

LABELING

I. TERMS

- A. Labeling -- All labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers; or accompanying such article
- B. Marking -- The application of the official inspection legend, any other official mark or lettering to, or on, any product or on the product's outside container
- C. Label -- A display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the immediate container of product
- D. Principal display panel -- The part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale

II. LABEL CONTROL PROGRAM

A. Authority

The Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act gives FSIS the authority for a *label control program*. Before a label can be used, either the establishment or FSIS approves it.

B. Amenable

Only "amenable" products may bear the mark of inspection. These products must use only approved labels. Amenable means that it falls under USDA's jurisdiction. To be amenable, the food item must contain 3% or more raw red meat and 2% or more cooked meat and/or poultry meat. For egg products to be amenable, the egg is broken and the contents further processed.

Examples of products that would **not** be amenable are some cheese spreads w/ meat (these items must contain 50% meat before they are inspected by FSIS); closed-faced sandwiches (when a piece of bread covers the top); bouillon cubes; soups that contain less than the required amount of meat/poultry; and other products where the small amount of meat is considered to be flavoring. Eggs in the shell, cooked (including hard cooked eggs) and freeze-dried eggs are **not** amenable. Any egg substitute or imitation egg product (e.g., "Egg Beaters" which are egg whites with coloring added) are also **not** amenable to FSIS regulations in their final form.

Open faced sandwiches are amenable (the product is not covered by bread).

C. Reasons for control

- ? require informative labeling
- ? prohibit false or misleading label
- ? prevent unfair trade practices

D. Establishments' responsibilities

Establishments have certain responsibilities related to labeling. These are:

- ? to properly package and identify product so it is not misleading;
- ? to maintain records of all labeling used;
- ? to use only accurate labels;
- ? to use labels on appropriate product;
- ? to ensure required features appear in mandatory locations on labeling; and
- ? to ensure printing, colors, and materials do not cause adulteration (leach into product) or give a false impression (make the product appear fresher, pinker).

E. FSIS' responsibilities

FSIS also has the responsibilities to:

- ? monitor product formulation and processing procedures
- ? verify that labels contain mandatory features and accurately reflect the finished product
- ? provide establishment labeling information to the Labeling Review Branch (LRB) for audits of generic approvals

III. LABEL APPROVALS**A. Washington Approval**

The Labeling Review Branch, located in Washington, D.C, grants sketch approval or temporary approval to acceptable applications. Approval is granted based on information provided with the application. A domestic label application consists of 2 copies of a label application, with labels attached.

B. Generic Approval

Establishments may print a final label and use the label under the generically approved labeling category without further authorization from FSIS. Each generic approval record consists of the actual product's label, (including previous generic labeling and sketch approvals by FLD, if appropriate), the product formulation, and processing procedures. Generic approvals must be in conformance with all labeling regulations and policy and must not otherwise be false or misleading in any particular.

IV. LABELING APPROVAL SYSTEM

On July 1, 1996, a new labeling approval system was implemented in the field. Under this system, the Meat and Poultry Inspection Regulations were modified in order to:

- ? Institute a single label review.
- ? Permit companies to make minor labeling changes without resubmitting each label for prior approval.
- ? Permit companies to produce certain simple labels without submission to the Agency.
- ? Reduce the inspection personnel's paperwork and recordkeeping burdens.

FSIS Directive 7221.1 (8/19/96) further explains the regulation's intent.

A. Labeling Approvals Granted by LRB

There are only two types of labeling approvals granted by LRB: temporary and sketch.

1. *Temporary* approvals are granted *only* by LRB, and the labeling is acceptable for use only for a limited amount of time, not to exceed six months. LRB will indicate the expiration date on the label application.

Temporary approvals for the use of labels that are deficient in some manner are granted only under certain extenuating circumstances and only if *all four* of the following conditions are guaranteed.

The proposed labeling does not misrepresent the product.

Use of the labeling would not present any potential health, safety, or dietary problems for the consumer.

Denial of the request for temporary label approval would create undue economic hardship.

No unfair competitive advantage would result from granting the temporary approval.

Pressure sensitive stickers placed on current labeling and covering information are considered temporary labels and must go to LRB for approval. No temporary approvals are given if the ingredients statements do not declare the presence of certain additives which are in fact present.

Examples of these are sweeteners, salt, monosodium glutamate, restricted ingredients, sulfites (over 10ppm), and allergens (e.g., milk products, egg products, fish, poultry, crustacea, mollusks, tree nuts, peanuts, wheat, legumes).

Coupons with (or without) expiration dates are considered generic.

“New” Product Labels

In the past, if a label bore the wording “new”, “improved”, “now” or a similar statement, the manufacturer would be granted temporary approval for it if it so qualified. Today, the label is given “sketch” approval. The regulations’ interpretation that labels bearing such wording may only be used for six months (180 days) is still effective. If the manufacturer wishes to use such a label beyond six months, then s/he must submit the labeling to LRB as a temporary and indicate on the “Application for Approval of Labels, Marking or Device” form that it is for an extension and the reason for an extension. An extension will be granted only under the conditions provided in FSIS Directive 7220.1, Policy Memo 107.

2. *Sketch.* A sketch indicates the proposed setup, wording and required information of the labeling. The sketch is labeling that is presented as a printer's proof or equivalent, which clearly shows all labeling features, size, location, and indication of final colors.

Sketches may be hand-drawn, computer generated, or any other reasonable facsimiles that clearly reflect and project the final version of the labeling. Final color indication could be by submission of a:

- color sketch,
- sketch with descriptive language of the final colors, or
- similar sketch of previously approved final labeling that has the same colors.

Establishments are required to submit only sketch labeling in those instances where generic approval is not possible, e.g., the labeling contains special claims, guarantees or foreign language or where the product is a non-standardized product. Those instances that do not require LRB approval are listed in the Generic Labeling section below.

Where labeling is required to be submitted to LRB for review and approval, a parent company for a corporation may submit only one labeling application (in duplicate form) for a product produced in other establishments which are owned by the corporation. The label file may be kept at the company headquarters office. If such is the case, when a LRB audit is conducted, the labeling records must be made available within 24 hours to the FSIS program employee carrying out the audit request.

When LRB approves a label or other labeling as a sketch, the label application is stamped to indicate approval, given a number, dated, and distributed. One copy is kept by LRB to put on microfilm, the other copy is mailed to the establishment. If a label expediter is used, the expediter mails the establishment its copy, and LRB keeps a copy.

Once a sketch has been approved, the establishment has the authority to print a final copy, generically approve the label and use the labeling without any further authorization from the Agency. For the establishment to do this, the sketch labeling was either not modified in final form, or was modified only within the parameters outlined in item (9) on the next page.

Label approval by LRB does not mean approval of the processing procedure.

B. Generic Labeling

Generic labeling is labeling which does not require approval by LRB (provided such labeling complies with the regulations and policies) prior to it being used on product in commerce. The establishment does not need to complete a label application form for generic labeling, but it does need to have a record of the labeling in its files. A generic labeling record includes the actual label, formula, processing procedure and any prior sketch approvals (if applicable).

As per the regulations, generic labeling is:

- (1) Labeling for a product which has a standard as specified in the regulations or the Standards and Labeling Policy Book, and which does not contain any special claims*, guarantees, or foreign language on a domestic product [e.g., cooked beef, Italian sausage]
- (2) Labeling for single-ingredient products which does not contain any special claims*, guarantees, or foreign language on a domestic product [e.g., ground beef, turkey breasts, pork chops]
- (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 IIC [e.g., military contracts]
- (4) Labeling for shipping (master) containers which contain fully labeled immediate containers [the only requirements for master container labeling are that it has an inspection legend and, if applicable, a handling statement]
- (5) Labeling for products not intended for human food; and labeling for poultry heads and feet for export for processing as human food
- (6) Meat and poultry inspection legends
- (7) 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 products, provided such devices contain no reference to the product and bear no misleading feature [e.g., free tee-shirt offer]
- (8) Labeling for consumer test products not intended for sale [must indicate such on the labeling]

Note: These first eight items are defining situations where labeling is not required to be submitted to LRB. If any of the eight are applicable, then no formal approval by LRB is needed.

The last item identifies original labeling that has received prior Agency approval, but may be changed as indicated and used **without** resubmitting it to LRB.

(9) Labeling which was previously approved by LRB as a “sketch”, and the final labeling was prepared without modification, or with the following modifications:

- ? All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible
- ? The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement (e.g., "lb." for "pound" and vice versa, or "tsp." for "teaspoon" and vice versa)
- ? An approved master or stock label from which the name and address of the distributor are omitted and a name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval)
- ? Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations used with approved labeling, e.g., floral arrangements, illustrations of animals, fireworks (the use of such designs will not make it necessary to apply additional labeling)
- ? A change in the language or the arrangement of directions pertaining to opening of the containers or serving the product
- ? The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information
- ? Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line
- ? Any change in the net weight amount
- ? The addition, deletion, or amendment of recipe suggestions for the product
- ? Any change in punctuation
- ? Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by LRB
- ? The addition or deletion of open dating information
- ? A change in the type of packaging material on which the label is printed
- ? Brand name changes, provided that there is no use of a term that connotes quality or other product characteristics, no geographic significance, and no affect to the name of the product
- ? The deletion of the word "new" on new product labeling
- ? The addition, deletion, or amendment of special handling statements
- ? The addition of safe handling instructions
- ? Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum and maximum limits for the use of such ingredients
- ? Changes in the color of the labeling, provided that sufficient contrast and legibility remain
- ? A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package
- ? A change in the establishment number by a corporation or parent company for an establishment under its ownership; addition, deletion or substitution of the official USDA poultry grade shield
- ? Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for serving sizes, provided the nutrition labeling information maintains its accuracy and consistency [The need to maintain uniform serving sizes for specific products is very critical to the overall integrity of the nutrient profile of products.]
- ? Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information
- ? The addition or deletion of a direct translation of the English language into a foreign language for

- products marked "for export only"
- ? Addition of a descriptive term as required by poultry regulations
- ? Poultry grading shield

These labeling modifications do not require further authorization from the Agency. The responsibility for ensuring that generic labels are in compliance with the regulations rests with the establishment. Since prior sketch approval is not always possible for product labeling, some manufacturers may be concerned with their ability to fully understand and consistently interpret the existing labeling policies and regulations. The potential exists for misbranded product entering the marketplace and penalties for misbranding and product recalls. Because some of the regulations and policies are complex to interpret, LRB will review labeling for multi-ingredient standardized products if the manufacturer submits it. However, it is the manufacturer's decision whether or not the labeling is generic or requires LRB approval. If the labeling is not generic, LRB will only give it a single review, that is, sketch approval only. Any modifications of that labeling would more than likely fall into the generic category.

The manufacturer must obtain sketch approval **at least once** for labeling with claims (quality, nutrient content, health, negative statements, geographical origin, etc.), guarantees, foreign language and nutrition information. After the initial approval, the labels can be modified and the establishment can treat them as generic labels. For example, the manufacturer can obtain LRB sketch approval for a beef label stating "Select" or "Choice." This label can then be modified for use with any beef cut the manufacturer wishes as long as it is appropriate (e.g., to be labeled "Choice", the product **must be** "Choice") by using generic labeling. Similarly with nutritional information, the manufacturer may have one panel approved for use on soup. This can be modified for use on all soups the manufacturer produces. Quantitative changes in nutrient amounts may be made without submitting it to LRB (i.e., the label change is considered generic). However, if the serving size changes, then LRB sketch approval is required.

Labeling prepared for the Child Nutrition (CN) Program will not be included in a generic approval category and will require review and sketch approval by FSIS. Any change to the CN label must be approved by the Food and Consumer Service.

V. STANDARDIZED PRODUCTS

Generic approval can be given to labeling for all standardized products with no claims, guarantees, and foreign language. These are products with a standard of identity or composition as given in the regulations (e.g., 318.19, 381.150), the Food Standards and Labeling Policy Book and the Labeling Policy Memos (FSIS Directive 7220.1). Simply put, **the product has a standard if there are provisions set forth for ingredient content or a specific product preparation method.**

There are two types of standardized products: specific and nonspecific.

A. SPECIFIC PRODUCTS

Specific products are those with a definition for ingredient content or a specific preparation method. This does not preclude additional ingredients or modified amounts in the actual formulation. These would include complex products like:

- ? Italian Sausage - at least 85% pork with pork fat, but no more than 35% total fat in the finished product; salt; pepper; fennel and/or anise
- ? Chicken Cordon Bleu - no less than: 60% chicken breast meat (sliced), 5% ham or Canadian Style Bacon, cheese (Swiss, Gruyere, Mozzarella or pasteurized processed Swiss); and no more than 30% batter and breading (if used)
- ? Chicken Enchiladas - at least 15% raw or 10.5% cooked chicken meat
- ? Pastrami – cooked cured beef with spices that has either been smoked or treated with smoke flavoring,

and single ingredient products:

- ? Ground Beef - beef (no organ meat, which includes tongue and heart), no added fat as such, a maximum of 30% fat, no more than 25% cheek meat
- ? Beef Loin T - bone Steak
- ? Boneless Turkey Breast (without added ingredients)

Note: LRB will not review label applications for amenable single ingredient products where the labeling does not bear special claims, guarantees or foreign language. These types of product labels are to be generically approved.

B. NONSPECIFIC PRODUCTS

These are products that do not have specific requirements. These types of products will either have a descriptive product name identifying the characterizing components and/or ingredients or a nonspecific product name. Examples of descriptive names are “Beef, Water and Binder Roast” or “Broiled Chicken, Mashed Potatoes and Gravy.” Nonspecific product names do not exist for poultry products since the poultry labeling regulations require the kind of poultry in the product name. Nonspecific names usually do not bear the terms “meat” or the species of meat, e.g., “beef” “pork,” etc., and must be accompanied by an ingredients statement. Examples of nonspecific names are “Red Hots,” “Sibyl’s Surprise” or “P & P Loaf.”

VI. NON-STANDARDIZED PRODUCTS

Products that have no standard of identity or composition are classified as non-standardized products. The labeling for these products must be approved by LRB.

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An example of a **non-standardized product** (of which there are few) is “reaction flavors”. These are end products of the chemical reactions that occur between reducing sugars and amino acids or proteins in the presence of heat. They are also called “process flavors”. Powdered beef flavor is an example. Other non-standardized products are those that are inspected voluntarily (e.g., ratites, buffalo, and venison).

As is evident, the vast majority of labels will fall into the generic category.

VI. KEY AREAS OF LABELS

A. Reviewing

When reviewing a label, some key areas are:

- ? All applicable information is given on the label application
- ? Correct number of applications are submitted
- ? A label is attached to each application
- ? Check for the 8 required features on every consumer-sized label (*Depending on the product, some features may not be necessary. For example, if the product is shelf stable, it does not need a handling statement.*)

B. 8 Required Features

1. Name of product -
 - a. common name
 - b. meets the product standard
2. Ingredients statement - (if needed)

order of predominance based on the amounts of ingredients used in the product preparation rather than amounts residing in the finished product
3. Inspection legend and establishment number-
 - a. sufficient size
 - b. legible
 - c. exact form and arrangement as in ?312.2 and ?381.96 (letter size must have same boldness and proportions as in the examples in the Regulations), conspicuous color
 - d. the establishment number may be located inside or outside of the legend
4. Handling statement - (if needed)

meets requirements of ?317.2(k) and ?381.125
5. Safe handling instructions (if needed)
 - a. all raw meat and poultry (any product not fully-cooked or ready-to-eat)
 - b. must be prominently displayed on the label

6. Net weight statement -
 - a. net quantity
 - b. conspicuous
 - c. in Avoirdupois weight or liquid measure
7. Signature line -
 - a. name of the manufacturer, packer, or distributor
 - b. address (city, state, zip code)
8. Nutrition labeling of meat and poultry products - (if needed)
 - a. all meat and poultry products except single ingredient raw product and product not for direct sale to consumers
 - b. small businesses are exempt if no nutritional claims or information are on the label

VII. LABELS FOR IMPORTED PRODUCT

A. Same As Domestic Label Requirements

1. Immediate containers

The same immediate container labeling requirements that apply for domestic product also apply for imported product. However, "Product of _____" must be immediately under the product name. Also, the mark of inspection shall be the official inspection mark of the foreign meat/poultry inspection system and the establishment number is the same that is assigned by the foreign inspection system and certified to the program.

2. Shipping containers

Shipping container labels must bear in English

? The product name

? The name of the country of origin

? Establishment number assigned by the foreign meat/poultry inspection system and certified to the program

B. Review

The LRB reviews every label that they receive for sketch or temporary approval. However, labels that are only to be generically approved will be returned unprocessed. The foreign companies are to use the generic system exactly as the domestic plants are supposed to do.

The import offices do not receive or retain labels at the points of entry. If there is a problem with the label, the import inspector will take action on the label or submit it for audit to the LRB. In addition, LRB may request a foreign establishment to send labels to Washington, D.C., for audit.

C. General information

All labeling must comply with FSIS labeling regulations found in 9 CFR §317.1 through §317.400 for meat and §381.115 through §381.141 (Subpart N) for poultry. Additional labeling requirements specific to foreign labels may be found in §327.14 or §381.205.

Nutrition labeling regulations can be found in §317.300 through §317.400 for meat and §381.400 through §381.500 for poultry. FSIS labeling policy is further defined in the FSIS Food Standards and Labeling Policy Book which also contains the FSIS Labeling Policy Memorandums which are also available in FSIS Directive 7220.1. Question and Answer Directives such as FSIS Directive 7260.1 pertaining to nutrition labeling are often issued to help explain and interpret major changes to labeling regulations. These publications often address specific foreign label approval issues.

The management of establishments certified under foreign inspection systems must maintain copies of all labeling used, along with the relevant product formulations and processing procedures. Foreign establishments are responsible for ensuring the accuracy of labeling for all product exported to the United States. Foreign inspection systems will verify that each establishment maintains complete labeling records and practices that result in compliance with current FSIS labeling regulations and policy. Where appropriate, foreign countries will declare a protein fat free (PFF) group number on the health certificate for product amenable to PFF analysis in accordance with the regulations. Also, Group II protein data must be supplied on the health certificate for sausage products which contain Group II protein ingredients.

Prior to exporting meat and poultry products to the U. S., foreign establishments will submit label sketches (in triplicate) in those circumstances where labeling is required to be submitted to LRB for approval. LRB will retain one copy of the approved sketch, return one copy to the submitting party, and send one copy to the International Programs Division (IPD). IPD will send the approvals to the foreign government's inspection system.

FSIS Foreign Programs Officers will verify a foreign inspection system's labeling controls by reviewing their labeling records (e.g., LRB sketch labeling approvals and generically approved labeling). When a shipment is presented for reinspection at the U. S. port of entry, FSIS import inspectors will ensure that the labeling contains all mandatory features and accurately reflects the finished product.