



Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

FSIS Labeling & Generic Labeling Overview

Labeling and Program Delivery Staff
August 24, 2021





Outline

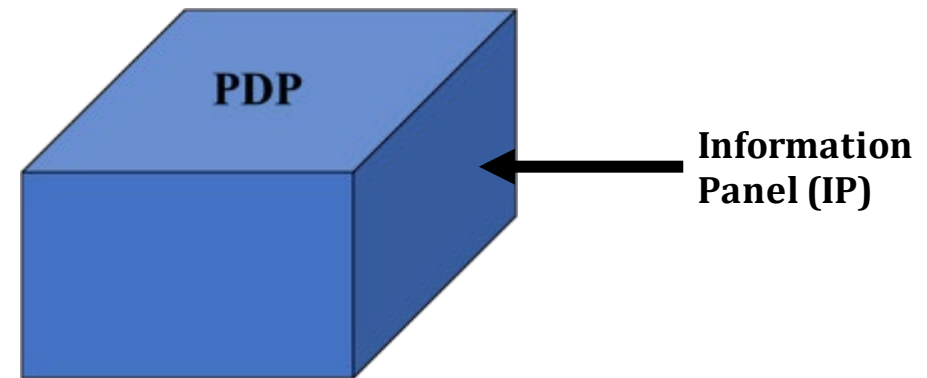
- **Required Labeling Features**
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 - **Export Labels**
 - **Special Statements & Claims**
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Required Labeling Features

Required Labeling Features

- Labels have up to eight (8) required labeling features
- Regulations specify where on the label some of the features must be located
 - Principal Display Panel (PDP)
 - PDP is the part of the label most likely to be displayed, presented... when offered for sale under customary conditions
 - 9 CFR 317.2(c) and (d), 9 CFR 381.116
 - Information Panel (IP)
 - 9 CFR 317.2 (m), 9 CFR 381.116(c)
 - IP is any portion of a label not on the PDP that is displaying certain mandatory features



Required Labeling Features – PDP

1. Product name
9 CFR 317.2(e)/381.117(a)
2. Handling Statement (on perishable products)
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

5. Name and place of business of the manufacturer, packer or distributor
9 CFR 317.2(g)(2)/381.122
6. Ingredient statement
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* (on not ready-to eat products)
9 CFR 317.2(l)/381.125(b)

* May appear on any panel

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(l) or 381.125(b)	Any panel	Products with a not-ready-to-eat meat or poultry component



Prior Label Approval Overview



Prior Label Approval Overview

- Only certain types of labeling requires 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))
- ALL OTHER labels that do not fit into one of the four categories **do not** require sketch approval by LPDS



Temporary Label Approval



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 extensions 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



Temporary Label Approval - 9 CFR

~~412.1(c)(4)~~

- 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



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 Exempt

Religious Exemption - 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, head-on, with or without the feet intact, in ready-to-cook form)



Export Labels Bearing Label Deviations



Export Labels with 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)
- Labels deviating from FSIS requirements except for net weight in metric units and foreign language need to be submitted for approval



Export Labels with Deviations - Examples

- 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



Special Statements and — Claims



Special Statements and Claims - 9 CFR

~~412.1(e)~~

- 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
- List will be periodically updated to reflect commonly asked questions regarding special statements and claims
- [FSIS Compliance Guideline for Label Approval](#) was last updated in July 2020



Special Statements and Claims - Examples

- Natural claims, e.g. “All Natural”, “100% Natural”
- Negative Claims, e.g., “no milk,” “no preservatives”
- Statements that identify a product as “organic”
- Front of Pack (FOP) nutrition statements, e.g., “0 grams trans fat per serving”
- Claims of the use of non-genetically engineered ingredients
- Claims regarding meat and poultry production practices (e.g., claims regarding the raising of animals such as “no antibiotics administered” or “vegetarian fed”)

Special Statements and Claims: Sketch Approval Required



Fully Cooked Organic Angus Beef Brisket

Rubbed with: water, salt, and organic spices.

Keep Frozen

Net Wt. 18 oz (1 lb 2 oz)



BEEF USED

- Grass-fed
- Free Range[®]
- No Added Antibiotics
- No Added Hormones Administered
- Source Verified and Traceable to TMB Ranch

*Never confined to a fed lot.



Distributed by TMB Ranch, Inc.
1234 Special Rd.
Elsewhere, VA 54321

Certified Organic by LPDS True 2 Earth



Regulatory Considerations for New Claims

- Claims must be truthful and not misleading (9 CFR 317.8 and 381.129)
- Establishments should:
 - Reach out to LPDS through askFSIS to confirm the acceptability of proposed language for a new claim before submission.
 - Explain the meaning and intent of the new claim
 - If applicable, provide documentation to support that the new claim is truthful and not misleading

Factual Statements and — Claims

Factual Statements and Claims: Generic Approval Permitted

- Some statements do not require submitting for approval and are approved generically under 9 CFR 412.2(b)
- Examples include:
 - Allergen or contains statements “contains: (name of ingredient)”
 - AMS Grading (USDA Prime, Choice, Select)
 - Flavor profiles (e.g. teriyaki flavored)
 - Foreign language on domestic products
 - Geographic claims (refer to 9 CFR 317.8(b)(1))

Modifications to Sketch Approved Labels with Special Claims

- Once a label is approved with a special statement or claim, changes can be made generically that are unrelated to the special claim, e.g., brand name, net weight, updating nutrition facts values, serving sizes (must be based on RACCs or longstanding appetizer RACC) and in some cases formulation changes
- [FSIS Compliance Guideline for Label Approval](#)

Points of Clarification

- FSIS Inspectors do not generically approve labels
- FSIS in-plant inspection personnel will continue to conduct in-plant label verification activities
- Labels will be generically approved if they meet the criteria listed in 9 CFR 412.2(b)
- Establishments do not generically approve labels Generically approved labels are approved by FSIS and display all applicable mandatory features in compliance with federal regulations

Statements and Claims: Generic Example

Generic statements and claims

Packed for: House of Kabob, Houston, TX 77252



NEW!

Fully Cooked

Chicken Kabobs

Grilled White Chicken Chunks on a wooden skewer

HALAL

Made with only White Chicken!!!



Serving suggestion

Ingredients: chicken breast, salt, pepper

Keep Refrigerated

Net Wt. 32 oz. (2 lbs.)

The image shows a product label for 'Chicken Kabobs'. On the left, the text 'Generic statements and claims' has three green arrows pointing to 'NEW!', 'HALAL', and 'Made with only White Chicken!!!'. The label itself is pink and contains the following text: 'Packed for: House of Kabob, Houston, TX 77252', 'INSPECTED U.S. DEPARTMENT OF AGRICULTURE P-42' seal, 'Fully Cooked', 'Chicken Kabobs', 'Grilled White Chicken Chunks on a wooden skewer', 'HALAL', 'Made with only White Chicken!!!', 'Ingredients: chicken breast, salt, pepper', 'Serving suggestion' (with an image of kabobs), 'Keep Refrigerated', and 'Net Wt. 32 oz. (2 lbs.)'.

Generic Label Approval Expansion

- Proposed revisions to 9 CFR part 412.1 include
 - export labels that deviate from FSIS requirements
 - labels listing “organic” ingredients in the ingredients statement
 - labels with geographic landmarks (e.g. foreign country's flag)
 - labels that make “negative” claims identifying the absence of certain ingredients or types of ingredients (e.g. No MSG Added)
 - labels of products that receive voluntary FSIS inspection (e.g., exotic species under 9 CFR part 352)
- Also proposing to cease evaluating labels submitted to FSIS that are eligible for generic approval
- FSIS is analyzing comments to the Proposed rule

Label Submission and Approval System

Label Submission and Approval System (LSAS)

- LSAS is the electronic submission system for label applications
- To get an LSAS account, you must first get an e-Authentication account
- Integrates and implements a secure electronic label application process for establishments to submit label applications and appeals
- Most labels are now submitted via LSAS; faster than paper
- The Generic Label Advisor (GLA) can assist you in determining if your label requires sketch approval
- Enrollment and use instructions at: <https://www.fsis.usda.gov/guidelines/2005-0002>

First Priority

- Labels which require LPDS evaluation as per 9 CFR 412.1
 - Temporary labels
 - Religious-Exempt product
 - Labels for Export bearing labeling deviations
 - Labels bearing special statements or claims
- Reviewed in the order in which they are received

Second Priority

- Labels which do not require LPDS evaluation as per 9 CFR 412.2
- Establishments may request voluntary evaluation by LPDS of generically approved label
- Applications for voluntary evaluation will be placed in a second priority queue, and will take longer to be reviewed

“Blanket” Approval

- Blanket approval allows certain information to be added to other products without having to submit each individual label bearing the same type of information for approval
- Refers to an approval that covers multiple labels or product lines
 - e.g. Front of Pack nutrition statements, Certified State programs
- Application for a blanket approval includes:
 - completed application form 7234-1
 - copy of at least one of the product labels
 - attachment that indicates a list of products or line of products to which the same information will be applied, e.g. FOP nutrition

Q&As

Q&A 1

- **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.

Q&A 2

- **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.

Q&A 3

- **Question:** May the establishment number be changed generically from one establishment number to another in the case of a label bearing a special statement or claim? For example, may Plant B use an approved label from Plant A by simply changing the Establishment number from A to B?
- **Answer:** Yes, this may be permitted under certain circumstances. If Plant B obtains a complete copy of the original label application and all associated supporting documentation necessary to support any special statements or claims on the original application approved for Plant A, then Plant B would have a complete label record on file and would be permitted to change the Est. number from A to B. In this case the information contained within the labeling application would be expected to remain the same (e.g. HACCP category, product formulation, processing procedures). Note: One exception is meat and poultry products labeled as “organic”

Q&A 4

Blanket Approval



The image shows a product label for Sliced Ham. At the top left is a circular inset showing a ham sandwich on a bun with lettuce and tomato, labeled "Serving suggestion". To the right of this is the "GO TEXAN." logo, which consists of a red outline of Texas inside a red circle, with the text "GO TEXAN." below it. Below the logo is a circular seal that reads "U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE EST. 38". The main title "Sliced Ham" is in large, bold, black font. Below it, the curing ingredients are listed: "Cured with: water, salt, sodium phosphate, honey, brown sugar." Further down, it says "Keep Refrigerated" and "Net Wt. 6 oz". At the bottom right, there is a nutritional facts table with three columns: "60 Cal", "1.5g Fat", and "10g Protein". This table is circled in orange, and a grey arrow points to it from the text "FOP" located to the right of the label.

Serving suggestion

GO TEXAN.

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

Sliced Ham

Cured with: water, salt, sodium phosphate, honey, brown sugar.

Keep Refrigerated

Net Wt. 6 oz

Per 6 slices		
60 Cal	1.5g Fat	10g Protein

FOP

Q&A 5

Updating Front of Pack Statement (FOP)



The image shows the front of a ham package with a teal background. At the top left is an oval image of a ham sandwich with the text "Serving suggestion" below it. In the top right corner are the "GO TEXAN." logo and a circular seal that reads "U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE EST. 38". The product name "Sliced Ham" is prominently displayed, followed by the curing ingredients: "Cured with: water, salt, sodium phosphate, honey, brown sugar." Below this, it says "Keep Refrigerated" and "Net Wt. 6 oz". At the bottom right, a nutrition facts table is shown with a red dashed circle around the "1g Sugars" entry and a red arrow pointing to it from the right.

Serving suggestion

Sliced Ham
Cured with: water, salt, sodium phosphate, honey, brown sugar.

Keep Refrigerated

Net Wt. 6 oz

Per 6 slices

60 Cal	1.5g Fat	10g Protein	1g Sugars
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Adding a new nutrient cannot be generically approved.

Egg Products Inspection Regulations

- Final Rule modernizing egg products inspection methods published October 29, 2020: Egg Products Inspection Regulations
- Effective date December 28, 2020 (some portions of the rule effective later, October 29, 2021 and October 31, 2022)
- 9 CFR 590.411 updated to provide for generic approval for certain egg products labels by incorporating 9 CFR 412.1 and 412.2

Egg Products Inspection Regulations

- FSIS approval is now required by 9 CFR 590.411 only for egg product labels that meet the criteria for mandatory FSIS label approval in 9 CFR 412.1 such as labels bearing special statements or claims or applications for temporary label approval.
- Labels that do not meet any of the criteria in 9 CFR 412.1 are approved generically if the label complies with all applicable labeling regulations as described in 9 CFR 590.412.
- Additionally, FSIS will no longer issue the PY-221 form nor provide an egg approval number for egg product label approvals. When FSIS approves egg product labels, the approval will still include an electronically stamped FSIS Form 7234-1, a sketch copy of the label and any supporting documentation submitted with the label.

Egg Products Inspection Regulations - Examples

NO SPECIAL CLAIM LABEL
GENERIC APPROVAL

Liquid Egg Whites with Citric Acid
Ingredients: egg whites, citric acid

KEEP REFRIGERATED



Net Weight
16oz (1lb) 454g

Distributed by: LPDS
Washington, DC 20250

SPECIAL CLAIM(S) LABEL THAT REQUIRES
APPROVAL

Organic Cage Free* Liquid Egg Whites with
Citric Acid
Ingredients: egg whites, citric acid

KEEP REFRIGERATED

*made from hens raised in an environment
without cages



Net Weight:
16oz (1lb) 454g

Distributed by:
LPDS
Washington, DC 20250
Certified Organic by LPDS
www.lpds.com

Resources

Compliance Guideline for Label Approval

- [FSIS Compliance Guideline for Label Approval](#) available on FSIS website.

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 that FSIS only needs to review for only one label

Food Standards and Labeling Policy Book

- FSIS has decided to stop adding policy guidance to the Food Standards and Labeling Policy Book
- FSIS will continue to amend or remove existing items in the book, as necessary, but it will no longer add new material to it
- The Agency will convey new labeling policy by other means, such as compliance guidelines
- [Food Standards and Labeling Policy Book](#)



Food Safety
And Inspection
Service

Office of Policy, Program and
Employee Development

August 2005

Food Standards and Labeling Policy Book

Revised for Web Publication August 2005
Replaces Publication Dated May 2003 and Removal of Publication Dated 1996

FSIS Constituent Update

- FSIS publishes “Tips for Faster Label Approval Process” every two weeks in the online FSIS Constituent Update
- Since 2019 sample topics include:
 - Supporting documentation guidance
 - Temporary label application suggestions
 - Clarifications on editing vs. appealing applications
- To sign up for FSIS email subscription service:
<https://www.fsis.usda.gov/news-events/news-press-releases/news-feeds-subscriptions>
- Archived listing of past Constituent Updates:
<https://www.fsis.usda.gov/news-events/news-press-releases>



Submit a Question
to askFSIS

- <https://www.fsis.usda.gov/askFSIS>
- Questions are sent to a main portal, triaged, and assigned to the correct expert based on subject matter.

Call:

- Main: 301.504.0878
- Distribution Unit: 301.504.0883

Labeling
Procedures

- <https://www.fsis.usda.gov/policy/fsis-guidelines>

[fsis.usda.gov](https://www.fsis.usda.gov)

