with this section, displays all mandatory features in a prominent manner in compli-

ance with part 317 or part 381, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service will select samples of generically approved labels from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with part 327 or part 381, subpart T, to determine compliance with label requirements. If the Agency finds that an establishment is using a false or misleading label, it will institute the proceedings prescribed in §500.8 of this chapter to revoke the approval for the label.

(b) Generically approved labels are labels that bear all applicable mandatory labeling features (*i.e.*, product name, handling statement, ingredients statement, the name and place of business of the manufacturer, packer or distributor, net weight, legend, safe handling instructions, and nutrition labeling) in accordance with Federal regulations and do not bear special statements and claims as defined in §412.1(e).

[78 FR 66838, Nov. 7, 2013, as amended at 88 FR 2812, Jan. 18, 2023]

§ 412.3 Approval of U.S.-origin generic label claims.

(a) The claims “Product of USA” and “Made in the USA” may be used under generic approval on labels to designate single ingredient products derived from animals born, raised, slaughtered, and processed in the United States.

(b)(1) The claims “Product of USA” and “Made in the USA” may be used under generic approval on labels to designate multi-ingredient products if:

(i) All ingredients that are produced under FSIS mandatory inspection or voluntary inspection services in the product are derived from animals born, raised, slaughtered, and processed in the United States;

(ii) All other ingredients in the product are of domestic origin; and

(iii) The preparation and processing steps for the multi-ingredient product have occurred in the United States.

(2) For purposes of this paragraph (b), spices and flavorings need not be of domestic origin for claim use, but all

¹ See 9 CFR 317.8(b)(40) and 381.129(f).

other ingredients of the product must be of domestic origin.

(c) Claims other than “Product of USA” and “Made in the USA” may be used under generic approval on labels to designate the U.S.-origin component of single ingredient and multi-ingredient products’ preparation and processing only if the claim includes a description of the preparation and processing steps that occurred in the United States upon which the claim is being made. Such labels must be truthful and not misleading.

(d) Claims may be used under generic approval on labels to designate the U.S. State, Territory, or locality-origin of single ingredient and multi-ingredient products or components of a product’s preparation and processing, only if the claim meets the requirements for use of U.S.-origin claims under paragraphs (a) through (c) of this section with regards to the U.S. State, territory, or locality origin.

(e) Display of the U.S. flag, or a U.S. State or territory flag, may be used under generic approval on labels to designate the United States, U.S. State, or U.S. territory origin of single and multi-ingredient products or components of a product’s preparation and processing, only if the display of the flag meets the requirements for use of U.S.-origin claims under paragraphs (a) through (d) of this section. For the purposes of the display of a flag that meets the requirements for use of U.S.-origin claims other than “Product of USA” and “Made in the USA” under paragraph (c) or (d) of this section, the display must be accompanied by a description of the preparation and processing steps that occurred in the United States, or in the U.S. State or territory, upon which the claim is being made.

(f) In addition to the requirements in §412.2, official establishments using and facilities choosing to use labels that bear the claims “Product of USA” or “Made in the USA” to designate products of U.S. origin must maintain records to support the U.S.-origin claim. Examples of the types of documentation that may be maintained to support the U.S.-origin claims “Product of USA” or “Made in the USA” include:

(1) A written description of the controls used in the birthing, raising, slaughter, and processing of the source animals and eggs, and for multi-ingredient products the preparation and processing of all additional ingredients other than spices and flavorings, to ensure that each step complies with paragraphs (a) and (b) of this section.

(2) A written description of the controls used to trace and, as necessary, segregate, from the time of birth through packaging and wholesale or retail distribution, source animals and eggs, all additional ingredients other than spices and flavorings, and resulting products that comply with paragraphs (a) and (b) of this section.

(3) A signed and dated document describing how the product is prepared and processed to support that the claim is not false or misleading.

(g) In addition to the requirements in §412.2, official establishments using and facilities choosing to use a U.S.-origin label claim other than “Product of USA” or “Made in the USA” to designate the U.S.-origin preparation and processing steps of a product must maintain records to support the qualified U.S.-origin claim. Examples of the types of documentation that may be maintained to support the qualified U.S.-origin claim include:

(1) A written description of the controls used in each applicable preparation and processing step of source animals and eggs, all additional ingredients other than spices and flavorings, and resulting products to demonstrate that the qualified U.S.-origin claim complies with paragraph (c) or (d) of this section. The described controls may include those used to trace and, as necessary, segregate, during each applicable step, source animals and eggs, all additional ingredients other than spices and flavorings, and resulting products that comply with the U.S.-origin claim from those that do not comply.

(2) A signed and dated document describing how the qualified U.S.-origin claim regarding the preparation and processing steps is not false or misleading.

[89 FR 19495, Mar. 18, 2024]