

§412.2

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

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handling instructions, and nutrition labeling) in accordance with Federal regulations. 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",¹ 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

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AUTHORITY: 21 U.S.C. 451–470, 601–695, 1031–1056; 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

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