PART 412—LABEL APPROVAL

§ 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 mis-
represent 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 cre-
ate undue economic hardship; and
(iv) An unfair competitive advantage
would not result from the granting of
the temporary approval.

(2) Extensions of temporary approv-
als may also be granted by the FSIS
Labeling and Program Delivery Staff
provided that the applicant dem-
onstrates that new circumstances,
meeting the above criteria, have devel-
oped since the original temporary ap-
proval 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 generi-
cally approved labels, as defined in
paragraph (b) of this section, and thus
is free to use such labels without sub-
mitting them to the Food Safety and
Inspection Service for approval, pro-
vided the label, in accordance with this
section, displays all mandatory fea-
tures 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 generi-
cally approved labels from the records
maintained by official establishments
and establishments certified under for-
eign inspection systems, in accordance
with part 327 or part 381, subpart T, to
determine compliance with label re-
quirements. If the Agency finds that an
establishment is using a false or mis-
leading label, it will institute the pro-
ceedings prescribed in §500.8 of this
chapter to revoke the approval for the
label.

(b) Generically approved labels are
labels that bear all applicable manda-
tory labeling features (i.e., product
name, safe handling statement, ingre-
dients statement, the name and place
of business of the manufacturer, packer
or distributor, net weight, legend, safe
handling instructions, and nutrition la-
beling) 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 nat-
ural and negative claims), such as a
statement that characterizes a prod-
uct’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”, and that com-
ply 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”) ap-
plied in accordance with the Food Al-
lergen Labeling and Consumer Protec-
tion Act are also deemed generically
approved.