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Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness





FSIS Labeling Overview and Compliance Guide for Label Approval

Labeling and Program Delivery Staff (LPDS)
September 2020

Food Safety and Inspection Service: Webinar Overview

- Background information
- Required labeling features
- Generic Labeling Regulations
- Compliance Guide update 2020
- Useful resources



Food Safety and Inspection Service: Background Information

Background Information

Food Safety and Inspection Service: Introduction

- U.S. Department of Agriculture (USDA) requires that meat and poultry products in interstate or foreign commerce are wholesome, not adulterated, and properly marked, labeled and packaged
- USDA's Food Safety and Inspection Service (FSIS) is responsible for the development of labeling requirements applicable to meat and poultry products
- FSIS is charged with developing the labeling policy by which it is determined if a meat or poultry product is misbranded

Food Safety and Inspection Service: Labeling and Program Delivery Staff (LPDS)

Staff within the Office of Policy and Program Development (OPPD) of FSIS, LPDS Functions include:

- Administering the Agency's prior label approval program
- Responding to inquiries (e.g., askFSIS and phone calls) on FSIS labeling regulations and policies
- Developing compliance policy guidance for special statements and claims (e.g., animal production raising claims)
- Writing regulations, FSIS Directives, FSIS Notices, and other policy guidance documents for meat, poultry, and egg product labeling and standards issues
- Providing labeling-related training for stakeholders and FSIS personnel

Food Safety and Inspection Service: Prior Label Approval

- Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) require food manufacturers to obtain prior approval for labels of meat and poultry products before products may be marketed
- Prior approval is granted in one of two ways:
 - Sketch approval of labels submitted to FSIS which is approved by the Labeling and Program Delivery Staff (LPDS)
 - Generic approval, which is approved by being in compliance with applicable regulations

Food Safety and Inspection Service: Types of Label Approval

Sketch

- Label review process by LPDS
- Printer's proof or equivalent submitted to FSIS that is sufficiently legible to clearly show all labeling features, size, and location
- May be hand drawn, computer generated or other reasonable facsimile
- Must clearly reflect and project the final version of the label
- Specific categories of labels require sketch approval
- 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

NOTE: Establishments are responsible for ensuring final labels applied to product are in compliance with FSIS regulations, including making modifications noted by LPDS during sketch review.

Generic

- The approval of labeling or modifications to labeling prior approved by the Agency without submitting such labeling to FSIS for sketch approval
- Requires that all mandatory labeling features are in conformance with FSIS regulations
- Although not submitted to FSIS for approval, generically approved labels are approved by if in compliance with applicable regulations

NOTE: FSIS Inspectors do not generically approve labels.

Food Safety and Inspection Service: Required Labeling Features

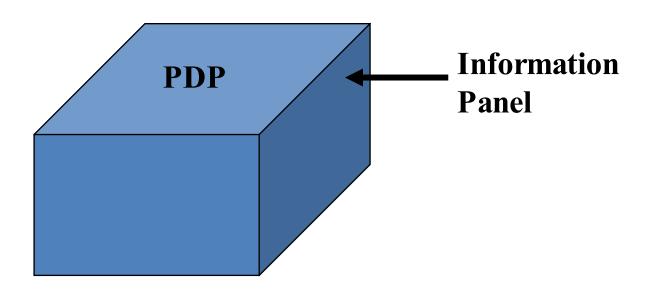
Required Labeling Features

Food Safety and Inspection Service: Required Labeling Features

- Labels have up to eight (8) required features
- Regulations specify where on the label some of the features must be located
 - Principal Display Panel (PDP)
 - 9 CFR 317.2(c) and (d), 9 CFR 381.116
 - Information Panel (IP)
 - 9 CFR 317.2 (m), 9 CFR 381.116(c)

Food Safety and Inspection Service: Principal Display Panel (PDP) and Information Panel (IP)

- PDP is the part of the label most likely to be displayed, presented...when offered for sale under customary conditions
- IP is any portion of a label not on the PDP that is displaying certain mandatory features



Food Safety and Inspection Service: Required Labeling Features

Four features are required on the PDP:

(1) Product name

9 CFR 317.2(e)/381.117(a)

(2) Handling Statement, if product is perishable

9 CFR 317.2(k)/381.125(a)

(3) Inspection Legend/Est. number

9 CFR 312.2(b)/381.96 &381.123(b)(2)

(4) Net weight for product sold at retail (except variable net weight products)

9 CFR 317.2(h)/381.121

Food Safety and Inspection Service: Required Labeling Features (cont'd):

The remaining four features may be located on the PDP or on the information panel:

(5) Name and place of business of the manufacturer, packer or distributor

9 CFR 317.2(g)(2)/381.122

(6) Ingredients statement displaying all ingredients in descending order of predominance

9 CFR 317.2(c)(2)/381.118

(7) Nutrition labeling (unless an exemption applies)

9 CFR 317.300-400/381.400-500

(8) Safe Handling Instructions if the product is not ready-to-eat (may be located on any panel)

9 CFR 317.2(I)/381.125(b)

Required Labeling Features: Summary Table

Feature	Reference	Location	Applies to
Product Name	9 CFR 317.2(c)(1) or 381.117	Principal display panel	All products
Inspection Legend	9 CFR 317.2(c)(5) or 381.123	Principal display panel	All products
Handling Statement (e.g. "Keep Frozen")	9 CFR 317.2(k) or 381.125(a)	Principal display panel	Products requiring special handling to maintain wholesomeness
Net Weight Statement	9 CFR 317.2(h) or 381.121	Principal display panel	Product sold at retail, unless the net weight is applied at retail
Ingredients Statement*	9 CFR 317.2(f) or 381.118	Information panel or Principal display panel	Products with multiple ingredients
Address Line	9 CFR 317.2(g) or 381.112	Information panel or Principal display panel	All products
Nutrition Facts Panel	by 9 CFR 317.300 or 381.400	Information panel or Principal display panel	Products not exempted by 9 CFR 317.400 or 381.500
Safe Handling Instructions	9 CFR 317.2(I) or 381.125(b)	Any panel	Not-ready-to-eat meat or poultry products

Food Safety and Inspection Service: Generic Labeling Final Rule

Generic Labeling Regulations

Food Safety and Inspection Service: Generic Labeling Final Rule

- Effective January 6, 2014, the 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 section
- Label approval regulations for meat and poultry products now in 9 CFR 412.1; approval of generic labels now in 9 CFR 412.2
 - Current regulations found online at www.gpo.gov

Food Safety and Inspection Service: Generic Approval

- Final rule amended the meat and poultry products inspection regulations to expand the circumstances under which the labels of meat and poultry products are generically approved by the Agency
- NOW, four categories of labels REQUIRE LPDS review.
- ALL OTHER labels that do not fit into one of the four categories <u>do not</u> require sketch approval by LPDS

Food Safety and Inspection Service: Generic Labeling Final Rule

- 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))

Temporary Label Approval (9 CFR 412.1(c)(4))

Temporary Label Approval

Food Safety and Inspection Service: LPDS Approval Required: 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
- Temporary approval not to exceed 180 days
 - Plant transfers are granted for up to 60 days
 - Additional 60-day extension may be granted
- Granted on a case-by-case basis
- Four conditions for temporary approval described in the regulations (9 CFR 412.1(f)(1)) must be met
- Approval process unchanged by the 2014 generic labeling rule
- Addition in the Compliance Guide

Food Safety and Inspection Service: Temporary Label Approval Submission

- Address the conditions cited in 9 CFR 412.1(f)(1)
- Clearly explain the specific labeling deficiencies that are present on the label
- Ingredients statement deficiencies must clearly list which ingredients are on the label but not in the product and which ingredients are in the product but not on the label
- Complete previously approved label information in Box 6b of Form 7234-1 or in the "Approval Information" section of LSAS
- If requesting extension of a temporary approval, explain in detail why the extension is necessary

Food Safety and Inspection Service: Temporary Label Approval: Examples

- Incorrect legend on label (e.g., poultry legend on a meat label)
- Order of predominance of ingredients has changed
- Specific multi-ingredient item has changed resulting in incorrect sublisting of some ingredient (e.g., spice mix)
- New ingredient has been added to formulation but is not on the label
- Address of the establishment has changed
- Incomplete product name (e.g., "smoke flavor added" qualifier missing)

Religious Exemption Statements (9 CFR 412.1(c)(1))

Religious Exempt Product Labels

LPDS Sketch Approval Required: 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

Poultry processed in accordance with:

- Buddhist religious beliefs (head and feet remain on eviscerated poultry)
- Confucian religious beliefs (poultry is not eviscerated, head and feet intact)
- Islamic (or Halal) religious beliefs (poultry is eviscerated, headon, with or without the feet intact, in ready-to-cook form)
- Updates in the Compliance Guidance

Food Safety and Inspection Service: Export Labels Bearing Labeling Deviations (9 CFR 412.1(c)(2))

Export labels bearing label deviations

LPDS Sketch Approval Required: Export Labels Bearing Labeling Deviations (9 CFR 412.1(c)(2))

- Exports of U.S. meat and poultry products occur under agreements between the U.S. government and foreign governments
- Agreements require U.S. government approval of labels on exported meat and poultry products that bear labeling deviations
- Includes ensuring that any changes made to labels on meat and poultry products are allowed per the importing country's laws (9 CFR 317.7 and 381.128)
- 412.1(c)(2) labels deviating from FSIS requirements with the exception of net weight in metric units and foreign language need to be submitted for approval



Food Safety and Inspection Service: Common Deviations on Export Labels that require label submission

- Nutrition Facts Panels in formats not permitted on domestic labels
- Ingredient statement deviations
- Not sublisting of certain standardized foods, e.g., cheeses or enriched flour
- No retained water statement

Food Safety and Inspection Service: Export Label Deviations which **do not** require LPDS sketch approval

- Net Weight in metric units
- Foreign Language
- Products that meet all of FSIS domestic requirements
- Products meeting the requirements in 9 CFR 412.1(c)(2): printed labels in foreign language or print labels that bear a statement of the quantity of contents in accordance with the usage of the country to which exported as described in 9 CFR 317.7 and 381.128.

Food Safety and Inspection Service:

Compliance Guideline for Label Approval

Compliance Guideline for Label Approval

Compliance Guideline for Label Approval

- FSIS Compliance Guideline for Label Approval is available on FSIS website <u>http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES</u>
- Compliance Guide for Label Approval includes information and examples about:
 - Appendix 1: Special statements and claims
 - Appendix 2: Factual statements and claims that can be generically approved
 - Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review
 - Appendix 4: Changes to labels approved with special statements and claims that require FSIS review
 - Appendix 5: Blanket approvals (product lines or multiple products with identical claims)
 - Appendix 6: Special statements and claims generically approved after receiving the first approval from FSIS

Food Safety and Inspection Service: Compliance Guideline for Label Approval Changes

- Appendix 1 has been updated to remove the certified Parma Ham example.
- **Appendix 1** has been updated to include several new special statements and claims (e.g. additional certification programs) that require FSIS approval before they can be used on labels of product in commerce.
- Appendix 2 has been updated to include several new factual statements and claims (e.g., Artisanal and Better is Possible) that do not require FSIS approval before they can be used on labels of product in commerce.
- Appendix 3 has been updated to include several examples of changes to labels with special statements and claims that can be made without additional FSIS review (e.g. addition of brand name that does not include a new claim and changes to the packaging.)

Food Safety and Inspection Service: Compliance Guideline for Label Approval Changes (cont'd)

- Appendix 4 has been updated with two new export examples (e.g. changes
 to an export label that create new labeling deviations not previously
 approved by FSIS and changes to an export label that impact previously
 approved special statements and claims.)
- Appendix 5 has been updated to include a new example (e.g. high pressure processed at establishment ABC) of blanket approvals (labels for product line or multiple products with identical claims.)
- Appendix 6 has been updated to include several new examples (e.g. employee owned certified and sustainable forestry initiative certified sourcing) of special statements and claims that can be generically approved after receiving the first approval from FSIS.
- Additional changes to the Compliance Guideline for Label Approval will be announced via the Constituent Update.

Appendix 1: Special Statements and Claims

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Appendix 1: 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 such as "Certified Halal"
- Gluten free: both certified and noncertified
- 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)
- Implied Nutrition Claims e.g., Heart Smart, Baked Not Fried, Made without Butter
- 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"

Appendix 1: Special Statements and Claims: Sketch Approval Required (continued)

- Natural claims, e.g. "All Natural", "100% Natural"
- Negative claims or "free" claims (e.g., no MSG, no MSG added, no preservatives)
- Statements that identify a product as "organic" or containing organic 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).
- Examples of new special statements and claims added to Appendix 1:
 - Certified select ingredients
 - Crossfit Certified
 - Real Ingredients
 - Whole30
- Additional special statements and claims can be found in Appendix 1 of the Compliance Guideline for Label Approval

Appendix 2: Factual Statements and Claims that are Generically Approved

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- Some factual statements and claims do NOT require submitting for approval and are approved generically under 9 CFR 412.2(b)
- Examples include:
 - Allergen or contains statements, e.g., "contains (name of ingredient)"
 - AMS Grading (USDA Prime, Choice, Select)
 - Flavor profiles (teriyaki flavored)
 - Foreign language on domestic products
 - Examples of new factual statements and claims added to Appendix 2:
 - Artisanal
 - Better is Possible
 - Farm to Fork
 - Fresh
- Additional special statements and claims can be found in Appendix 2 of the Compliance Guideline for Label Approval

Appendix 1: Special Statements and Claims: Sketch Approval Required Label Example



Special Statements and Claims

Appendix 2: Factual Statements and Claims that are generically approved: Generic Label Example



Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review

Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review

Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review

- Many changes can be made to labels previously sketch approved by LPDS.
- An example of this is changing information such as the establishment number (except for products labeled as organic), signature line, preparation instructions, or vignette for a label that was previously approved with a special statement or claim. These changes are generically approved as they will not affect the special statement or claim.

Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review examples

- Addition of cooking instructions
- Addition of a bar code
- Changing an approved claim to a synonymous claim (e.g., changing from "no antibiotics used" to "raised without antibiotics")
- Changes to the handling statement
- Changes to the product name
- Changes to the signature line including export labels with deviations
- Changes to the values in the nutrition facts panel
- Removal of ingredients in product without the addition of new ingredients
- Removal of nutrition front of pack icon

Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review examples

- Examples of new changes added to Appendix 3:
 - Addition of a brand name or changes to a brand name that does not include a new claim
 - Adding new establishments for certification claims that cover multiple establishments
 - Addition of logo or changes to a logo that does not include a new claim
- Additional new changes can be found in Appendix 3
- Additional changes that can be made to labels approved with special statements and claims without additional LPDS review can be found in Appendix 3 of the Compliance Guideline for Label Approval

Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review examples: Label Example



Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review examples: Label Example



Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review examples: Question and Answer

- Question: Can a previously approved label with a raised without antibiotic claim change the cut name generically?
- Answer: Yes, the cut name (i.e., chicken breast to chicken thigh) can be changed generically provided the source of the chicken is the same as that used for the prior approved label

Appendix 4: Changes to labels with special statements and claims that require FSIS review

Appendix 4: Changes to labels with special statements and claims that require FSIS review

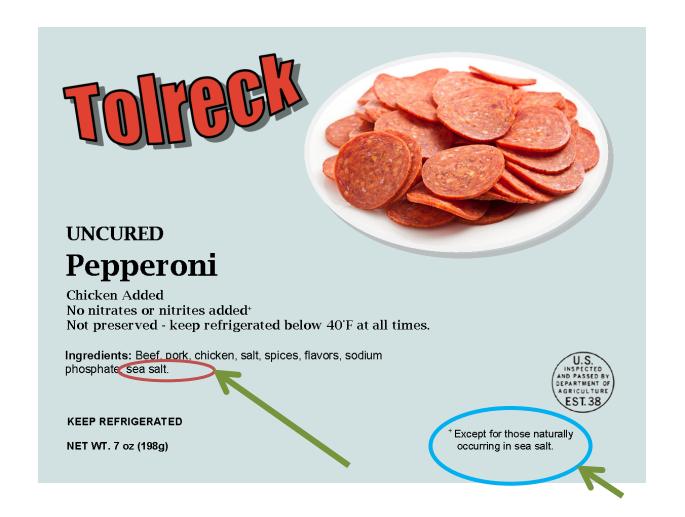
Food Safety and Inspection Service: Appendix 4: Changes to labels with special statements and claims that require FSIS review

- This is a list of changes to labels with special statements and claims that require FSIS review
- An example of this: A label with a negative claim (e.g., "No MSG") was approved by LPDS, and the establishment wants to use a new seasoning mix that includes ingredients that were not included in the product formula for the previously approved label. In this case, the establishment is required to resubmit the label to LPDS for approval so the Agency can verify the new ingredients do not contain naturally occurring sources of MSG.

Food Safety and Inspection Service: Appendix 4: Changes to labels with special statements and claims that require FSIS review (continued)

- Addition of additional nutrients to labels with FOP statement
- Changes to the establishment number of labels with an organic claim
- Change to the ingredients without changing the label
- Examples of new changes to Appendix 4:
 - Changes to an export label that create new labeling deviations not previously approved by FSIS (e.g., addition of a nutrition facts panel that was not included in the prior approval)
 - Changes to an export label that impact previously approved special statements and claims (e.g., including an ingredient that is not acceptable for natural)
- Additional changes that cannot be made to labels approved with special statements and claims without additional LPDS review can be found in Appendix 4 of the Compliance Guideline for Label Approval

Appendix 4: Changes to labels with special statements and claims that require FSIS review: Label Example



Appendix 4: Changes to labels with special statements and claims that require FSIS review: Label Example



Appendix 4: Changes to labels with special statements and claims that require FSIS review: Question and Answer

- Question: My label was approved with "no MSG," "gluten free" and "no artificial colors claims." I want to add a new seasoning packet and add the additional claim of "no preservatives." Can I do that generically?
- Answer: No, because the "no preservatives" is tied to the ingredients in the product, and the label needs to be evaluated for compliance with the claim.
 Additionally, FSIS need to verify whether the new seasoning packet is consistent with the other previously approved claims.

Appendix 5: Blanket Approvals (Product Line or Multiple Products with identical claims)

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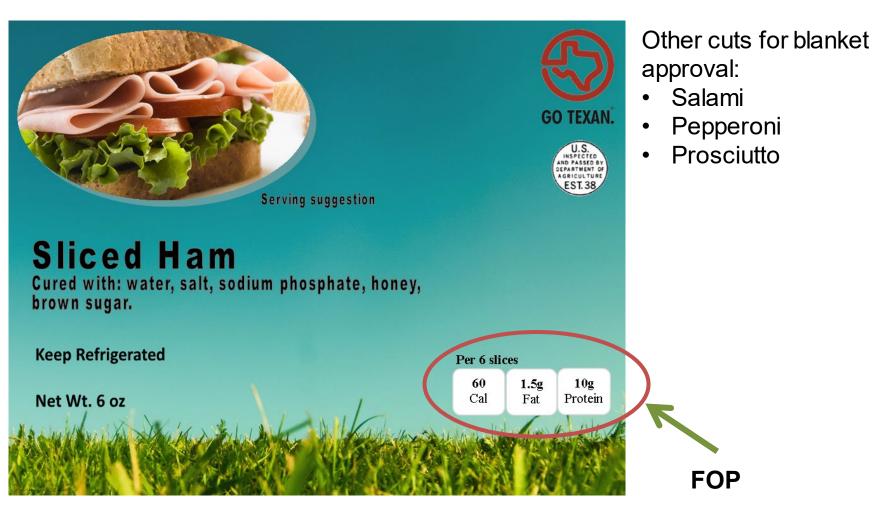
Appendix 5: Blanket Approvals (Product Line or Multiple Products with identical claims)

- The addition of a special claim to an entire product line of products or multiple products does not require every single label to be submitted to LPDS for approval.
- In certain situations, establishments may submit a blanket approval request by submitting a complete application and label for one product. The establishment would attach a list of the other products that would be covered by this approval.

Appendix 5: Blanket Approvals (Product Line or Multiple Products with identical claims) (cont'd)

- Addition of animal raising claim to product line that also bears an ingredient related claim
- Addition of Front of Pack (FOP) statements to multiproducts in the same product line or company
- Examples of new blanket approvals added to Appendix 5:
 - Addition of state endorsement programs that have a geographic emblematic design (e.g., Go Texan)
 - High pressure processed at establishment ABC
- Additional blanket approval examples can be found in Appendix 5 of the Compliance Guideline for Label Approval

Appendix 5: Blanket Approvals (Product Line or Multiple Products with identical claims): Label example



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Appendix 5: Blanket Approvals (Product Line or Multiple Products with identical claims): Label example



Adding a new nutrient cannot be generically approved.

Appendix 5: Blanket Approvals (Product Line or Multiple Products with identical claims): Questions and Answers

- Question: My company has a beef sausage line with approval for a No MSG claim, the company wants to add a made with grass fed beef claim. Can that be done through a blanket approval?
- Answer: Yes, the label can be approved through a blanket approval. This is provided that the only thing changing is the beef and no other ingredient. The establishment would submit one application with a list of the products covered by the approval. In addition, the submission would need to have support for the animal product claim included in the application.

Appendix 6: Special Statements and Claims that FSIS needs to review for only one label

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Food Safety and Inspection Service: Appendix 6: Special Statements and Claims that FSIS needs to review for only one label

- There are certain types of special statements and claims that LPDS only needs to evaluate once to ensure compliance.
- Subsequent approvals for additional products can be generically approved provided the establishment has support in its labeling record for the claims on the label.
- If the claim on the label is changed from the initial LPDS, the label would need to be resubmitted to for evaluation.

Food Safety and Inspection Service: Appendix 6: Special Statements and Claims that FSIS needs to review for only one label (continued)

- Nutrition FOP
- Certified Halal/Certified Zabihah Halal
- Certified Kosher
- For cooking only at establishment xyz
- Examples of new claims added to Appendix 6:
 - Certified Women's Business Enterprise
 - Employee Owned Certified
 - FDA nutrition facts panel- one approval from FSIS per format (e.g., full format, simplified, linear, tabular, dual column, or aggregate format)
- Additional information on Special Statements and Claims generically approved after first approval from LPDS can be found Appendix 6 of the Compliance Guideline for Label Approval

Appendix 6: Special Statements and Claims that FSIS needs to review for only one label: Label Example



Food Safety and Inspection Service: Appendix 6: Special Statements and Claims that FSIS needs to review for only one label: Question and Answer

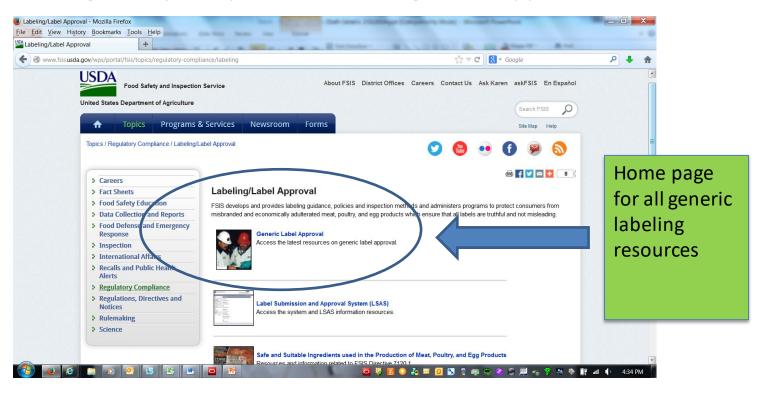
- Question: My establishment was approved to make a certified halal chicken hot dog. The company now wants to make a certified halal chicken sausage. Can we do this generically?
- Answer: Yes, the label can be approved generically because LPDS has already approved the documentation for the certified halal claim. The establishment can add the claim to the other labels made at the company generically provided the documentation is current.

Food Safety and Inspection Service: Resources

Resources

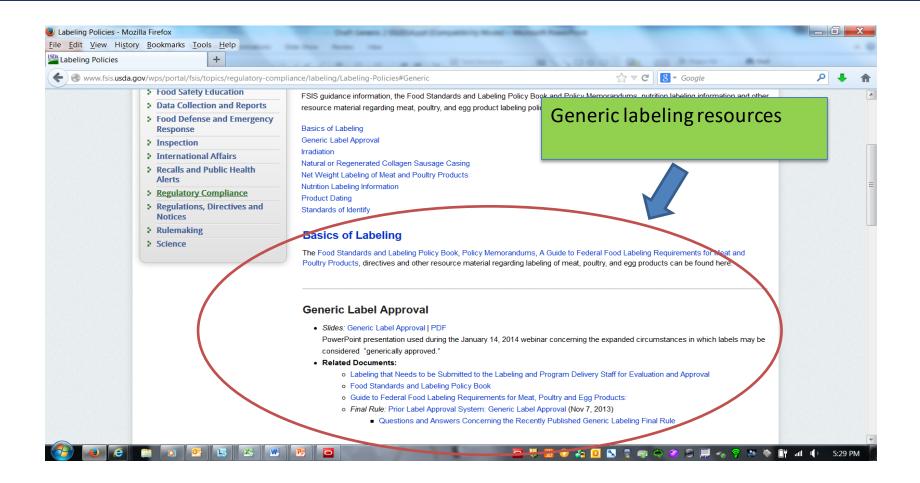
http://www.fsis.usda.gov

► Topics → Regulatory Compliance → Labeling/Label Approval



Note: Other labeling resources may also be found on this page

Generic Labeling Home Page



Food Safety and Inspection Service: Available Resources

FSIS Main Labeling Website:

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling

Generic Labeling Resources:

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Labeling-Policies

Allergens - Voluntary Labeling Statements:

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/ingredients-guidance/allergens-voluntary-labeling-statements/allergens-voluntary-labeling-statements

Additional resources section of the Compliance Guideline





Submit questions through askFSIS http://askfsis.custhelp.com
Call LPDS at (800) 233-3935

Questions

Questions?

