Legally Speaking: Making Claims About Your Product

Jeffrey Canavan, MPA, RD
Deputy Director
Labeling and Program Delivery Staff (LPDS)
Food Safety and Inspection Service (FSIS)
Generic Label Update
Nutrition Related Claims
Country of Origin Labeling (COOL)
Natural Update
Animal Production Raising Claims
Contacting LPDS
Questions and Answers
## Required Features on a Label

Up to 8 Required Features:

<table>
<thead>
<tr>
<th>Features</th>
<th>CFR</th>
<th>Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>317.2(e)/381.117(a)</td>
<td>PDP</td>
</tr>
<tr>
<td>Handling Statement</td>
<td>317.2(k)/381.125(a)</td>
<td>PDP</td>
</tr>
<tr>
<td>Net Weight Statement</td>
<td>317.2(h)/381.121</td>
<td>PDP</td>
</tr>
<tr>
<td>Inspection Legend/Est. number</td>
<td>312.2(b)/381.96 &amp; 381.123(b)(2)</td>
<td>PDP</td>
</tr>
<tr>
<td>Ingredients Statement</td>
<td>317.2(c)(2)/381.118</td>
<td>PDP or IP</td>
</tr>
<tr>
<td>Signature Line</td>
<td>317.2(g)(2)/381.122</td>
<td>PDP or IP</td>
</tr>
<tr>
<td>Nutrition Facts</td>
<td>317.300-400/381.400-500</td>
<td>PDP or IP</td>
</tr>
<tr>
<td>Safe Handling Instructions</td>
<td>317.2(l)/381.125(b)</td>
<td>Any panel</td>
</tr>
</tbody>
</table>
May be a printer’s proof or equivalent that is sufficiently legible to clearly show all labeling features, size, and location.

May be hand drawn, computer generated, or other reasonable facsimiles that clearly reflects and projects the final version of the label.

Certain types of labels require sketch approval (discussed later in this presentation).
Sketch approved labels reviewed by LPDS are either “approved” or “approved as modified”

A “Sketch” label is the concept of a label while “Final” label is the label that is applied to product before distribution in commerce

Establishments are responsible for ensuring final labels applied to product are in compliance with FSIS regulations
Terms Defined: Generic Approval

- Generic labeling approval refers to the approval of labeling or modifications to labeling prior approved by the Agency without submitting such labeling to FSIS for sketch approval.

- Generic labeling approval requires that all mandatory labeling features are in conformance with FSIS regulations.

- Although such labeling is not submitted to FSIS for approval, generically approved labels are approved by being in compliance with applicable regulations.

NOTE: FSIS Inspectors do not generically approve labels. Establishments do not generically approve labels. FSIS approves labels through generic labeling regulations.
By regulation, FSIS specified when a generic approval could be undertaken by an establishment (9 CFR 317.5 and 381.133)

Prior to the new rule:

- Specific product labels were eligible for generic approval (e.g., with a standard in FSIS regulations)
- Certain changes could be made generically to sketch approved labels (e.g., change to formula provided it did not change order of predominance of ingredients statement)
On November 7, 2013, FSIS published a final rule that amended the meat and poultry products inspection regulations to expand the circumstances under which the labels of meat and poultry products would be deemed to be generically approved by the Agency.

Effective January 2014, four categories of labels now REQUIRE sketch approval.

ALL OTHER labels that do not fit into one of the four categories do not require sketch approval by LPDS and may be generically approved.
Final rule amended FSIS regulations to combine the previous regulations that provided for labeling approval (9 CFR 317.4 and 381.132) and generically approved labeling (9 CFR 317.5 and 381.133) for meat and poultry products into one new section.

New label approval regulations for meat and poultry products now in 9 CFR 412.1; approval of generic labels now in 9 CFR 412.2.
Only certain types of labeling require submission for evaluation by LPDS:

- Labels for temporary approval (9 CFR 412.1(c)(4))
- Labels for products produced under religious exemption (9 CFR 412.1(c)(1))
- Labels for products for export with labeling deviations (9 CFR 412.1(c)(2))
- Labels with special statements and claims (9 CFR 412.1(c)(3))

FSIS will continue to require the submission of such labels because they are more likely to present significant policy issues that have health or economic significance.
Definition: Temporary Label Approval (9 CFR 412.1(c)(4))

- A temporary label approval may be granted for labels with a regulatory deviation that does not pose any potential health, safety, or dietary problems to the consumer.

- Approval not to exceed 180 days
  - Plant transfers are granted for up to 60 days.

- Temporary label approval granted on a case-by-case basis.
Labels with Religious Exemption Statements (9 CFR 412.1(c)(1))

- Religious-exempt product (poultry) does not receive the mark of inspection and, therefore, deviates from the general labeling requirements for meat and poultry products.

- Ritually-slaughtered meat and poultry products receive the mark of inspection (Kosher, Halal) and may be approved generically provided that they don’t meet one of the other labeling categories requiring sketch approval.
Exports of U.S. meat and poultry products occur under agreements between the U.S. government and foreign governments.

Approval of labels on meat and poultry products to be exported bearing labeling deviations includes ensuring that deviations are allowed per the importing country’s laws (9 CFR 317.7 and 381.128).

Labels marked “for export only” that bear labeling deviations and therefore cannot be used domestically must be sketch approved by LPDS.
Detailed list of special statements and claims requiring LPDS approval and examples of claims eligible for generic approval is available on FSIS website


List includes commonly used special statements and claims
Examples of special statements and claims:

- 3rd party raising claims or programs (i.e. Global Animal partnership, AMS Process verified or certified programs, American Heart Association (AHA) claims)
- Claims regarding meat and poultry production practices (i.e. claims regarding the raising of animals such as “no antibiotics administered” or “vegetarian fed”)
- Breed claims (Berkshire, Angus, Hereford, etc)
- Certified claims, Certified Halal
- Gluten free: both certified and non certified
- Health claims defined in 21 CFR Subpart E, e.g. dietary saturated fat and cholesterol and risk of coronary heart disease (21 CFR 101.75)
Special Statements and Claims: Sketch Approval Required
(continued)

- Implied Nutrition Claims for example Heart Smart, Baked Not Fried, Made without Butter
- Statements that identify a product as “organic” or containing organic ingredients
- Instructional or disclaimer statements concerning pathogens, such as “for cooking only”; “not tested for E. coli O157:H7”; or “For high pressure pasteurization at establishment ABC”
- Natural claims, e.g. “All Natural”, “100% Natural”
- Negative claims or “free” claims (no MSG, no MSG added, no preservatives)
Special Statements and Claims: Sketch Approval Required (continued)

- Omega 3 factual statements
- “Whole Grain”, “Made with Whole Grains”, “Made with whole wheat” claims
- Nutritional Front of Pack statements, for example “0 grams trans fat per serving”, Nutrition facts Up Front
- Claims of the use of non-genetically engineered ingredients
- Claims that are undefined in FSIS regulations or the Food Standards and Labeling Policy Book (Note: natural and negative claims are defined in the policy book but will continue to be required to be submitted for approval).
Special Statements and Claims: Sketch Approval Required

Special Claim (Breed Claim)

Special Claim (Natural Claim)
Special Claims (Organic Claims and logo)
Some statements and claims are not considered “special” under 9 CFR 412.1 (e), e.g. statements of fact.

- Statements and claims of this type may be approved generically (9 CFR 412.2(b)).

- The next two slides review examples of statements that are not considered special and may be approved generically.
Statements: Generic Approval Permitted

- All, 100%, pure
- Allergen or "Contains (name of ingredient)" statements (e.g., contains soy)
- AMS Grading (Prime, choice, grade A)
- Child Nutrition Boxes
- Flavor Profiles (e.g. made with fennel, teriyaki flavored, made with real cheese, only white meat)
- Foreign Language on domestic products
- Geographic claims (refer to 9 CFR 317.8(b)(1))
Statements: Generic Approval Permitted

- Green Claims/Environmental Claims
- Halal, Kosher (not certified)
- Hand pulled style/hand pinched style
- Handcrafted, handmade, hand slaughtered, hand crafted style
- Home Style
- For HRI only, Institutional use only, etc
- Nutrition Claims (defined)
- Ready in/Cooks in (number of minutes or seconds)
- Oven roasted or similar statements
Points of Clarification

- FSIS Inspectors do not generically approve labels.
- Labels will be generically approved if they meet the criteria listed in 9 CFR 412.2(b).
- FSIS in-plant inspection personnel will continue to verify labels as part of the General Labeling task.
- Establishments do not generically approve labels. Generically approved labels are approved by FSIS.
Points of Clarification

- Labels that do not fit into one or more of the four categories of labels requiring sketch approval are generically approved by their compliance with applicable regulations.

- If an establishment elects to submit a generically approved label to LPDS for review, the label will be assigned a lower priority than those labels that require sketch approval by LPDS.
Grade Marks (e.g., Prime, Choice, and Select) are not required features on meat products. May be voluntarily applied on labeling

COOL labeling administered by AMS. Not a required feature for on product labeling. FSIS allows statements to be voluntarily applied to meat and poultry products that are defined as a covered commodity in 7 CFR Part 65, Subpart A, that is to be sold by a retailer as defined in 7 CFR 65.240. Must comply with the requirements in 9 CFR 65.300 and 65.400
“X mg Omega 3 Fatty Acids per serving” from meat or poultry fed special diets

If a particular ingredient is being added as the source, must identify source, e.g., “X mg Omega 3 Fatty Acids from Fish Oil in Breading”
Animal Production Raising Claims

- Process Verified and Organic
- Natural
- Breed Claims
- No Hormones Added
- No Antibiotics Administered
- Animal Welfare Claims
- GE Claims
For over 30 years FSIS has evaluated animal production claims by considering information on animal production practices submitted by companies as part of their label approval requests.

The Agency approved these claims if the animal production information submitted with the label application supported the claim being made and the claim was truthful and not misleading.
Background for Claims

Point of purchase materials used in conjunction with products bearing animal production claims, while they generally are not reviewed by this office, should meet the requirements of Policy Memo 114A for Point of Purchase Materials.

Labels bearing animal production claims are required be approved prior to use in commerce. Labels are approved with the understanding that inspectors can be assured as to the source of the product. Inspectors monitor labels being applied to meat and meat products at the establishment.
For most animal production claims, the documentation needed to support these claims are:

1. A detailed written protocol explaining controls for assuring the production claim from birth to harvest. If purchased, include protocol information from the supplier;

2. A signed affidavit declaring the specifics of the animal production claim(s) and that the claims are not false or misleading;
3. Product tracing and segregation mechanism from time of slaughter and/or further processing through packaging and wholesale or retail distribution;

4. A protocol for the identification, control, and segregation of non-conforming animals/product;

5. A complete, current feed formulation using common and usual language or copies of the feed tags; and

6. If a third-party certifies/verifies a claim, a current copy of the certification/verification should be provided
In some cases, establishments can use purchased product labels to support carrying identical claims over to a new product (e.g., repackaging).

Examples of claims include Breed Claims, Diet Claims, and Raising Claims.

Companies cannot duplicate claims certified or verified by a third party entity. For example, Organic, Process Verified Program, or Certified Humane cannot be carried forward without the company having its own certification or verification.
Duplicating Claims from Purchased Product Label

Documentation Needed:

- 1) A copy of the incoming purchased label bearing the claims being duplicated OR a copy of the prior label approval and label of sourced product; and

- 2) A protocol for the identification, control, and segregation of non-conforming animals/product;
This seal is your assurance that the fresh pork in this package has met these stringent criteria:

- Every order is traceable to quality verified farms.
- Product is selected based on carcass weight and muscle percent.
- Product is continuously evaluated and selected for meat quality characteristics.
Required USDA to develop national standards for organically produced agricultural products

- To assure consumers such products meet consistent standards
- To facilitate commerce in organically produced fresh and processed food
- Documentation needs to be submitted to FSIS to support compliance with organic standards
Product Labeled “Natural”

Processing-related meaning (FSIS Policy Memo 055 and Food standards and Labeling Policy Book):

- Contains no artificial ingredients
- Is only minimally processed
  - Fresh meat and poultry automatically qualify
- All single ingredient raw unprocessed beef products meet definition in Food Standards and Labeling Policy Book and may be labeled as “Natural”
Breed Claims

- Examples of this type of claim: Angus, Wagyu (American Kobe), Hereford, Berkshire, Duroc, Muscovy, Silkie, and Heritage Poultry, Pork or Beef Breeds

- Documentation needed: Documents 2-4, and a detailed written protocol explaining controls for assuring the phenotype (for example, hide color) or genotype (traceable to one registered parent or two registered grandparents with a breed association) for the breed
Other examples of this type of claim: Raised Without Growth Promotants (Stimulants)

Hormones are only approved for use in beef cattle and sheep production. They are not approved for use in veal calves. Therefore, the phrase “no hormones administered” on veal cannot be approved unless it is immediately (directly) followed with the statement “Federal regulations prohibit the use of hormones in poultry (or pork, veal, or exotic, non-amenable meat products)”

Documentation needed: Documents 1 – 4
Other examples of this type of claim: No Antibiotics Administered, No Antibiotics Administered the last 150 days, and Raised Without Sub-therapeutic Antibiotics

Documentation needed: Documents 1 – 5. When applicable, provide the feed tag or ingredient listing from the feed supplier for all rations and supplements
Examples of this type of claim: Humanely Raised, Sustainably Farmed, and Raised with Environmental Stewardship

Documentation needed: Documents 1 – 4

These terms should be defined according to the company’s or producer’s standard and the label should clearly state for the consumer the condition under which the animal is raised or what the term means, for example, Humanely Raised on Family Farms, without Confinement. Document 1 (above) should clearly describe the living/raising conditions of the animals throughout its lifespan (including the various seasons)
They look weirder every summer! Who knows what crazy chemicals they’re being raised on!
A Good Win! Farms©
est 2010

Without Added Antibiotics
Humanely – Barn Roaming, Never Confined to a Lot
Grass Fed
With Environmental Stewardship

Net Weight: 48 oz (3 lbs)

Distributed By:
20101 Beltsville Rd
Sunnyside, MD 12345

Ingredients: Beef

Keep Refrigerated

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.

- Keep refrigerated or frozen. Thaw in refrigerator or microwave.
- Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.
- Cook thoroughly.
- Keep hot foods hot. Refrigerate leftovers immediately or discard.
FSIS allows companies to state on their labels that they meet a third-party certifying organization’s standards, provided that the third-party organization and the company can show that the claims are truthful, accurate, and not misleading and provided that there are resources to help consumers understand exactly what the claim and the certification mean.

The National Organic Program is one example of a third-party certifying organization.
For example, FSIS has approved labels that state the products meet the standards of a third-party certifier regarding the use of feed that was not genetically engineered, e.g. “This pasture raised beef is fed a vegetarian diet that was produced in compliance with the Non GMO Project standard for avoidance of genetically engineered ingredients.”

The Agency has not developed any new policy regarding non-GE products and is not certifying that the labeled products are free of genetic engineering or genetic modifications.

The labels approved state that the products meet the standards of a third party certifier regarding the use of non-GE feed and other raising practices.

FSIS has determined that certain statements of this type are truthful and not misleading, and that they are claims that are verifiable.
The askFSIS application is able to notify users when posted answers are updated
http://askfsis.custhelp.com/cgi-bin/askfsis.cfg/php/enduser/std_alp.php

“Ask Karen" is a knowledge base with information for consumers about preventing foodborne illness, safe food handling and storage, and safe preparation of meat, poultry, and egg products
http://www.fsis.usda.gov/Food_Safety_Education/ASK_KAREN/index.asp

Important Note: Establishments should submit questions through askFSIS, do not submit questions to askFSIS and “Ask Karen”