

## SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

### PART 412—LABEL APPROVAL

Sec.

412.1 Label approval.

412.2 Approval of generic labels.

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) Sketch labels for products for foreign commerce whose labels deviate from FSIS regulations, with the exception of printing labels in foreign language or printing labels that bear a statement of the quantity of contents in accordance with the usage of the

country to which exported as described in § 317.7 and part 381, subpart M of this chapter.

(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 claims, logos, trademarks, and other symbols on labels that are not defined in the Federal meat and poultry products inspection regulations or the Food Standards and Labeling Policy Book, (except for “natural” and negative claims (e.g., “gluten free”), health claims, ingredient and processing method claims (e.g., high-pressure processing), structure-function claims, claims regarding the raising of animals, organic claims, and instructional or disclaimer statements concerning pathogens (e.g., “for cooking only” or “not tested for *E. coli* O157:H7”). Examples of logos and symbols include graphic representations of hearts and geographic landmarks. Special statements and claims do not include allergen statements (e.g., “contains soy”) applied in accordance with the Food Allergen Labeling and Consumer Protection Act.

(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.

#### §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 compliance 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, safe 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 reg-

ulations. Labels that bear claims and statements that are defined in FSIS's regulations or the Food Standards and Labeling Policy Book (except for natural and negative claims), such as a statement that characterizes a product's nutrient content, such as "low fat," has geographical significance, such as "German Brand," or makes a country of origin statement on the label of any meat or poultry product "covered commodity",<sup>1</sup> and that comply with those regulations are also deemed to be generically approved by the Agency without being submitted for evaluation and approval. Allergen statements (e.g., "contains soy") applied in accordance with the Food Allergen Labeling and Consumer Protection Act are also deemed generically approved.

## PART 416—SANITATION

Sec.

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AUTHORITY: 21 U.S.C. 451-470, 601-695; 7 U.S.C. 450, 1901-1906; 7 CFR 2.18, 2.53.

SOURCE: 61 FR 38868, July 25, 1996, unless otherwise noted.

#### §416.1 General rules.

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

[64 FR 56417, Oct. 20, 1999]

#### §416.2 Establishment grounds and facilities.

(a) *Grounds and pest control.* The grounds about an establishment must be maintained to prevent conditions

<sup>1</sup> See 9 CFR 317.8(b)(40) and 381.129(f).