



United States Department of Agriculture

OneUSDA “Do right and feed everyone”



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:

FSIS Labeling Overview

Labeling and Program Delivery Staff (LPDS)

Sept 24, 2020

Presentation by:

Tawana Harrington, Staff Officer, USDA-FSIS

Cindy Watkins, Staff Officer, USDA-FSIS

Food Safety and Inspection Service:

Presentation

Overview

- Background information
- Required labeling features
- Generic Labeling Regulations
- Compliance Guide For Label Approval
- Animal Raising Claims
- Label Examples
- Useful resources



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.

Required Labeling Features

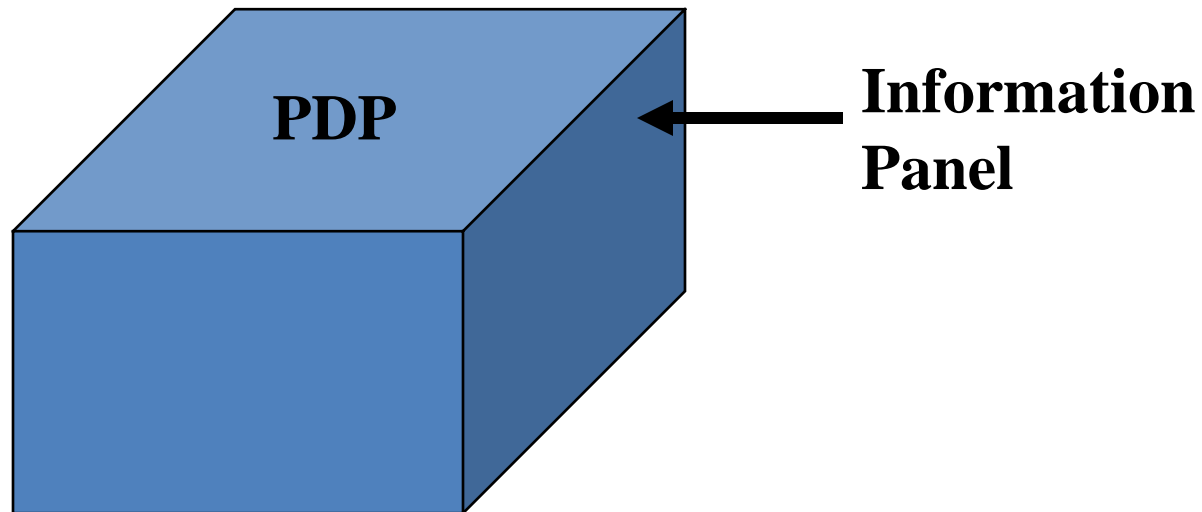
Food Safety and Inspection Service: Required Labeling Features

- 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(l)/381.125(b)

Food Safety and Inspection Service:

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	Not-ready-to-eat meat or poultry products

Generic Labeling Regulations

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 **do not** 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))

Food Safety and Inspection Service:

Compliance Guideline for Label Approval

Compliance Guideline for Label Approval

Food Safety and Inspection Service:

Compliance Guideline for Label Approval

- FSIS Compliance Guideline for Label Approval is available on FSIS website <http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES>
- 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

Appendix 1: Special statements and claims

Food Safety and Inspection Service:

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”

Food Safety and Inspection Service:

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

Food Safety and Inspection Service:

Appendix 2: Factual Statements and Claims that are Generically Approved

Appendix 2: Factual statements and claims that are generically approved

Food Safety and Inspection Service:

Appendix 2: Factual Statements and Claims that are Generically Approved

- 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

Food Safety and Inspection Service:

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

Food Safety and Inspection Service:

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.

Food Safety and Inspection Service:

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

Food Safety and Inspection Service:

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

Food Safety and Inspection Service:

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

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

Food Safety and Inspection Service:

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.

Food Safety and Inspection Service:

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 multi products 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

Food Safety and Inspection Service:

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

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

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

Animal Raising Claims

Food Safety and Inspection Service:

Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission

- On October 5, 2016, FSIS announced the availability of and requested comments on its ***Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission***
- FSIS published the guideline to assist establishments in preparing their label approval application and to facilitate LPDS's review of these labels
- We received over 4,600 comments
- ***December 17, 2019 FSIS Provided a Federal Register Notice and Animal Raising Claims Guidelines in Final Form***
- (<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Claims-Guidance>)

Food Safety and Inspection Service: Examples of claims covered in the guideline

**Diet- 100% Grass Fed, Grass Finished,
Vegetarian Fed**

**Animal Welfare and Environmental
Stewardship- “Humanely Raised,
“Sustainably Sourced” “Raised with Care”**

**Negative Hormones Use- “No Added Hormones”
“No Hormones Administered Ever”**

**Negative Antibiotic Use- “Raised without
Antibiotics” “No Added Antibiotics” “No
Antibiotics Ever” “No Sub-Therapeutic
Antibiotics”**

Food Safety and Inspection Service: Examples of claims covered in this guideline (cont'd)

Breeds: Beef- (Angus, Piedmontese, Wagyu),
Poultry: (Silkie, Plymouth Rock) Pork (Berkshire,
Duroc) (Heritage Breeds)

Organic- Certified Organic by National
Organic Program, Agricultural
Marketing Service (AMS)

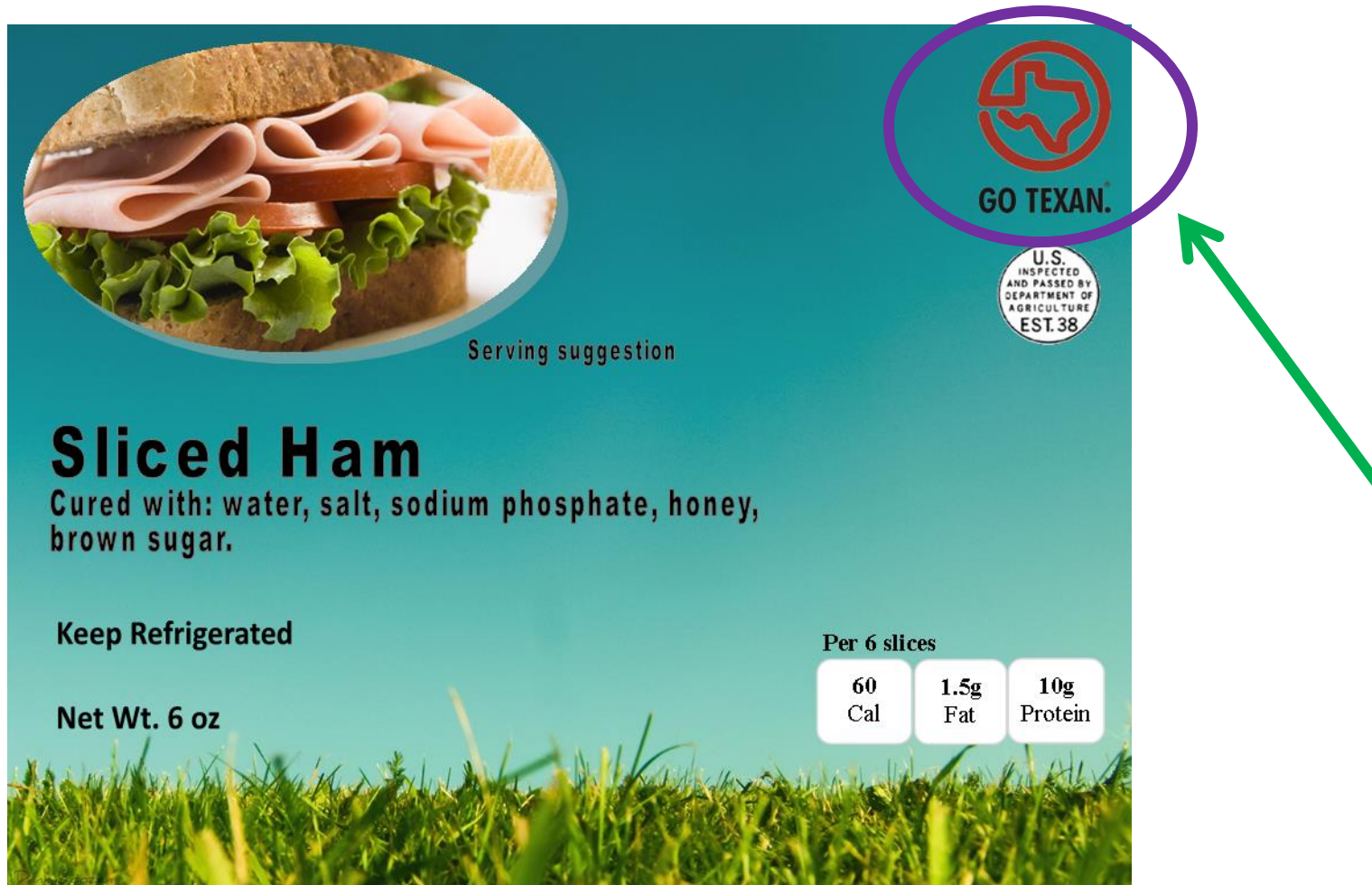
AMS, Process Verified Program (PVP) –
3rd Party Certification

Living/Raising/Raising Conditions (Free Range,
Pasture Raised, Cage or Crate Free, Free to Roam)

Label Examples

Food Safety and Inspection Service:

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



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
------------------	--------------------	-----------------------

GO TEXAN.

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

Food Safety and Inspection Service: Non-Genetically Engineered Claim Example

A Good Win! Farms® est 2010

All Natural**
Raised without
Added Antibiotics
No Added Hormones†

Fed a vegetarian diet
with No GMO
feed ingredients*

Organic Premium Fresh
Young Chicken



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.

KEEP REFRIGERATED

NET WT.
48 OZ (3 LB)

INSPECTED U.S. DEPARTMENT OF AGRICULTURE P-42

USDA ORGANIC

*This pasture raised chicken is fed an organic vegetarian diet with no GMO feed ingredients in compliance with the National Organic Program regulation.

**Minimally Processed, No Artificial Ingredients

†Federal Regulations do not permit the use of hormones in poultry.

Distributed by A Good Win! Farms®
1224 Unique Dr.
Orlando, VE 00122
Certified Organic by ABC Green.

Food Safety and Inspection Service:

Examples of claims covered in this guideline (cont'd)



**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

Food Safety and Inspection Service: Special Statements and Claims: Sketch Approval Required

Special Statements and Claims

Beef Raised

- Without Added Antibiotics
- Barn Roaming, Never Confined to a Lot
- Grass Fed
- Organic

Beef Flat Iron Steak

USDA ORGANIC

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.

A Good Win! Farms®
est 2010

All Natural*



***Minimally Processed, No Artificial Ingredients**

Keep Refrigerated

Net Weight: 48 oz (3 lbs)

Distributed By:
20101 Beltsville Rd
Sunnyside, MD 12345
Certified Organic by
LPDD Organic
Certifying

Resources

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

Food Safety and Inspection Service: Questions

Questions?

