Generic Label Approval

FSIS Labeling and Program Delivery Staff (LPDS)

January 14, 2014

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 one of two ways:
  - Sketch approval which is approved by the Labeling and Program Delivery Staff (LPDS)
  - Generic approval which is approved by being in compliance with applicable regulations

Terms Defined: Sketch Approval

- Label review process by Labeling and Program Delivery Staff (LPDS)
- 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 Approval (continued)…

- 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

- FSIS regulations approve some labels generically
- 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, therefore…
- Generically approved labels applied to product are consistent with the Agency's prior labeling approval system

NOTE: FSIS Inspectors do not generically approve labels. Establishments do not generically approve labels. FSIS approves labels through generic labeling regulations.

Generic Approval Prior to January 6, 2014

- By regulation, FSIS specified when a generic approval could be undertaken by an establishment (9 CFR 317.5 and 381.133)
- Generic approval forgoes the need to obtain sketch approval
- Prior to the new rule
  - specific labels were eligible for generic approval AND
  - certain changes could be made generically to sketch approved labels

New Generic Labeling Final Rule

- 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

New Generic Labeling Final Rule

- 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

New 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))

- 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

Key Concept

New Generic Labeling Final Rule introduces the four categories of labels that require prior approval by LPDS:

- Temporary labels
- Religious exemption
- Exports with labeling deviations
- Special statements and claims

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

Temporary Label Approval

- Approval process unchanged by the new generic labeling rule
- FSIS assesses the public health risk and potential economic adulteration when deciding to grant approval for the use of a temporary label
- The regulations are not specific enough to assist establishments in determining when a temporary label may be granted
- For these reasons, FSIS is not expanding the scope of generic labeling approval to include temporary label approvals and extensions.

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
- Labels for religious-exempt product must be submitted to LPDS for sketch approval
- 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

Labels Intended for Export Which Bear 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 meat and poultry products to be exported bearing 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 marked "for export only" that bear labeling deviations and therefore cannot be used domestically must be sketch approved by LPDS

Special Statements and Claims Defined in 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
  http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES

- List includes commonly used special statements and claims

Special Statements and Claims: Sketch Approval Required

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)

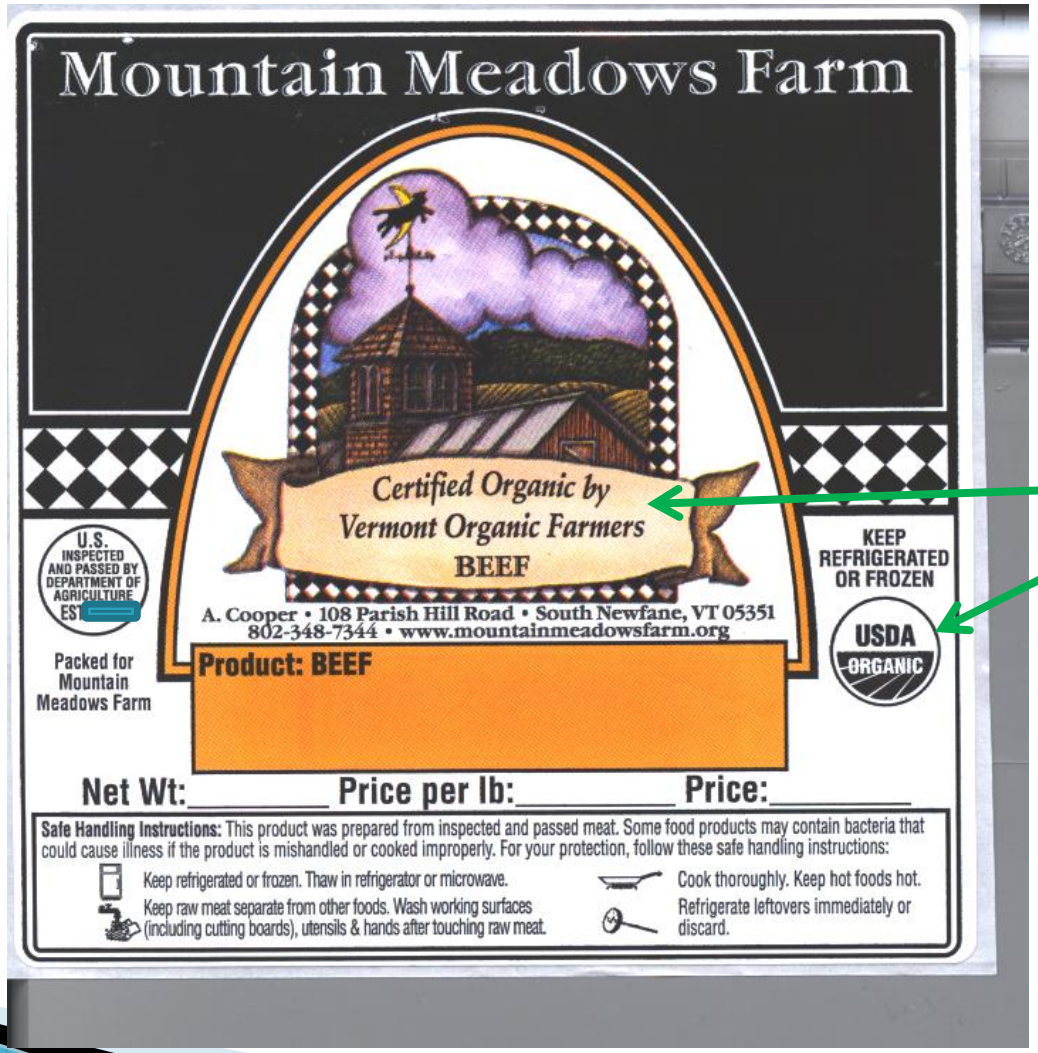
- Omega 3 factual statements
- "Whole Grain", "Made with Whole Grains", "Made with whole wheat" claims
- Nutritional Front of Pack statements, for example "0 grams trans fat per serving", Nutrition facts Up Front
- Claims of the use of non-genetically engineered ingredients
- Claims that are undefined 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 Statements and Claims: Sketch Approval Required (continued)



Special Claims (Organic Claims and logo)

Other Statements Not Considered Special

- 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

Industry Impact

- Expected to be a cost-saving measure for the industry: $8.7 million over ten years
- FSIS is committed to providing guidance and resources that will help companies take advantage of this new rule without needing to hire additional personnel

FSIS Impact

- Estimate that allowing more labels to be generically approved will reduce current label approval volume by roughly 70 percent
  - decrease from 846,000 submissions to 261,000 submissions over a 10-year period
  - $2.9 million saved over ten years
- Cost savings in fewer staff hours spent evaluating labels can be redirected towards other Agency initiatives

Consumer Impact

- Will enhance market efficiency by promoting a faster introduction of new products into the marketplace to meet demand
- Frees up FSIS' resources so they can be redirected to other food safety issues
- In-plant inspection personnel will continue on-site labeling evaluations

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

First Priority Labels

- 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
- Will be reviewed in the order in which they are received

Second Priority Labels

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

Voluntary Evaluation of Generically Approved Labels: LSAS

- Type “generic” in the box entitled “Other claim description” in Step 3: Special Claims Information of the LSAS label submission process
- Generic-labels not marked as “generic” will be returned via LSAS with a note that the label may be generically approved
  - Generic-labels may be resubmitted through LSAS for voluntary review by noting “generic” in the “other claim description” box
  - When a label that may be generically approved is returned electronically, no response is necessary if voluntary review is not requested
- LSAS labels with requests for voluntary review will be added to the second priority queue

Voluntary Evaluation of Generically Approved Labels: Paper

- Type “Generic” after “Other claims” in Block 10 of FSIS Form 7234-1
- Establishments submitting paper labels that may be generically approved not marked as “Generic” in Block 10 will be contacted by LPDS to determine if voluntary review is requested
  - If voluntary review is requested, the paper label will be placed in the second priority queue
  - If voluntary review is not requested, the label will be returned to the establishment
- If no contact is made with the establishment, the labels will be placed in the second priority queue

Note on Voluntary Review

- LPDS will assess all labels to determine if label review is required
- LPDS determination that a label may be generically approved is NOT a label review
- Notification by LPDS that a label may be generically approved should not be mistaken for LPDS approval of the label
  - It is the establishment's responsibility to ensure that the final label meets all applicable labeling regulations
  - Generically approved labels do not require approval by LPDS
  - As noted earlier, generically approved labels that are voluntarily submitted for approval will be placed in the second priority queue and may take longer to be reviewed
  - Labels that may be generically approved placed in the second priority queue may be used by the establishment provided that the labels are in compliance with applicable regulations

Second Priority Review Process

- Paper and LSAS labels reviewed by LPDS will be marked as either:
  - Sketch Approved
  - Sketch Modified, with required changes noted
  - Returned
    - Returned labels are not required to be resubmitted to LPDS for approval since they are approved generically once the noted changes are made
    - Returned labels resubmitted to LPDS will be placed at the bottom of the second priority queue on the day they are received
    - There is no resubmittal priority for labels that may be generically approved

Labeling Consultants

- Labels that may be generically approved submitted through labeling consultants with no note of “generic” in Box 10 will be returned to the consultant for confirmation that voluntary review is requested
- Labels may be submitted back to LPDS with “generic” noted in Box 10 if voluntary review is requested
- Labels will be placed in the second priority queue on the day that they are received complete with “generic” noted in Box 10

Extraordinary Circumstances

- Labels that may be generically approved and are voluntarily submitted for review do not qualify as an extraordinary circumstance
- Any label that may be generically approved does not require LPDS approval to enter commerce, therefore emergency review will not be granted
- Special note on final product labeling "Tagged" for labeling non-compliance
  - Final label must be brought in to compliance by correcting the non-compliance
  - Requests for the temporary use of final labels not in compliance with FSIS regulations and policies must be submitted to LPDS for review. Emergency reviews may be requested in this instance.

Points of Clarification

- Generic Rule does not apply to egg products
  - Expanding the generic labeling criteria for processed egg products is being considered as a separate rule
- Generic Rule also does not apply to exotic species under voluntary inspection

Food Standards and Labeling Policy Book

- Available online at: http://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccf-a2d5-b95a128f04ae/Labeling_Policy_Book_082005.pdf?MOD=AJPERES
- Provides additional guidance regarding FSIS standards outside of the regulations
- Used in conjunction with the Meat and Poultry Inspection Regulations and FSIS Directives and Notices
- Composite of policy and day-to-day labeling decisions
- Claims found in the Policy Book may be approved generically except: natural claims, negative claims

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 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 policy guides

Questions and Answers

Are previously approved labels containing special statements or claims eligible for generic approval when the only modification involves changes unrelated to the special statement or claim?

Yes. Previously approved labels containing special statements or claims may be generically approved if the modifications to the label are unrelated to the special statement or claim.

Questions and Answers

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?

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).

Questions and Answers

Labels with negative claims must be submitted to FSIS for approval. How does FSIS define "negative claims" ?

"Negative" labeling claims are defined in the Food Standards and Labeling Policy Book. Negative claims refer to statements highlighting the absence of an ingredient or another constituent of the food, an example of which, "gluten free," has been codified in 9 CFR 412.1 (e). "No milk" is another example of a negative claim that highlights the absence of an ingredient or another constituent of a food. A negative claim may also identify the absence of certain types of ingredients e.g. "no preservatives" or "no artificial coloring" based on the product formulation.

NOTE: Nutrient content claims (e.g. fat free, cholesterol free) are not considered negative claims under the Policy Book entry.

Questions and Answers

Is the child nutrition (CN) box on a meat or poultry product considered a special statement or claim and require sketch approval?

No. The CN information in CN boxes is reviewed and evaluated for approval by the Agricultural Marketing Service (AMS), removing it from the realm of a special statement or claim.

Questions and Answers

May statements on labels that are defined in FSIS's regulations or the Food Standards and Labeling Policy Book be generically approved?

With the exceptions of "natural" and negative claims, yes, defined statements may be approved generically. Examples of such claims that will no longer require sketch approval by FSIS include:

- A statement that characterizes a product's nutrient content that is consistent with the applicable Agency regulations, such as "low fat"
- Addition of a nutrition facts panel to a product sold at retail
- A statement that has geographical significance, such as "Italian Style"

Questions and Answers

Do non-standardized products still require LPDS Sketch approval?

The fact that a product does not have a standard described in the FSIS Food Standards and Labeling Policy Book or specified in the regulations has no bearing on whether or not the label requires sketch approval. A non-standardized meat or poultry product may be generically approved provided it does not fall into one or more of the four categories of labels requiring approval in 9 CFR 412.1(c): temporary approval, labels for export with labeling deviations, religious exempt, or labels bearing special statements or claims.

Questions and Answers

Will allergen statements require approval by LPDS staff?

No. FSIS will not view the addition of an allergen statement (e.g., “contains soy”) applied in accordance with the Food Allergen Labeling and Consumer Protection Act (FALCPA) as a special statement or claim that requires sketch approval.

Questions and Answers

Will labels containing foreign languages on products for sale in the US that do not have special statements or claims require prior approval by LPDS staff?

No. While the previous meat and poultry inspection regulations did not permit the generic approval of a label adding or deleting a direct translation of the English language into a foreign language for product sold in the U.S., this final rule will allow it. These types of labels do not fall into any of the categories of labels that must be submitted to FSIS for evaluation and review.

Questions and Answers

Do front-of-package labeling statements that meet the requirements for nutrient content claims, including statements of quantity, qualify for generic approval?

No. FSIS considers certain front-of-pack (FOP) labeling statements, such as those highlighting select nutrients from the nutrition facts panel placed on the principal display panel, to be nutrient content claims. However, unlike traditional nutrient content claims, such as "low fat," that are defined in FSIS regulations, there are no guidelines for the multiple types of FOP labeling statements on labeling.

Questions and Answers

What are the record keeping requirements for generically approved label?

Establishments are required to keep records of all labeling, both generically approved and approved by FSIS, along with the product formulation and processing procedures, as prescribed in 9 CFR 320.1(b)(11), 381.175(b)(6), and 412.1. The final rule added the requirement that any additional documentation needed to support that the labels are consistent with the Federal meat and poultry regulations and policies on labeling also be kept.

Available Resources

- FSIS Labeling Website:
  http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling
- Guide to Federal Food Labeling Requirements for Meat, Poultry and Egg Products:
  http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16-fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES
- Final Rule:
  http://www.fsis.usda.gov/wps/wcm/connect/3b0efaeb-9a81-4532-a1cc-b4d1cdb30f4a/2005-0016F.pdf?MOD=AJPERES
- Questions submitted through askFSIS : http://askfsis.custhelp.com
- Call LPDS at (301) 504-0878