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INTRODUCTION

Processed food and beverage products must be properly labeled according to applicable state and federal regulations. The Tennessee Department of Agriculture (TDA) Consumer and Industry Services regulates food and beverage labels for the state. The Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) are the two primary federal agencies that regulate food and beverage product labeling.

Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), the USDA's Food Safety and Inspection Service (FSIS) has regulatory authority over meat and

poultry product labeling. USDA's FSIS develops and enforces policy for meat product labeling and ensures that meat products are properly labeled before they are marketed. Meat product labels must receive approval from the FSIS before they are used in commerce. Their role includes the verification that all statements and claims on meat product labels are truthful and not misleading.

Efforts to differentiate products through special statements and claims have become increasingly prevalent in retail food marketing. In 2016, the USDA's Economic Research Service (ERS), using data from Mintel's Global New Product Database (Mintel GNPD), indicated that more than 70 new label claims or tags were introduced to the retail food market [1]. The study shows that an increasing percentage of new food and beverage products includes special claims related

to health and convenience. According to the National Grocers Association's 2015 Consumer Survey Report, more than 77 percent of consumers "Almost Always" or "Sometimes" consider health claims when purchasing new food products, although this figure is down from approximately 81 percent in 2014 and 2013 and 84 percent in 2012 [2].

Meat products are no exception to the trend in the use of special statements and claims on labeling. Meat product labels and promotional materials often feature production claims (e.g., grass fed, grain fed, no added hormones, USDA-Certified Organic, pasture raised, etc.) and health statements (e.g., low fat, heart healthy, etc.). Using special statements and claims on meat product labels can be a useful branding and marketing strategy to differentiate products from competitors and to help capture a

targeted segment of customers. A customized meat product label adds value to meat products, which, in turn, may increase the amount customers are willing to pay for those products.

Direct farm marketers often make special claims about their meat product's quality and production methods on their promotional materials, websites and social media. Few direct farm marketers in Tennessee, however, make special statements and claims on their meat product labels. This may be attributed, in part, to producers' lack of information about USDA's FSIS label approval process for special statements and claims.

This publication provides information to help value-added meat producers understand federal and Tennessee-specific labeling regulations and navigate label approval processes. Topics discussed include USDA FSIS definitions of labels and labeling, minimum labeling requirements at the federal and state levels, USDA FSIS label approval processes, and the steps involved in requesting and gaining approval to use special statements and claims on meat product labels.

To simplify terminology for the purposes of this document, the term "meat" will be used in reference to amenable livestock and poultry products covered in the Federal Meat Inspection

Act and the Poultry Products Inspection Act. Amenable products are inspected by USDA officials without a fee-for-service to the processor. Amenable livestock products include those derived from cattle, sheep, goats, swine, horses, mules and other equines. Amenable poultry products include those derived from domesticated chickens, turkeys, ducks, geese and guineas.



USDA FSIS DEFINITIONS OF LABELS AND LABELING

USDA FSIS has regulatory authority over meat product labeling [3]. Understanding how the FSIS defines and distinguishes labels and labeling can help producers meet federal regulatory requirements when using special statements and claims.

Labels are applied to meat product packaging to provide consumers with product information. In Title 9 Code of Federal Regulations (C.F.R.) § 317.2 (a), the term “label” is defined as “a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the immediate container (not including package liners) of any product.”

The FSIS definition of “labeling” is broader than its definition of “label,” as it includes the general definition of a meat product label and encompasses the promotional material used at the point of sale. “Labeling” is defined in 9 C.F.R. § 301.2 as “all labels and other written, printed, or graphic matter: (1) Upon any article or any of its containers or wrappers, or (2) Accompanying such article.” [3] Therefore, FSIS regulates the content of labels affixed to meat products

and point-of-purchase materials that are used for meat products such as brochures, pamphlets, signs or other promotional devices [3].

The FSIS requires approval of all labels applied to meat products before their use in commerce. FSIS does not require preapproval of point-of-purchase materials, even if these materials contain special statements and claims describing the farm’s production practices or product characteristics. Special statements and claims made on point-of-purchase promotional materials, which are considered labeling by the FSIS, should be consistent with the statements and claims made on meat product labels, however. Special statements and claims should not be used on point-of-purchase materials if they have not been approved by FSIS for use on meat product labels [4]. The FSIS has the authority to take corrective action against meat product labels and point-of-purchase promotional materials considered false or misleading.

Label:

“a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the immediate container (not including package liners) of any product.”

Labeling:

“all labels and other written, printed, or graphic matter:
(1) Upon any article or any of its containers or wrappers, or
(2) Accompanying such article.” [3]



MINIMUM LABELING REQUIREMENTS

Minimum label requirements are determined by USDA FSIS and TDA. FSIS regulations stipulate that meat product labels contain a minimum set of eight mandatory labeling features. The TDA requires two additional label components for specified products. All minimum label requirements are listed in Table 1.

TABLE 1. MINIMUM LABEL REQUIREMENTS BY USDA FSIS AND TDA
USDA FSIS REQUIREMENTS
<ol style="list-style-type: none">1. Product name2. Handling statement (e.g., “Keep Frozen,” “Keep Refrigerated,” or “Perishable – Keep Refrigerated or Frozen”)3. USDA mark of inspection/establishment number4. Net weight for product sold at retail5. Signature line (name or trade name and address of the manufacturer, packer or distributor)6. Safe handling instructions7. Nutrition labeling (For single-ingredient, raw major cuts of beef, pork, lamb and poultry, nutrition labeling must be included on the package or posted at the point of sale. Ground or chopped products must include nutrition labeling on the package unless processed at a small plant.)¹8. Ingredients statement (for multiple ingredient meat products only)
TDA REQUIREMENTS
<ol style="list-style-type: none">9. Price per pound (kilogram) (for random weight, non-frozen products only)10. Total price (for random weight, non-frozen products only)

¹USDA FSIS Nutrition Facts charts for display at the point-of-sales are available online at <http://tiny.utk.edu/nutritioninformation>. For more information, see the section “Nutrition Labeling Requirements for Single-Ingredient Products and Ground or Chopped Meat and Poultry Products” on page 8 in *Basic Regulatory Considerations for Retail and Non-retail Meat Sales in Tennessee*, available online at <https://tiny.utk.edu/PB1829>.

FSIS regulations specify that labeling features one (1) through four (4) in Table 1 be displayed on the principal display panel (PDP), which corresponds to the front, most visible portion of the meat package. Labeling features five (5) through eight (8) may be placed on the PDP or the information panel (IP). The IP can be located on the front, side or back of the meat product package [5].

In addition to the eight labeling requirements set by FSIS, the TDA Consumer and Industry Services, Weights and Measures Section regulates the proper labeling of the net weight, price per pound (or kilogram) and total price for meat products sold in Tennessee. TDA's Weights and Measures requirements depend on whether the meat products are sold frozen or non-frozen and whether the products are random or standard weight. Random weight products are of variable net weight, such as chuck roasts packaged according to their exact weight (e.g., 3.45 pounds and 4.23 pounds). Standard weight products all have the same weight, such as 1-pound packages of ground lamb.

For random weight, non-frozen meat products, regulations specify that the price per pound and total price are plainly and conspicuously included on the label (Tennessee Code Annotated § 47-26-917). Due to the TDA's "Waiver of Declaration of Unit Price on Frozen Random Weight Packages" released in 2015, random weight, frozen meat products can either clearly indicate the price per pound on the label or plainly and conspicuously display the price per pound on a sign, poster, board, shelf, etc., located in close proximity to where the meat products are sold. The total price for frozen meat products can either be included on the label or calculated at the point of sale [6, 7].

Standard weight meat products – non-frozen or frozen – must include the net weight on the label. Standard weight items are not required to include the price per pound and total price on the label. However, the price of the product should be plainly and conspicuously displayed at the point of sale.

For more details regarding the TDA's weights and measures regulations, producers can reference the publication *Retail Meat Sales in Tennessee: Basic Weights and Measures Regulations*, available at <https://tiny.utk.edu/D1-CPA> [7].

Nutrition Facts

Serving Size 4 oz (112g)
raw, as packaged.
Servings Per Container varied

Amount Per Serving		
Calories	150	Calories from Fat 50
		% Daily Value*
Total Fat	6g	9%
Saturated Fat	2.5g	13%
Cholesterol	70mg	23%
Sodium	75mg	3%
Total Carbohydrate	0g	0%
Protein	24g	48%
Iron	15%	•

Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, and calcium
* Percent Daily Values are based on a 2,000-calorie diet

Center for Profitable Agriculture





**Retail Meat Sales in Tennessee:
Basic Weights and Measures Regulations**

April 2015
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Marketing Specialist
Center for Profitable Agriculture

Retail meat sales in Tennessee must comply with state weights and measures regulations as written in Tennessee Code Annotated § 47-26-901 to § 47-26-906. The regulations outline requirements for the allowable units of sale and related weighing and labeling requirements for meat products as well as the agency responsible for enforcing the regulations. The rules are in place in part to "prevent unfair or deceptive dealing by weight or measure in any commodity or service advertised, packaged, sold or purchased within the state." This fact sheet summarizes the weights and measures regulations related to retail meat sales in Tennessee as of the date of publication and provides some examples to illustrate how the requirements may be implemented.

The weights and measures regulations are enforced by the Weights and Measures section of the Tennessee Department of Agriculture's (TDA) Consumer and Industry Services Division, formerly known as Regulatory Services. The Weights and Measures staff members have the ability to inspect products for accuracy of net weight and related labeling information. If a violation is identified, a stop sale order may be given, and the product cannot be sold until it is in compliance. A warning letter describing the problem and what needs to be done to correct it may be issued. The second time a violation is found, a civil penalty may be assessed at a rate of up to \$500 per violation. The violator may then correct the issue and pay the civil penalty or request a hearing.

The following points summarize the weights and measures regulations for the retail sale of meat and meat products in Tennessee at the time of publication.

- The name of the product and the name and address of the manufacturer, packer or distributor must be displayed on all packages (TCA 47-26-916) *

*Note that this publication only discusses labeling requirements according to the weights and measures regulations. Other regulations impose additional requirements on some labels.

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Retail Meat Sales in Tennessee: Basic Weights and Measures Regulations
<https://tiny.utk.edu/D1-CPA>



Figure 1 shows an example of a Tennessee producer's meat product label. The principal display panel of this example label contains the first seven of eight minimum labeling requirements stipulated by FSIS. The producer could choose to post nutrition information at the point of sale, rather than include it on the label. This particular product is exempt from including an ingredients statement, the eighth minimum labeling requirement, because it is a single-ingredient product.

Although not required for frozen meat, the label includes the price per pound and total price of the product. The producer could alternatively post the price per pound at the location where the meat is sold and calculate the total price at the point of sale for consumers.

7) Nutrition Facts

5) Signature Line

3) USDA Mark of Inspection

2) Handling Statement

6) Safe Handling Instructions

1) Product Name

4) Net Weight



Figure 1. The first seven of eight minimum labeling features required by FSIS are contained in the principal display panel (PDP) of this example label. The first seven minimum labeling features are signaled in the label and include 1) the product name, 2) handling statement (i.e., “Keep Refrigerated”), 3) USDA mark of inspection, 4) net weight, 5) signature line (in this case, the name and address of the processor), 6) safe handling instructions and 7) nutrition labeling. The producer also satisfies TDA’s additional marketing requirements by including the price per pound and total price on the bottom portion of the label. (Image used with permission from Double A Farms.)

USDA LABEL APPROVAL PROCESS: GENERIC APPROVAL AND SKETCH APPROVAL

To adhere to federal regulations, all labels used on meat products must be approved by FSIS before their use in commerce. Labels are approved in one of two ways: 1) generic approval and 2) sketch approval (9 C.F.R. § 412.1-412.2). Generically approved labels do not require a formal label application submission to FSIS for evaluation and approval. Sketch-approved labels undergo a formal label application submission, evaluation and approval process. The following sections describe each label approval method and discuss the criteria by which meat product labels with statements and claims require generic or sketch approval.

GENERIC APPROVAL

Generically approved meat product labels contain the minimum set of eight mandatory USDA labeling features (9 CFR § 412.2) and may also include statements and claims deemed factual by FSIS without the need for additional validation or verification [3]. FSIS publication, *A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products*, [3] provides the following description of generic approval: “Products for which a standard of identity applies may be generically approved, provided that the labeling does not contain any special claims, including quality claims, nutrient content or health claims, negative claims, geographical origin claims, or guarantees.”² FSIS regulatory authorities state that “FSIS’s meat and poultry regulations permit certain labels, including those that are not likely to present significant policy issues that have health or economic significance, to be ‘generically approved’ without having to be submitted to the Agency’s headquarters-based labeling staff, as long as the labels comply with the regulations. Although not submitted to FSIS, generically approved labels are approved by FSIS by being in compliance with applicable regulations.” [8]

FSIS inspection program personnel (IPP) stationed in federally inspected meat processing facilities also do not approve labels. According to FSIS Directive 7221.1 [9], FSIS IPP’s general label verification activities include periodically verifying, through random selection of meat products in federally inspected meat processing establishments, that meat product labels contain the eight mandatory labeling features and that facilities are maintaining all relevant supporting labeling records such as product formulation, processing procedures, and special statements and claims documentation. Meat processing establishments should ensure that meats packaged in their facilities are properly labeled according to FSIS labeling requirements.

EXAMPLES OF GENERICALLY APPROVED CLAIMS

A list of generically approved, factual statements and claims for meat product labels (with the exception of “natural” and “negative claims”) is provided in the USDA *FSIS Food Standards and Labeling Policy Book* [10].³ In this document, FSIS provides definitions and requirements that producers must follow to correctly use specified generically approved statements and claims listed. A more condensed list of generically approved label claims is available in *FSIS Compliance Guidance for Label Approval* [11].⁴ Four examples of generically approved statements and claims that direct farm marketers apply to their meat product labeling include:

1. Geographic claims.
2. State endorsement programs without a geographic emblematic design.
3. “Aged,” “Aged Beef” and “Dry aged.”
4. “All,” “100%,” “Pure.”

The four generically approved statements and claims may be used on meat product labels without having to be submitted to the FSIS headquarters as long as producers use the terms in accordance with FSIS’s definitions and requirements for each statement or claim.

²The USDA FSIS is responsible for creating standards of identity for meat and poultry products [3]. A standard of identity specifies a food product’s common name and in many cases establishes a product’s preparation method, quality standards, mandatory and optional ingredients, and minimum and maximum amounts of ingredients. A standard of identity may include additional labeling requirements such as qualifying statements to describe the meat product. Identity standards are intended to provide transparent production standards for food manufacturers and help protect consumers from misbranded products.

³*Food Standards and Labeling Policy Book*. Available at http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf.

⁴*FSIS Compliance Guidance for Label Approval*. Available at <https://tiny.utk.edu/FSISCompliance>.

Example 1:

Geographic claims



A geographic claim is a factual statement regarding the product's origin that, with some exceptions, is generically approved when used on meat product labels. For example, a meat product label with the statement "Tennessee Beef" or "Produced in Tennessee" is generically approved as long as the meat is produced and processed in Tennessee. If the label uses a geographic logo or flag to communicate the origin of the meat product, such as the outline of the state of Tennessee, sketch label approval, discussed in the next section, would be required because geographic logos and flags are considered a type of special statement and claim. Producers can refer to the USDA FSIS publications, *Food Standards and Labeling Policy Book*, and *FSIS Compliance Guidance for Label Approval*, for more examples of acceptable geographic claims under generic approval.

Geographic claims used on meat product labels must accurately reflect whether any component of production or processing occurs in another state. Because Tennessee shares borders with several states, producers near state lines may raise their livestock in-state but use an out-of-state USDA-inspected meat processing facility. If a producer raises their animal in Tennessee but has the meat processed in another state, such as Kentucky, a meat product label with the statement "Produced in Tennessee" would not be an acceptable claim for generic approval. The label could, however, include the claim, "Produced in Tennessee, Processed in Kentucky."

Example 2:

State endorsement programs without a geographic emblematic design



Producers affiliated with state endorsement programs are often able to include the program's logo on their meat product label under the generic approval system, as long as the logo's design does not portray a geographical image of the state. Producers should provide their processor with documentation that supports the use of the logo to include in their labeling records. Meat product labels containing geographic logos or flags that show a map or

outline of a specific region would require sketch approval. In Tennessee, meat product labels featuring the Pick Tennessee Products logo, the Tennessee Department of Agriculture's promotional program for state-made products, would be generically approved because its design does not have a geographic outline of the state. The use of a state endorsement program emblem that includes the word "Certified" also requires sketch approval.

Example 3:**“Aged,” “Aged Beef” and “Dry Aged”**

Producers selling aged meat may be interested in communicating this product characteristic to their customers. Meat product labels with the statements “Aged,” “Aged Beef,” or “Dry Aged” are generically approved as long as the statements are used in accordance with the labeling definitions and requirements stipulated in USDA FSIS *Food Standards and Labeling Policy Book* [10]. Although the three terms have similar meanings, FSIS labeling requirements regarding their use on meat product labels vary depending on whether “Aged,” “Aged Beef” or “Dry Aged” is employed.

The USDA FSIS defines “Aged” as “the process by which fresh meat (carcasses or cuts) is held in a controlled environment for a specified period of time of slaughter, to allow enzymatic activity to degrade complex proteins and promote the development of flavor and tenderness.” [10] FSIS requires that meat products labeled as “Aged” include a qualifying statement that specifies the number of days in which the meat was aged. For example, meat aged for 15 days should state, “Aged 15 days,” on the meat product label.

FSIS describes “Aged Beef” as the process by which “the beef products (carcass or cuts) are maintained in a fresh unfrozen state for a minimum of 14 days from the day of slaughter.”

According to USDA FSIS *Food Standards and Labeling Policy Book* [10], meat products labeled as “Aged Beef” that are sold to non-retail customers, such as hotels, restaurants, and institutions (HRIs), must specify on the principal display panel (PDP) the type of aging process performed (i.e., wet aged or dry aged) and the minimum number of days the meat was aged. For example, dry-aged meat products sold to restaurants following the “Aged Beef” claim guidelines must use the statement, “Dry aged for a minimum of ___ days.” Meat products using the “Aged Beef” claim that are sold to retail customers, however, need only to specify the minimum number of days in which the meat was aged. For example, dry-aged meat products sold to farmers market customers could contain the statement, “Aged for a minimum of ___ days.”

According to USDA FSIS, “Dry Aged” refers to the process by which “Fresh Meat is held (without vacuum packing) for various periods of time (usually 10 days to 6 weeks) under controlled temperatures (34° F to 38° F), humidity, and airflow to avoid spoilage and ensure flavor enhancement, tenderness, and palatability.” [10] Meat product labels with the term, “Dry Aged,” do not need a qualifying statement regarding the number of days in which the meat was dry-age processed [10].

Example 4:**“All,” “100%,” “Pure”**

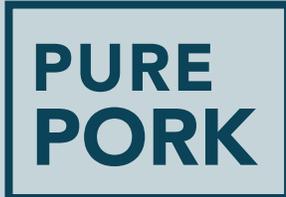
Meat product labels with the terms “All,” “100%” or “Pure” are generically approved as long as the statements are a truthful description of the product. A producer selling bratwurst, for example, may want to market their product as “100% Beef” or “100% Pork.”



**100%
BEEF**



**100%
PORK**



**PURE
PORK**



**ALL
BEEF**

SUMMARY OF GENERIC APPROVAL

Producers should remember that generically approved labels:

- ✓ Follow the eight mandatory labeling requirements according to FSIS regulations.
- ✓ Do not require a formal label application submission to FSIS.
- ✓ May contain statements and claims of fact as defined by FSIS.
- ✓ Cannot contain special statements and claims, including quality claims, certain nutrient content or health claims, negative claims, certain geographical origin claims, or guarantees. Labels with special statements and claims require sketch approval by the FSIS.

SKETCH APPROVAL

Labels bearing special statements and claims that cannot be generically approved require sketch approval. Sketch approval involves a formal application submission, evaluation and approval process by FSIS Labeling and Program Delivery Staff (LPDS). The application must be accompanied by a sample label, hence the term “sketch,” as well as documentation supporting the special statement and claim.

Acceptable label sketches include a printer’s proof, a computer-generated image, a hand-drawn copy or any other label replica that clearly displays the label’s features, size and location on the meat product [5]. Documentation supporting special statements and claims may include a producer affidavit describing their production protocol, feed tags or third-party certification. The Appendix section provides an example label sketch and producer affidavit for a farmer seeking approval to use the special claim, “100% Grass-Fed Beef,” on their meat product label.

EXAMPLES OF SPECIAL STATEMENTS AND CLAIMS REQUIRING SKETCH APPROVAL

There is no comprehensive list of special statements and claims requiring sketch approval because there is an infinite number of potential statements and claims that can be created by producers. The *FSIS Compliance Guidance for Label Approval* [11] provides the most up-to-date list of various special statements and claims requiring sketch approval by FSIS LPDS. Some examples of special statements and claims listed in the *FSIS Compliance Guidance for Label Approval* document that direct marketing meat producers often use on their meat product labels that require sketch approval include:

Animal Raising and Production Claims

- ◆ No Added Hormones (May require a disclaimer such as, “Federal regulations prohibit the use of hormones in poultry.” See additional information later in this section.)
- ◆ Raised Without Antibiotics
- ◆ Not Fed Animal By-Products
- ◆ Grass Fed
- ◆ Grass Fed, Grain Finished
- ◆ Pasture Raised
- ◆ Free Range
- ◆ Free Roaming
- ◆ Sustainably Raised
- ◆ Humanely Raised
- ◆ Breed claims
 - ◇ Angus, Hereford, etc.
- ◆ Local claims
 - ◇ Local, Locally Raised, Locally Grown, Locally Sourced, etc.

- ◆ Third-party raising claim programs
 - ◇ Agriculture Marketing Service (AMS) Process Verified, American Grass-fed Association, etc.
- ◆ Certified claims
 - ◇ USDA Certified Organic, Certified Naturally Grown

Natural Claims

- ◆ All Natural, 100% Natural

Nutrition Claims

- ◆ Omega fatty acid claims, Heart Healthy, etc.

Negative or “Free” Claims

- ◆ No Artificial Ingredients, No Preservatives, Gluten Free

In some cases, farm names contain special statements and claims. For example, a farm named “Smith Grass-Fed Beef” includes a grass-fed beef animal production claim. In this example, if the farm name is displayed outside of the label’s signature line (i.e., where the name or trade name and address of the manufacturer, packer or distributor are located), the producer would be required to obtain sketch approval from FSIS LPDS.

In addition, not all claims are appropriate for every type of meat product. For example, because hormones can only be administered in beef cattle and lamb production, the use of the statement, “No hormones administered,” for poultry, pork or veal must be immediately followed with the statement, “Federal regulations prohibit the use of hormones in _____.”

UNAPPROVABLE CLAIMS

Some statements and claims cannot be proved and, thus, cannot be used on meat product labeling. The FSIS has published a list of unapprovable claims [12]. Producers should familiarize themselves with the following list of unapprovable claims developed by FSIS to avoid making untruthful or misleading claims on meat product labeling and avoid requesting approval of statements and claims that FSIS has already classified as unapprovable:

- ◆ Antibiotic free
- ◆ Hormone free
- ◆ Residue free
- ◆ Residue tested
- ◆ Naturally raised
- ◆ Naturally grown
- ◆ Drug free
- ◆ Chemical free

SUMMARY OF SKETCH APPROVAL

Producers should remember that sketch-approved labels:

- ✓ Follow the eight mandatory labeling requirements according to FSIS regulations.
- ✓ Contain special statements and claims that must be verified by the FSIS LPDS.
- ✓ Require a formal label application submission to FSIS LPDS, which includes a label sketch that clearly displays the label’s features, size and location on the meat product and supporting documentation that justifies the special statements and claims.

STEPS TO SUBMITTING A SPECIAL CLAIM FOR SKETCH APPROVAL

A step-by-step explanation of the sketch approval application process may help producers prepare and submit their label approval application to FSIS LPDS. The sketch approval application process can be summarized in five steps.

STEP 1: Communicate with Processor

Producers should communicate their plans of submitting a label approval application with their meat processor [14]. USDA-inspected meat processing facilities are the entities that ultimately need approval from FSIS LPDS. USDA-inspected meat processing facilities perform general meat labeling tasks and require FSIS approval to apply labels to meat products that contain special statements and claims. Labels cannot be added to meat products by the producer outside of the processing facility.⁵

STEP 2: Develop the Label Sketch

Producers will need to develop the label sketch to submit with the label application. The label sketch can be a printer's proof, a computer-generated image, a hand-drawn copy or any other label reproduction as long as it clearly displays the label's features, size and location on the meat product [5]. By working closely with their meat processor, producers can ensure that their label sketch contains the eight mandatory labeling requirements stipulated by FSIS. Further, some local meat processing facilities can help producers design the label sketch, though they may charge an additional fee for this service. Appendix A shows an example label sketch for the special label claim, "100% Grass-Fed Beef."

STEP 3: Prepare Supporting Documentation

Producers requesting approval to use special statements and claims on meat product labels will need to compile and submit adequate supporting documentation to justify their special statements and claims. FSIS requires supporting documentation to help verify that the special statements and claims used on meat product labels are truthful and not misleading to consumers. Supporting documentation provides a detailed explanation of how the proposed statements and claims accurately describe the meat product. The quantity and quality of supporting documentation submitted with the label approval application varies by the characteristics of the special statements and claims (i.e., production claims, breed claims, negative claims, etc.). Some of the more common supporting documentation includes:

- ◆ Signed affidavits and testimonials on company letterhead confirming the truthfulness of the special statements and claims.
- ◆ Product identification and segregation system for conforming and non-conforming meat products.

- ◆ Production protocols from birth to harvest, such as livestock identification and segregation methods via tags or other animal marking devices.
- ◆ Feed formulation documentation for livestock, including information on animal diet during inclement weather (e.g., specific diet regime for grass-fed or grain-fed beef).
- ◆ Operational protocol for sick and injured animals.
- ◆ Third-party verification and certification documentation.
- ◆ Scientific evidence that helps confirm the special statements and claims used on product labeling.

The USDA FSIS publication, *Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions*, provides details regarding the required supporting documentation for special statements and claims, including "Grass Fed," "Pasture Raised," "Free Range" and "Raised without Antibiotics." [15] Appendix B features an example producer affidavit for making the special claim, "100% Grass-Fed Beef."

⁵Labels can be added to meat products at a licensed retail food store. However, any special statements and claims featured on these labels would need to be approved by FSIS [3].

STEP 4: Complete Label Approval Application

After developing their label sketch and supporting documentation, producers will need to complete the label approval application, FSIS Form 7234-1 [16]. Producers have the option of submitting the paper-based form (Figure 2) or electronic application form using the online Label Submission and Approval System (LSAS).

The paper-based FSIS Form 7234-1 can be accessed through the USDA FSIS Labeling Procedures webpage at <https://tiny.utk.edu/FSISForm7234-1>. Producers will need to download the label approval application form to a computer, as applications must be typed.

The online Label Submission and Approval System (LSAS) is an alternative to the paper-based FSIS Form 7234-1 [17]. Relative to the paper-based application form, online label approval applications for special statements and claims are more quickly processed through LSAS. The LSAS software is most useful for meat processing facilities submitting, storing and updating label approval applications and records for multiple enterprises.

However, individual producers can also use the system. More information about the LSAS is available at <https://tiny.utk.edu/label>.

Producers will need to consult with their meat processor to complete FSIS Form 7234-1, as the application form requests the meat processing facility's establishment number, product formula (for multi-ingredient products) and processing procedures. If a producer uses several processors, label approval applications must be submitted and approved for each establishment.

Producers making special statements and claims for meat product labels will mark "Sketch" in Section 6a and will check "Yes" in Section 10, where applicants are asked to indicate whether there are "any special claims, guarantees, or foreign languages on the label." Page 5 in the paper-based FSIS Form 7234-1 provides detailed instructions for completing and submitting the label approval application.

<p>According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0092. The time required to complete this information collection is estimated to average 75 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This form has been approved by OMB for web distribution.</p> <p style="text-align: right;">PAGE _____ of _____</p>					
<p>U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE</p> <p style="text-align: center;">APPLICATION FOR APPROVAL OF LABELS, MARKING OR DEVICE</p> <p>FSIS has determined that information provided in items 11, 15, and 16 is exempt from mandatory disclosure under the Freedom of Information Act 5 U.S.C. 552(b)(4).</p> <p>APPLICANT: See Page 5 for instructions.</p>		<p>1. AGENT NAME, ADDRESS, TELEPHONE NO. (If using an Agent, complete this block, otherwise leave blank.)</p>	<p>2. FOR USDA USE ONLY</p>	<p>3. FOR USDA USE ONLY</p>	<p>4. ESTABLISHMENT NO. / FOREIGN COUNTRY (If applicable)</p>
<p>4a. TYPE OF PRODUCT</p> <p><input type="checkbox"/> Egg <input type="checkbox"/> Meat</p> <p><input type="checkbox"/> Poultry <input type="checkbox"/> Other</p>					
<p>5a. NAME OF PRODUCT</p>					
<p>5b. HACCP PROCESS CATEGORY (Select one)</p> <p><input type="checkbox"/> 03J: Slaughter - all species</p> <p><input type="checkbox"/> 03B: Raw Product - ground</p> <p><input type="checkbox"/> 03C: Raw Product - not ground</p> <p><input type="checkbox"/> 03D: Thermally processed - commercially sterile</p> <p><input type="checkbox"/> 03E: Not heat treated - shelf stable</p> <p><input type="checkbox"/> 03F: Heat treated - shelf stable</p> <p><input type="checkbox"/> 03G: Fully cooked - not shelf stable</p> <p><input type="checkbox"/> 03H: Heat treated but not fully cooked - not shelf stable</p> <p><input type="checkbox"/> 03I: Product with secondary inhibitors - not shelf stable</p>		<p>6a. TYPE OF APPROVAL REQUESTED</p> <p><input checked="" type="checkbox"/> SKETCH <input type="checkbox"/> TEMPORARY</p> <p><input type="checkbox"/> EXTENSION OF TEMPORARY</p>		<p>7a. AREA OF PRINCIPAL DISPLAY PANEL (Square inches)</p>	
		<p>6b. WAS THE LABEL PREVIOUSLY APPROVED?</p> <p><input type="checkbox"/> YES Date of approval: _____</p> <p><input type="checkbox"/> NO Prior approval number: _____</p> <p>Number of labels on hand: _____</p> <p>Number of days requested: _____</p>		<p>7b. TOTAL AVAILABLE LABELING SPACE FOR ENTIRE PACKAGE (Square inches)</p>	
<p>8. Does this label include a "USDA-AMS Child Nutrition Program CN-Logo?" <input type="checkbox"/> Yes <input type="checkbox"/> No</p>				<p>9. (FOR USDA-AMS USE ONLY) CN Identification Number Assigned</p>	
<p>10. Are there any special claims, guarantees, or foreign language on the label? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO (If yes, check all that apply)</p> <p><input type="checkbox"/> Allergen Statements</p> <p><input type="checkbox"/> Animal Production/Breed/Raising</p> <p><input type="checkbox"/> Certified/Verified</p> <p><input type="checkbox"/> Environmental/Green</p> <p><input type="checkbox"/> Export Only Labels w/deviations from Domestic Requirements</p> <p><input type="checkbox"/> Foreign Language</p> <p><input type="checkbox"/> Geographic/Undefined Style</p> <p><input type="checkbox"/> Grading Terms</p> <p><input type="checkbox"/> Guarantees</p> <p><input type="checkbox"/> Natural/Organic</p> <p><input type="checkbox"/> Nutrition/Health</p> <p><input type="checkbox"/> Religious Exemption</p>					
<p>11. NAME AND ADDRESS OF FIRM (Below and between dots)</p>			<p>12. SIGNATURE OF APPLICANT OR AGENT</p>		<p>13. DATE</p>
<p>14. (FOR USDA USE ONLY) CONDITIONS APPLYING TO USE OF LABELS OR DEVICE</p>					

Figure 2. FSIS Form 7234-1 has sixteen sections that must be completed. The above image shows the application form's sections one through ten.

STEP 5: Submit Label Approval Application

Once the producer has prepared their label sketch, gathered the appropriate supporting documentation and completed FSIS Form 7234-1, the label approval application is ready for submission to FSIS LPDS. Applying for sketch approval well before marketing products gives producers time to modify their label approval application, special statements or claims, and label sketch, if requested by FSIS LPDS.

The complete application can be submitted to FSIS by either the producer or processor. If submitting the paper-based FSIS Form 7234-1, a complete label approval application requires:

- ◆ Two copies of FSIS Form 7234-1.
- ◆ Two copies of the label sketch.
- ◆ All appropriate supporting documentation.

Producers should also provide their meat processing facility with additional copies of FSIS Form 7234-1, the label sketch and the supporting documentation for their records [8]. If all meat product labels, including statements and claims made on labels, will be identical except for the cut names, producers may submit FSIS Form 7234-1, a label sketch for at least one cut as an example, and attach a list of other cuts for which the label will be used. FSIS refers to this as “blanket approval” [5].

The paper-based FSIS Form 7234-1 application can be mailed using the U.S. Postal Service [18] to:

USDA, FSIS, OPPD, LPDD
Labeling Distribution Unit
 Stop Code 3786, Patriots Plaza III, 8-168
 1400 Independence Avenue, SW
 Washington, DC 20250-3700

Alternatively, paper-based applications can be mailed using UPS, FedEx, or courier to the following address:

USDA, FSIS, OPPD, LPDD
Labeling Distribution Unit
 Patriots Plaza III, 8-168
 355 E. Street, SW
 Washington, DC 20024-3221

Once the producer’s label approval application is received, FSIS LPDS will evaluate the label approval application and send notification regarding whether the label has been approved for use in commerce. The length of the approval process depends on the nature of the special statements and claims, whether the application is submitted by mail or electronically, the quality of the application and supporting documentation and FSIS LPDS staff availability [13]. The label evaluation and approval process can take ten or more business days.

Label applications are returned to the meat processing facility and marked in one of three ways:

1. Sketch approved.
2. Sketch modified, with required changes noted.
3. Returned.

Sketch-approved labels have been approved by FSIS LPDS for use in commerce. Sketch-approved labels are approved for use in the processing facility whose establishment number is included in the label approval application. In some cases, producers may change their processing facility but already have a sketch-approved label with their previous processor. With the exception of organic claims, as long as producers submit their entire labeling record (i.e., FSIS Form 7234-1, the label sketch and supporting documentation) to their new processing facility, producers are not required to re-submit a label approval application to FSIS [8].

Sketch-modified labels have been approved by FSIS LPDS for use in commerce after the recommended changes to the label sketch have been made. Producers do not need to re-submit sketch-modified labels for further evaluation. If a label approval application is marked as “Returned,” the label has not been approved by FSIS LPDS, and the producer must re-submit the label approval application after appropriate modifications [5].

SUMMARY

Understanding USDA FSIS's labeling requirements can simplify the label approval process for making special statements and claims on meat product labels. Producers making special statements and claims on their meat product labels and point-of-purchase promotional materials should remember:

- ✓ Meat product labels are approved by FSIS prior to their use in commerce.
- ✓ Labels can be generically approved or sketch approved, depending on the type of information included on the meat product label.
- ✓ Meat product labels with special statements and claims must be sketch approved by FSIS LPDS.
- ✓ Sketch approval for special statements and claims requires that producers submit a label approval application to FSIS LPDS. A complete application includes FSIS Form 7234-1, the label sketch and supporting documentation to justify the special statements and claims made on labels.



REFERENCES

1. United States Department of Agriculture, Economic Research Service (USDA-ERS). (2017). *New Products*. Available at <http://www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products.aspx>.
2. National Grocers Association (NGA). (2015). *Supermarket Guru's Consumer Survey Report*. Available at [http://www.nationalgrocers.org/docs/default-source/Surveys-Reports-\(2015-2016\)/consumersurveyreport2015.pdf?sfvrsn=2](http://www.nationalgrocers.org/docs/default-source/Surveys-Reports-(2015-2016)/consumersurveyreport2015.pdf?sfvrsn=2).
3. United States Department of Agriculture, Food Safety and Inspection Services (USDA-FSIS). (2007). *A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products*. Available at http://www.fsis.usda.gov/shared/PDF/Labeling_Requirements_Guide.pdf.
4. USDA-FSIS. (1994). *FSIS Policy Memoranda, Policy Memo 114A*. Available at http://www.fsis.usda.gov/OPPDE/larc/Policies/Policy_Memos_082005.pdf.
5. USDA-FSIS. (2014). *FSIS Labeling Overview and Generic Label Approval*. Slides available at <http://www.fsis.usda.gov/wps/wcm/connect/99e27c2d-4eef-4796-a8de-b6bf5c36971e/labeling-generic-label-approval.pdf?MOD=AJPERES>.
6. Leffew, M., & Holland, R. (2015). *Basic Regulatory Considerations for Retail and Non-retail Meat Sales in Tennessee*. PB-1829. Center for Profitable Agriculture. Available at <https://ag.tennessee.edu/cpa/CPA%20Publications/PB1829revised.pdf>.
7. Leffew, M. (2015). *Retail Meat Sales in Tennessee: Basic Weights and Measures Regulations*. D-1. Center for Profitable Agriculture. Available at <https://extension.tennessee.edu/publications/Documents/D1.pdf>.
8. USDA-FSIS. (2015). *Questions and Answers Concerning the Recently Published Generic Labeling Final Rule*. Available at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/faq-generic-labeling>.
9. USDA-FSIS. (2014). *FSIS Directive 7221.1 Rev. 1. Prior Labeling Approval*. Issued January 6, 2014. Available at <http://www.fsis.usda.gov/wps/wcm/connect/9a2ebc76-2d43-4658-841a-f810b1f65f04/7221.1.pdf?MOD=AJPERES>.
10. USDA-FSIS. (2005). *Food Standards and Labeling Policy Book*. Available at http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf.
11. USDA-FSIS. (2015). *FSIS Compliance Guidance for Label Approval*. Available at <http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES>.
12. USDA-FSIS. (2015). *Animal Production Claims: Outline of Current Process*. Available at <http://www.fda.gov/ohrms/dockets/dockets/06p0394/06p-0394-cp00001-41-Tab-38-USDA-vol1.pdf>.
13. USDA-FSIS. (2015). *Frequently Asked Questions About the FSIS Label Approval Process and Label Evaluation Procedures Conducted by the Labeling and Program Delivery Division (LPDD)*. Available at http://www.fsis.usda.gov/wps/wcm/connect/bca2efcd-6d95-40e0-86fd-9ee61b69202d/FAQ_Label_Approval_Process.pdf?MOD=AJPERES.
14. Blacklin, Sarah. (2014). *Special Labeling Claims and the Approval Process for Niche Meat Production*. LF-003. The Center for Environmental Farming Systems. Available at <https://cefs.ncsu.edu/resources/special-claims-and-the-approval-process-for-niche-meat-production/>.
15. USDA-FSIS. (2016). *Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions*. Available at <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Claims-Guidance>.
16. USDA-FSIS. (2011). *FSIS Form 7234-1: Application for Approval of Labels, Marking, or Device*. Available at http://www.fsis.usda.gov/wps/wcm/connect/4aeeca8c-8ba6-4288-a222-e6ca8764a9f7/FSIS_7234-1_Approval_of_Labels.pdf?MOD=AJPERES.
17. USDA-FSIS. (2015). *Label Submission and Approval System (LSAS)*. Available at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/label-submission-and-approval-system>.
18. USDA-FSIS. (2015). *Label Application Guidance*. Available at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/label-application-guidance>.

APPENDIX

The sketch approval label application process for special statements and claims requires a sketch of the meat product label and supporting documentation to justify the special statements and claims. An example label sketch (Appendix A) and producer affidavit (Appendix B) for the special claim, “100% Grass-Fed Beef,” were created to help direct farm marketers understand the label approval application requirements for sketch approval.

Appendix A. Example Label Sketch for “100% Grass-Fed Beef” Claim*

pick
TENNESSEE

Farm Name & Logo

U.S.
INSPECTED
AND PASSED BY
DEPARTMENT OF
AGRICULTURE
EST. 38

100% Grass-Fed Beef*
Meat Cut Name

Our Guarantee

- Animal's diet is based only on seasonal forages, hay and haylage.
- No grain or grain supplements fed to cattle.

Keep Frozen

Distributed By:
[Farm Name]
Address Line

NET WEIGHT
0.00 LBS

Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

1. Keep refrigerated or frozen. Thaw in refrigerator or microwave.
2. Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.
3. Cook thoroughly.
4. Keep hot foods hot. Refrigerate leftovers immediately or discard.

*Notes

- ◆ The ingredients statement is not required in this label sketch because the example label will be used for single-ingredient meat products only.
- ◆ USDA FSIS regulations state that nutrition labeling of single-ingredient, raw major cuts for beef, pork, lamb and poultry products can be displayed either on the meat product label or be provided to the customer at the point of purchase via signs, posters, brochures, etc. This producer does not include nutrition information on the label, as it will be displayed at the point of purchase. For more information, producers can refer to the section, “Nutrition Labeling Requirements for Single-Ingredient Products and Ground or Chopped Meat and Poultry Products,” in *Basic Regulatory Considerations for Retail and Non-retail Meat Sales in Tennessee* available online at <https://tiny.utk.edu/PB1829> [6].

Appendix B. Example Producer Affidavit for “100% Grass-Fed Beef” Claim**[Farm Name] 100% Grass-Fed Beef Protocol**

All cattle are produced exclusively on a forage diet, other than mother’s milk, from birth until harvest. No grain or grain supplements are fed to cattle marketed as [Farm Name] 100% Grass-Fed Beef. In the unlikely event cattle are known to have accessed and consumed grain or grain supplements, affected cattle will be segregated and removed from the grass-fed program.

All cattle are produced from birth until harvest by [Farm Name]. Calves graze with their mothers on pasture until weaning. Fence-line weaning allows calves to remain on pasture while limiting stress. Weaned calves are moved to new pasture through rotational grazing management practices as often as needed to meet their nutritional requirements and based on forage availability and quality. Cattle are provided free-choice access to fresh water, loose mineral and salt.

Cool season forages consist of annual ryegrass, pearl millet, red and white clover, tall fescue, wheat and forbs. Warm season forages of bermudagrass, big and little bluestem, gamagrass, red and white clover and forbs. Cattle are fed hay and haylage during times of limited forage growth or availability. Hay and haylage are produced from alfalfa and excess forage on [Farm Name], when possible. High quality hay is purchased when necessary to supplement farm stores and provide proper nutrition.

The protocol above is an accurate account of the production methods used by the owner/operator to produce grass-fed beef by [Farm Name] as of [date].

[Signature]

[Typed Name]

[Title e.g., Owner/Operator]

Date _____
[Date signed]

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