

without an official certificate issued in quadruplicate by a Program employee, a brand or other marking device containing an official inspection legend, or simulation thereof, shown in §312.2(a), §312.3(a) (only the legend appropriate for horse carcasses and parts of horse carcasses), §312.3(b) (only the legend appropriate for other equine (nonhorse) carcasses and parts of other (nonhorse) equine carcasses) or §312.7(a).

(1) The certificate is a Food Safety and Inspection Service form for signature by a Program employee and the official establishment ordering the brand or other marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the brands or other marking devices of the type and quantity listed on the certificate.

(2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the remaining two copies shall be given to the brand or other marking device manufacturer.

(3) The manufacturer of the brands or other marking devices shall engrave or otherwise mark each brand or other marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each brand or other marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the brands or other marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such brands or other marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such brand or other marking device which does not bear an identifying number, or, under the direction of the inspector-in-charge, mark such

brand or other marking device with a permanent identifying number.

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

[35 FR 15580, Oct. 3, 1970, as amended at 50 FR 21422, May 24, 1985]

#### §317.4 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 §317.5(b). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with part 320 of this subchapter. 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 §317.4(d), for all products, except as provided in §317.5(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 §317.4(a) 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 form) 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 §317.2. FSIS will accept sketches that are hand drawn, computer generated or other reasonable facsimiles that clearly reflect and

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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 §317.4(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 §317.5(b)(7).

(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.

(g) The inspector-in-charge shall approve meat carcass ink brands and meat food product ink and burning brands, which comply with parts 312 and 316 of this subchapter.

[60 FR 67454, Dec. 29, 1995]

### §317.5 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, is author-

ized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accordance with this section and shows all mandatory features in a prominent manner as required in §317.2, 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 part 327 of this subchapter, as required in §317.4, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in §335.12.

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

(1) Labeling for a product which has a product standard as specified in part 319 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 beef steak or lamb chops) 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 §316.13;